Cannabis and the Regulatory Void

Background Paper and Recommendations
California Medical Association
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Summary
In 2010, the California Medical Association (CMA) House of Delegates ordered the formation of a technical advisory committee to recommend policy on marijuana [cannabis]¹ legalization and appropriate regulation and education. The CMA Legalization and Taxation of Marijuana Technical Advisory Committee (TAC) found that the public movement toward legalization of medical cannabis has inappropriately placed physicians in the role of gatekeeper for public access to this botanical. Effective regulation is possible only if cannabis is rescheduled at the federal level.

Policy Recommendation includes:
- “Reschedule” medical cannabis in order to encourage research lending to responsible regulation.
- Regulate recreational cannabis in a manner similar to alcohol and tobacco.
- Tax cannabis
- Facilitate dissemination of risks and benefits of cannabis use.
- Refer for national action.

¹ Note: “Marijuana” is a slang term for the dried leaves and flowers of the varieties of the cannabis plant that are rich (1-20+%) delta-9-tetrahydrocannabinol, or “THC” - the primary psychoactive cannabinoid found in the cannabis plant. Throughout this background paper, the scientific term “cannabis” will be used, except where the term “marijuana” is contained in a direct quotation or referring to an official title.
Cannabis and the Regulatory Void

Prepared by the California Medical Association, Marijuana Technical Advisory Committee.

Introduction
Cannabis is a plant ("botanical") known popularly as marijuana, which has medicinal qualities and is also psychoactive. Federal law classifies cannabis as a Schedule I drug meaning it has no accepted medical use and a high potential for abuse and therefore cannot be prescribed by physician for any use outside of research settings. That is, it is "illegal" to prescribe this botanical. The Schedule I classification has limited research on the potential therapeutic usefulness or potential risks of cannabis and its various chemical components (cannabinoids, terpenoids and falvonoids). The Schedule I classification of cannabis has contributed to several public policy dilemmas.

The federal illegality of cannabis coupled with the decriminalization of cannabis in California has inappropriately placed physicians in the role of "gatekeeper." Those wishing to gain access to cannabis to avoid criminal penalties currently look to physicians for a recommendation of medicinal cannabis. Unfortunately, for California physicians, the popular justification for decriminalization actions has been a declaration of the medical efficacy of cannabis when, in reality, current data have shown that the medical indications for cannabis are very limited. For the medical uses listed in Proposition 215, other drugs with documented effectiveness are available and may be more commonly used for treatment.

Despite extensive law enforcement and other prohibition-related efforts at the state and federal levels, unregulated cannabis continues to be easily accessible, often at low cost. For this and several other reasons further outlined in this white paper, the California Medical Association (CMA) has recognized that the criminalization of cannabis is a failed public health policy. Based on the growing momentum of medical cannabis decriminalization nationally (16 states and the District of Columbia have decriminalized medical cannabis), there may also be growing public support in several states for decriminalization of the cultivation, transport and use of cannabis.

Recognizing the growing national conversation surrounding cannabis, the California Medical Association (CMA) in 2010 adopted policy HOD 101a-10 stating:

That CMA recognizes there is a public movement toward legalization of marijuana and that CMA convene a TAC to develop a comprehensive white
paper recommending policy on marijuana legalization and appropriate regulation and evaluation.

Thus, the Legalization and Taxation of Marijuana Technical Advisory Committee (TAC) was formed to consider the issue of cannabis legalization, taxation, regulation, and education from the standpoint of a physician. The conclusions of this report stem from the physician’s code of ethics which states, “First, do no harm,” placing patient safety and public health as the central goals.

The TAC recognizes two intersecting issues in this policy review: the use of medical cannabis and the use of recreational cannabis. CMA’s most direct concern is medical cannabis as it addresses the potential benefits and risks of this now largely unstudied botanical and its chemical components. CMA is also concerned with a failed policy of prohibition for recreational use which coincides with a crescendo of public repudiation of that policy. Additionally, CMA is concerned with the current inappropriate justification for decriminalization as it relates to its medical utility. While policy options are not new (think about alcohol prohibition a century ago), we do need to reconsider the risks and benefits of this policy itself for individual patients and for the population as a whole.

**Discussion**

*Literature Review*

Research surrounding cannabis that meets modern scientific standards has remained limited due to cannabis’s status as a federally restricted Schedule I substance. Cannabis should be subject to the scrutiny of the federal Food and Drug Administration’s (FDA) regulatory process in order to allow for further clinical research and to work toward standardizing the substance so physicians are no longer required to serve as gatekeepers of a substance that has not been subjected to the scientific process. In 2001, the American Medical Association (AMA) Council on Scientific Affairs advocated that the National Institutes of Health (NIH) implement administrative procedures to facilitate grant applications to conduct well-designed clinical research into the medical utility of cannabis.

Such research has recently increased, but not to a level that allows for the development

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of an evidence-based regulatory scheme for cannabis. In the past ten years, there have been approximately twelve U.S. clinical trials investigating the therapeutic properties of inhaled cannabis and more than twenty clinical studies worldwide studying the use of cannabis-derived medications in the treatment of various medical conditions. Therefore, the future may provide a clearer distinction for cannabis-derived medications.

However, even with regard to cannabis used recreationally, there is a need for oversight and quality control, just as there is with alcohol, tobacco, and food products. Such oversight and quality control, aimed at protecting personal and public health, can be accomplished with legalization and regulation at both the federal and state levels. Thus far, the criminalization of cannabis has proven to be a failed public health policy for several reasons, including:

a) The diversion of limited economic resources to penal system costs and away from other more socially desirable uses such as funding health care, education, transportation, etc.;

b) The social destruction of family units when cannabis users are incarcerated, rather than offered treatment and other social assistance;

c) The disparate impacts that drug law enforcement practices have on communities of color;

d) The continued demand for cannabis nationally, which supports violent drug cartels from Mexico and other international sources;

e) The failure to decrease national and international supplies of cannabis from criminal and unregulated sources;

f) The failure of the federal government’s limited actions through the “War on Drugs” in mitigating substance abuse and addiction.

Currently in California, the use of medicinal and recreational cannabis has been decriminalized. In 1996, California’s Proposition 215 decriminalized the cultivation and use of cannabis by seriously ill individuals upon a physician’s recommendation and, in 2004, the Medical Marijuana Program Act enacted an identification card program to

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5 “Drug courts are not the answer: Toward a health-centered approach to drug use.” Drug Policy Alliance, 2011.


8 Ibid.
achieve greater consistency in the application and enforcement of the original initiative.\textsuperscript{9} Regarding the recreational use of cannabis in California, Health & Safety Code § 11357 was implemented on January 1, 2011, making possession of less than one ounce of cannabis a civil infraction rather than a criminal misdemeanor as it had previously been categorized.

In focusing on the medicinal use of cannabis, its decriminalization has gained momentum throughout the nation. However, aside from these actions at the state level, very little clinical research or regulation of cannabis exists due to its current federal illegality.

Cannabis components may have some medicinal efficacy as well as a variety of health risks. Cannabis may be effective for the treatment of pain, nausea, anorexia, and other conditions, but the literature on this subject is inadequate, dosage is not well standardized, and cannabis side effects may not be tolerated.\textsuperscript{10} Cannabis use has also been associated with several health risks including addiction,\textsuperscript{11} memory loss and slower reaction time,\textsuperscript{12} development of psychotic disorders,\textsuperscript{13} and reproductive risks.\textsuperscript{14}

Cannabis acquired in California today is unregulated. Both medical and recreational cannabis have no mandatory labeling standards of concentration (one cannabis clinic labels one lollipop as “Three Doses”) or purity (are there harmful pesticides or herbicides present?)

**Legalization vs. Decriminalization**

The legalization of cannabis is a continuing source of debate at both the national and state levels. Legalizing cannabis consists of allowing for the cultivation, sale, and use of the substance. The Netherlands has maintained a drug policy that distinguishes between “hard” and “soft” drugs – cannabis, although technically illegal, is viewed as a soft drug. There, soft drugs are those believed to be less addictive and to have fewer dangers associated with their use. The Dutch government officially tolerates the

\textsuperscript{9} California Health & Safety Code §11362.5.
personal possession and use of cannabis and also licenses and regulates cannabis cafes, arguing that regulation creates, at the consumer level, a separation for the market for cannabis from the market for hard drugs.

Decriminalization of cannabis may consist of a range of activities such as reducing penalties for cannabis-related offenses. Portugal became the first European country to decriminalize personal possession of cannabis, cocaine, heroin, and methamphetamine in 2001. Therapy is now offered in place of criminal penalties for drug possession. In 2006, five years after implementing decriminalization policies, Portugal reportedly had a lifetime cannabis use in people over age fifteen of 10 percent – the lowest in the European Union.\textsuperscript{15}

\textbf{Federal Law}

Congress made cannabis use illegal when it enacted the Controlled Substances Act in 1970 (21 U.S.C. § 811). Under federal law, cannabis is currently classified in statute as a Schedule I drug, along with drugs such as heroin, LSD and peyote. The Controlled Substances Act holds that it is illegal for anyone to knowingly or intentionally possess a Schedule I substance because substances classified under this schedule are deemed to have high potential for abuse, no currently accepted medical use in treatment, and a lack of accepted safety for use of the drug under medical supervision. Therefore, the intended use of cannabis, whether medical or recreational, is irrelevant under the Controlled Substances Act.

On June 6, 2005, the United States Supreme Court ruled that the federal Controlled Substances Act is valid even as applied to intrastate, noncommercial cultivation, possession and use of cannabis for personal medical use on the advice of a physician.\textsuperscript{16} The Court’s ruling maintains the existing federal prohibition against possession, cultivation, and distribution of cannabis.

Federal law establishes a clear prohibition against knowingly or intentionally distributing, dispensing, or possessing cannabis (21 U.S.C. § 841-44). A person who aids and abets another in violating federal law, 18 U.S.C. § 2, or engages in a conspiracy to purchase, cultivate, or possess cannabis, 21 U.S.C. § 846, can be punished to the same extent as the individual who actually commits the crime. The penalty for a first-time violation of these provisions in the case of less than 50 kilograms of cannabis is imprisonment for a term of up to five years, a fine of up to $250,000, or both. The penalty for a violation committed after a prior drug conviction is imprisonment for a term of up to ten years, a fine of $500,000, or both (21 U.S.C. § 841(b)(1)(D)).

\textsuperscript{15} Szalavitz. \textit{Time}. August 26, 2009.

\textsuperscript{16} Gonzalez \textit{v. Raich} (2005) 525 U.S. 1, 162 L.Ed.2d 1, 125 S.Ct. 2195.
Other federal sanctions are also possible. If a physician were to aid and abet or conspire in a violation of federal law, the federal government might revoke the physician’s Drug Enforcement Agency (DEA) registration through an administrative procedure. Physicians should also be aware that a felony conviction relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance results in mandatory exclusion from the Medicare and Medi-Cal programs (42 U.S.C. § 1320a-7(a)(4)).

Because cannabis remains an illegal substance at the federal level, it is currently impossible to adequately evaluate or regulate the substance nationally. The charge of this TAC was to consider whether appropriate regulation or taxation is technically irrelevant absent the federal legalization of cannabis because, in order to consider supporting a taxation or regulatory scheme, cannabis must first be legalized. Merely decriminalizing cannabis on a state-by-state basis is not sufficient because illegal substances would not be regulated at the federal level, which is where most of the regulation of labeling, quality control, safety, etc. of, for example, alcohol and tobacco takes place. Colorado is the first non-federal jurisdiction attempting to regulate cannabis absent such federal action.

**State Law**

At the state level, California has seen a handful of efforts moving toward decriminalization of cannabis under certain circumstances. On November 5, 1996, the people of California approved Proposition 215, which decriminalized the cultivation and use of cannabis by seriously ill individuals upon obtaining a physician’s recommendation (Health & Safety Code § 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 medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction” (Health & Safety Code § 11362.5(b)(1)(A)-(B)).

In order to further clarify Proposition 215, the Medical Marijuana Program Act (MMP) was enacted on January 1, 2004 (Health & Safety Code §§ 11362.7-11362.83). The MMP enacted an identification card program to achieve greater consistency in the application and enforcement of the original initiative. The MMP also clarified that a primary caregiver may be paid a “reasonable compensation” for services provided to a qualified

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patient “to enable that person to use marijuana” and that patients and primary caregivers may “cooperatively” and “collectively” cultivate. The MMP requires the California Department of Public Health to maintain a program for the voluntary registration of qualified medical cannabis patients and their primary caregivers through a statewide identification card system. The voluntary registration program is administered through a patient’s county of residence, where the eligible patient submits an application and provides medical records containing written documentation by the attending physician stating that the patient has been diagnosed with a qualifying medical condition and that the physician recommends the use of cannabis for medical purposes.

Further decriminalization was enacted on September 30, 2010 when Health & Safety Code § 11357 was signed into law. Effective January 1, 2011, this statute makes possession of less than one ounce of cannabis a civil infraction rather than a criminal misdemeanor as it had previously been categorized.

In November 2010, California Proposition 19, the “Regulate, Control and Tax Cannabis Act of 2010,” attempted to decriminalize the recreational use of cannabis in California, while this use would have remained illegal at the federal level. Proposition 19 would have permitted adults 21 years and older to possess up to one ounce of cannabis for private use and would have also allowed local governments to license and tax its sale. Proposition 19 would also have maintained the current prohibitions for driving under the influence of cannabis, allowed for employers to address workplace impairment (that is, not to drug test their employees for cannabis use), and prohibited the use of cannabis in the presence of minors. Proposition 19 failed with 53.5 percent of voters voting “no” on the proposition and 46.5 percent of voters supporting the initiative.

Medicinal Efficacy
The CMA Council on Scientific and Clinical Affairs (CSA) has developed a set of medical cannabis recommendation guidelines for physicians indicating the limited conditions for which the medical use of cannabis may be effective.18 CSA has opined that the literature on this subject is inadequate, cannabis dosage is not well standardized, and cannabis side effects may not be tolerated. Dosage is not currently well-standardized and limited medical benefits have been established with the available research. Currently, California law only allows patients with a physician recommendation for medical cannabis to cultivate or use the substance.

CSA has also concluded that components of medical cannabis may be effective for the

treatment of pain, nausea, anorexia, and other conditions.\textsuperscript{19} Cannabinoids are presently thought to exhibit their greatest efficacy when implemented for the management of neuropathic pain, which is a form of severe and often chronic pain resulting from nerve injury, disease, or toxicity.\textsuperscript{20} The University of California Center for Medicinal Cannabis Research (CMCR) recently reported to the California legislature upon the results of a number of studies. Among these, four studies involved the treatment of neuropathic pain and all four demonstrated a significant improvement in pain after cannabis administration.\textsuperscript{21}

Other possible clinical benefits of cannabis have been discussed in the literature prompting the call for scientific study. Several national organizations have taken policy positions as a means of encouraging additional study of cannabis. Most notably, a Consensus Conference sponsored by the National Institutes of Health (NIH)\textsuperscript{22} and a review panel convened by the Institute of Medicine\textsuperscript{23} advocated that controlled studies be performed for analgesia, appetite stimulation and cachexia, and nausea and vomiting following chemotherapy. In 2001, the American Medical Association (AMA) Council on Scientific Affairs advocated that the NIH implement administrative procedures to facilitate grant applications to conduct well-designed clinical research into the medical utility of cannabis.\textsuperscript{24} In 2008, the American College of Physicians (ACP) also urged “an evidence-based review of marijuana’s [cannabis] status as a Schedule I controlled substance to determine whether it should be reclassified to a different schedule.”\textsuperscript{25} One year later (2009), the AMA’s House of Delegates put forward a clear-cut message that marijuana’s [cannabis] Schedule I status was no longer

\textsuperscript{19} “Medical Marijuana.” The Medical Letter® On Drugs and Therapeutics. No. 52, January 25, 2010: 1330.
\textsuperscript{22} “Workshop on the Medical Use of Marijuana.” National Institutes of Health, Bethesda, MD, 1997.
appropriate and interfered with legitimate medical research.\textsuperscript{26} Most recently, the California Medical Association’s House of Delegates adopted policy urging that marijuana’s [cannabis] status as a federal DEA Schedule I controlled substance be reviewed with the goal of facilitating research (HOD 102a-10).

\textbf{Risks of Cannabis Use}

The literature documents several personal health risks, both short and long-term, associated with cannabis use. According to the National Institute on Drug Abuse (NIDA), cannabis use can result in distorted perceptions, impaired coordination, difficulty thinking and problem solving, and problems with learning and memory.\textsuperscript{27} These effects can last for days or weeks and may result in long-term personal health problems such as addiction, anxiety, depression, psychosis, respiratory problems, and heart attack. Epidemiologic data from a national comorbidity study indicate that about nine percent of adult cannabis users become addicted and that this risk is substantially increased among individuals who begin using before age eighteen.\textsuperscript{28} Further evidence suggests that cannabis can adversely affect adolescents who initiate use early and young adults who become regular users because adolescents and young adults have a much greater vulnerability to the toxic effects of cannabis on the brain.\textsuperscript{29} These conditions also have second-hand effects by posing health risks to those members of the public around the user.

Those who oppose the decriminalization and legalization of cannabis cite these and other potential threats that the use of this substance poses to public health and safety. Epidemiological studies have been inconclusive regarding whether cannabis use causes an increased risk of motor vehicle accidents; in contrast, unanimity exists that alcohol use increases crash risk.\textsuperscript{30} In tests using driving simulation, neurocognitive impairment varies in a dose-related fashion, and symptoms are more pronounced with highly automatic driving functions than with more complex tasks that require conscious control.\textsuperscript{31} Cannabis smokers tend to over-estimate their impairment and compensate


\textsuperscript{27} “Marijuana.” National Institute on Drug Abuse. June 2009.


\textsuperscript{31} Ibid.
effectively while driving by utilizing a variety of behavioral strategies. Public health risks correlated with adolescent cannabis include poorer educational outcomes and occupational attainment. Under the current prohibition of cannabis, public health is also affected by increased rates of crime surrounding cannabis cultivation, sale and use. The California Legislative Analyst’s Office estimates that the incarceration and parole supervision of cannabis offenders costs the state tens of millions of dollars annually.32

Policy Recommendations
Cannabis is currently not sufficiently regulated. In order to allow for a robust regulatory scheme to be developed, cannabis must be moved out of its current Schedule I status within the DEA’s official schedule of substances. Rescheduling cannabis will allow for further clinical research to determine the utility and risks of cannabis, which will then shape the national regulatory structure for this substance.

CMA policy has acknowledged the criminalization of cannabis to be a failed public health policy (HOD 704a-09) and has recognized a public movement toward the legalization of cannabis (HOD 101a-10). Cannabis illegality has perpetuated the effective prohibition of clinical research on the properties of cannabis and has prevented the development of state and national standards governing the cultivation, manufacture, and labeling of cannabis products, similar to those governing food, tobacco and alcohol products, most of which are promulgated by federal agencies.

So what shifts in public policy could protect public health and benefit personal health? In order to fully evaluate and regulate cannabis, it should be legalized and decriminalized.

Solutions
Sustain physicians as “gatekeepers” until a proper gate is built: CMA believes that the physician role as “gatekeeper” should be sustained, under Council on Scientific and Clinical Affairs (CSA) guidelines, until such time as the legal and regulatory environment has changed from one in which medicinal cannabis is decriminalized at the state level but illegal at the federal level to a desired environment in which cannabis use is legalized and regulated at both the state and federal levels.

Reschedule cannabis: The federal Controlled Substances Act classifies cannabis as a Schedule I controlled substance, therefore preventing prescriptions from being written for the substance and subjecting it to production quotas by the Drug Enforcement Agency (DEA). These production quotas make it extremely difficult to acquire cannabis for clinical research purposes, thus contributing to the lack of data currently available

about cannabis. As of 2010, CMA supports the rescheduling of cannabis to facilitate further clinical research (HOD 102a-10). This clinical research should be targeted at determining the safety and efficacy of cannabis and its constituent active chemicals.

Three options exist for rescheduling cannabis and supporting further research:

1. Move cannabis to an appropriate scientific schedule within the current DEA scheduling structure;
2. Place cannabis on its own schedule with parameters unique from other enumerated schedules;
3. Support the development of local cannabis regulations as an interim alternative pending federal action.

The route to challenging cannabis’s status as a Schedule I controlled substance is by filing a rule-making petition with the DEA Administrator. The Administrator has the authority to reschedule substances by considering the “scientific evidence of [the substance’s] pharmacological effect, if known” and “the state of current scientific knowledge regarding the [substance].”

Because the DEA has historically denied petitions to reschedule cannabis, CMA should encourage the formation of a national coalition between state medical societies, medical specialty societies, and other relevant groups for the purpose of building support for cannabis rescheduling. The national movement whereby 16 states and the District of Columbia have decriminalized the use of medical cannabis should serve as a model for building this coalition. With strength in numbers and the power to place the necessary political pressure on the DEA, this coalition should consider jointly petitioning the DEA to reschedule cannabis.

Regulate medical cannabis: Rescheduling medical cannabis to allow for further clinical research is the acceptable avenue for providing an opportunity to formulate a workable, evidence-based federal and state regulatory structure that protects public health and safety. By allowing adequate research to determine the utility, safety and efficacy of cannabis as well as the necessary controls for the substance’s production, distribution, taxation, etc., cannabis regulation is able to mirror that of other prescribed medications. The appropriate regulatory bodies can use funds collected through a cannabis tax to enforce violation of the implemented standards. The regulation of cannabis should address several broad areas, including:

Research: As with any drug or pharmaceutical product, the properties of cannabis should be thoroughly studied through clinical research to determine utility, safety, and efficacy for potential medicinal uses. The outcome of this

clinical research should be used to determine an appropriate regulatory framework for cannabis control.

**Production & Distribution:** Production of cannabis should be held accountable to quality control measures and standardization. All vendors should be licensed and distribution of cannabis should include restrictions on purchase and use to all minors. All cannabis supply should be subject to purity, concentration and product labeling standards. Labeling standards should include warning labels, similar to those on tobacco and alcohol products. Pending federal regulation of cannabis, local regulatory structures should be implemented in order to control the production and supply of cannabis.

**Public Safety:** Workplace safety should remain a priority, with the enactment of prohibitions against workplace intoxication, similar to the treatment of alcohol use. Also, regulations surrounding driving safety and zero-tolerance for school possession should be implemented.

**Advertising:** Public advertisement of cannabis should be subject to time and place provisions, similar to tobacco and alcohol, with sanctions including loss of licensure for those entities that violate this provision.

**Reporting:** An outcomes reporting system is needed to track beneficial and adverse effects of cannabis in real-time.

**Regulate recreational cannabis:** Consider permissive federal authority for states to regulate this more widely used cannabis for purity (strength) and safety (contaminations) with current, education and research on outcomes of such policy. These actions would mirror alcohol and tobacco control. While an unlikely political act nationally at this time, Colorado is already attempting this without federal authority. Growing local discontent with federal non-actions coupled with increasing violence among cannabis dealers (“cartels”) in Mexico could help leverage this action. CMA should authorize responsible collaboration with groups which support such state level action.

**Tax cannabis:** A tax should be levied on cannabis as a means of collecting funds dedicated to regulation, enforcement and education.

**Facilitate dissemination of the benefits and risks of cannabis use as determined by clinical research:** The outcomes of clinical cannabis research should be publicly shared so as to educate the public.

**Support educational efforts:** Various educational campaigns targeting different demographics are needed. These educational activities can be funded through an earmarked portion of the cannabis tax. The goal of these educational campaigns should be to reduce cannabis use among children, adolescents, and young adults. Separate campaigns should be launched targeting the public, physicians, and medical students.
Within the general public demographic, smaller targeted campaigns will educate specific cohorts such as youth, adults, and law enforcement officials.

Refer for national action: National advocacy is essential to promoting the adoption of consistent, effective regulations at the federal level. Without a national solution, a patchwork of state-by-state decriminalization efforts will persist, thus exposing physicians and members of the public to liability and federal criminal sanctions.

White paper dissemination: This white paper shall be distributed to interested CMA members, component medical societies, specialty societies, and other interested organizations.