STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

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Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor

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Testimony on HB 15, HB 1024, and HB 1158 Related to Medical Use of Marijuana
Joint Hearing of the Health and Government Operations Committee and the Judiciary Committee

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Thank you for the opportunity to testify on several proposals related to the use of marijuana for medical purposes in Maryland.

Since last year, a workgroup that was convened as a result of legislation developed two alternate proposals for legislative consideration. These proposals are reflected in House Bills 1024 and 1158. In my testimony, I will review these proposals and House Bill 15 and provide the Department's position on their merits as policy.

I will also discuss a significant shift in federal oversight of state marijuana programs that has occurred since the General Assembly last considered this issue.

Most significantly, the legislation under consideration could place state employees at risk of federal prosecution for violation of the Controlled Substances Act. Maryland Assistant Attorney General Kathryn M. Rowe recently stated that "the programs established under [HB 1024 and HB 1158] involve conduct that could expose State employees to a potentially significant risk of liability." [Emphasis added].

Because of this risk, unless and until federal policy changes, the Administration opposes the proposed legislation.

Background

Marijuana contains pharmacologically active compounds, called cannabinoids, which have therapeutic value. Some of these compounds have been isolated, studied, and approved by the U.S. Food and Drug Administration for specific indications.

In contrast to the approved use of these isolated compounds, the use of the marijuana plant itself for medical purposes is controversial. The controversy is related not only to marijuana's legal status as a controlled substance, but also because marijuana has not been characterized, studied, and determined by the U.S. Food and Drug Administration to be safe and effective. In addition, while some patients have found that marijuana has helped a variety of symptoms, others have suffered adverse effects including memory problems, severe anxiety, panic attacks, and psychosis.

In testimony last year, the Department described three approaches to the use of the marijuana plant for medical purposes.[1]

- A *green light* approach supports broad access to the marijuana plant for medical purposes, based on the contention that the benefits outweigh the risks for a wide variety of clinical conditions.

- A *red light* approach opposes access to the marijuana plant for medical purposes, until a science-based regulatory agency finds that data demonstrates that the benefit outweighs the risk. I noted, for example, that on this basis the Council on Science and Public Health American Medical Association opposes "drug approval … by ballot initiative or state legislative action."

- A *yellow light* approach sees the evidence for specific uses as promising but not definitive and supports the limited use of the marijuana plant for medical purposes as part of a monitored research program. The Institute of Medicine's comprehensive 1999 report recommended such an approach, supporting the availability of marijuana for medical purposes through research programs with specific controls, including:

    1. Treatment is of less than six months duration;
    2. Failure of all approved medications to provide relief has been documented;
    3. The symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs;
    4. Such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness; and
    5. This direct supervision is accompanied by an oversight strategy comparable to an institutional review board process that could provide guidance, within 24 hours of a submission by a physician, on the appropriateness of providing marijuana to a patient for a specified use.

    The Institute of Medicine committee also recommended that patients receiving marijuana to smoke be "fully informed of their status as experimental subjects using a harmful drug delivery system."

[1] Testimony of Dr. Joshua M. Sharfstein, Secretary, Maryland Department of Health and Mental Hygiene, 2011 Legislative Session, on S.B. 308/H.B. 291. Available online at http://bit.ly/wYT65G.

The Department expressed concern about a variety of specific aspects of the legislation as proposed in the 2011 Session. We also took the position that the marijuana plant was most analogous to an investigational product with potential benefits and potential risks for patients. We concluded by stating that the Department would be open to exploring the feasibility of a "yellow light" model for marijuana for medical purposes in Maryland. We supported amended legislation that passed the General Assembly that sought to develop a model proposal for consideration this year.

Recent Developments – Science

The Department continues to support the position of the Institute of Medicine that there are potential benefits and potential risks to the use of the marijuana plant for medical purposes, but that it has not been demonstrated that the benefits exceed the risks for defined indications.

In June 2011, the Drug Enforcement Administration denied a petition to reschedule marijuana, on the grounds that scientists at the Department of Health and Human Services had found in 2006 that "marijuana has a high potential for abuse … marijuana has no currently accepted medical use in treatment in the United States … [and] marijuana lacks accepted safety for use under medical supervision."[2]

There remains significant concern in the public health community about the diversion and abuse potential of marijuana. Specifically, marijuana use among teenagers is growing, with more than one in three 12th graders reporting use in the past year. The rate of use is the highest it has been since 1981. This increase corresponds to a decline in 12th graders' perception of risk from marijuana use.[3] Marijuana poses a wide range of health threats to teenagers, including impairment of judgment, addiction, and exacerbation of mental health disorders.

The Workgroup

As amended and enacted in the 2011 Session, Senate Bill 308 required the Secretary to convene a workgroup to develop and assess the feasibility of a State-specific proposal for providing access to marijuana to patients in the state for medical purposes. Along the lines of a "yellow light" model, the legislation required the workgroup to present draft legislation that would:

- Provide for oversight and responsibility by programs located in academic medical research institutions in the State;
- Provide for the licensing of a program by the State;
- Establish a program and review process that includes consideration for best practices and procedures for obtaining review and input that is external to the Department;

[2] See Federal Register, 8 July 2011, 40552-40589.

[3] National Institute on Drug Abuse, National Institutes of Health. Monitoring the Future: National Results on Adolescent Drug Use, 2011. Available online at http://bit.ly/z2rek5.

- Expand the base of information on the use of marijuana for medical purposes on a scientific and policy implementation basis; and
- Implement a program as soon as feasible with the goals of implementation by January 2013.

The legislation also required the workgroup to provide guidance on the criteria for assessing applications from academic research institutions, including:

- Determining the medical conditions to be treated and the duration of therapy proposed;
- Identifying sources of marijuana;
- Determining patient eligibility and informed consent;
- Conducting any associated research projects;
- Reporting data and outcomes;
- Instituting strict controls against illegal diversion; and
- Identifying grants or other sources of funding to facilitate the affordability of the program.

As detailed in its December 9, 2011 report to the legislature, the workgroup developed two proposals.[4]

The first proposal is the basis for HB 1024. This proposal would create a Commission that would have the authority to permit (under State law, but not under federal law) academic research institutions to design and implement programs that make marijuana available for medical purposes to defined groups of patients. The supervising researchers would be able to characterize the marijuana and be able to report back on the outcomes and adverse effects. Marijuana would come from growers who are separately authorized by the State. Eleven workgroup members supported this proposal. Individuals who exclusively supported this proposal included Major Kevin Anderson, Major Sam Billotti, Nancy Rosen Cohen of the Maryland chapter of the National Council on Alcoholism and Drug Dependence, oncologist Dr. Paul Celano, rehabilitation medicine specialist Dr. Trudy Hall, addiction medicine specialist Dr. Joseph Liberto, and myself.

The second proposal is the basis for HB 1158. This proposal would go beyond the academic center model envisioned by the legislative language enacted last year establishing the workgroup. It would create a Commission that would have the authority to permit (under State law, but again not under federal law) any physician who has received training and authorization to recommend marijuana to patients for a wide range of conditions. In addition, the Commission would authorize academic research institutions to develop projects as outlined in the first proposal. In addition to separate licensing for growers, the second approach would also provide for state oversight of a network of dispensers of marijuana for medical purposes. Ten workgroup members supported this approach. Individuals only supporting this proposal included Delegate Dan Morhaim, Senator Jamie Raskin, Senator David Brinkley, hospice nurse-administrator Lynn Billing, patient Deborah Moran, and marijuana policy project attorney Karen O'Keefe.

[4] Medical Marijuana Model Program Workgroup. Report to the Legislature. 9 December 2011.

Commission members who supported both versions included Delegate Kathleen Dumais, researcher Dr. Ryan Vandrey, State's Attorney Dario Broccolino, and pharmacist Philip Cogan. FOP representative Michael Young did not support either of the proposals.

The Federal Government

In the last year, the approach of Department of Justice and U.S. Attorneys to programs contemplated by HB 15, HB 1024, and HB 1158 has shifted. Federal prosecutors have asserted that a state program on the medical use of marijuana does not shield state residents – or state employees – from potential criminal prosecution.

Indeed, when asked to review HB 1024 and HB 1158, Maryland's Attorney General has found a "potentially significant risk of liability" to state employees.

Some concerning developments include:

April 2011. As the Washington state legislature was considering legislation that was similar to HB 291/ SB 308 as introduced, Governor Christine Gregoire sought input from two U.S. Attorneys in her state. In April 2011, the prosecutors wrote that the legislation "would create a licensing scheme that permits large-scale marijuana cultivation and distribution" and that "state employees who conduct activities mandated by the Washington legislative proposals would not be immune from liability under the [Controlled Substances Act]."[5] Gov. Gregoire vetoed key parts of the legislation, explaining her view that "no state employee…should be required to violate federal criminal law in order to fulfill duties under state law."[6]

June 2011. In June, the U.S. Department of Justice issued a new memorandum on enforcement of federal law in the context of state programs related to marijuana. Deputy Attorney General James Cole stated that "persons who are in the business of cultivating, selling or distributing marijuana, and those who knowingly facilitate such activities, are in violation of the Controlled Substances Act, regardless of state law."[7] Recently, in reflecting on this Department of Justice memo, Maryland Assistant Attorney General Kathryn M. Rowe has stated, "I would read [the Cole memo] to mean that…the [Justice] Department's prosecutorial priorities might well include the prosecution of state-regulated marijuana growers and dispensaries, particularly if those operations are growing or selling marijuana on a large scale."[8]

February 2012. In February, the U.S. Attorney in Delaware wrote to the office of Governor Jack Markell about his state's law on marijuana for medical purposes. This law permits access only through several

[5] Letter from U.S. Attorneys Jenny A. Durkan and Michael C. Ormsby to Governor Christine Gregoire. 14 April 2011.

[6] Governor Christine Gregoire. Veto Message. 29 April 2011.

[7] James M. Cole. Memorandum for United States Attorneys. 29 June 2011.

[8] Letter from Assistant Attorney General Kathryn M. Rowe to Delegate Dan Morhaim. 2 March 2012.

nonprofit centers. The U.S. Attorney nonetheless wrote that "growing, distributing, and possessing marijuana, in any capacity, other than as part of a federally authorized research program, is a violation of federal law regardless of state laws permitting such activities."[9] The U.S. Attorney also noted that "state employees who conduct activities mandated by the Delaware Medical Marijuana Act are not immune from liability under the Controlled Substances Act."[10] Based on this input, Delaware Governor Jack Markell suspended implementation of his state's law on marijuana for medical purposes because he refused to "put our state employees in legal jeopardy."[11]

March 2012. U.S. Attorney Rod Rosenstein advised me that the Department of Justice's approach to marijuana for medical uses would be the same in Maryland as it is in Delaware. He noted that the Department of Justice maintains that the possession or distribution of marijuana clearly violates federal criminal law, and that prohibition applies regardless of state law.

In reviewing the legal landscape with respect to House Bills 1024 and 1158, Assistant Attorney General Kathryn M. Rowe recently stated:

> [N]either House Bill 1024 nor House Bill 1158 would establish a program that lies clearly and wholly outside the announced enforcement priorities of the Department of Justice. Both proposals would provide for State regulation of marijuana growers, and people who cultivate marijuana for distribution to others would not be considered "caregivers" under the terms of the Cole memo. House Bill 1158 also provides for the participation of dispensaries and pharmacies in the program it would establish. Consequently, the programs established under both bills involve conduct that could expose State employees to a potentially significant risk of liability.

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[9] Letter from Charles M. Oberly, III to Michael A. Barlow, Legal Counsel, Office of the Governor, Delaware. 9 February 2012.

[10] Ibid.

[11] Statement from Governor Markell on Medical Marijuana Law. 12 February 2012.

Proposed Legislation

HB 15 is not based on either Workgroup proposal. It would require the Department to develop a registry and issue patient ID cards that would permit use of marijuana under State law. It would authorize a network of distribution centers. It permits very broad use of marijuana, including for anxiety, depression, pain, bipolar disorder, and others. The bill provides, among other things, for the Department to issue regulations, staff a commission, and provide ID cards. The legislation provides if the Department does not issue regulations by September 1, 2012, virtually anyone could file an action in circuit court to compel it to do so, and if the Department did not respond to an application within 20 days, a notarized copy of a statement could be deemed a valid registry identification card.

The Department opposes HB 15. It constitutes a “green light” approach to marijuana for medical purposes, an approach which is not supported by the scientific evidence. Such a policy would create a significant diversion issue and expose state employees to potential prosecution.

HB 1024 is based on a proposal from the Workgroup. As a policy matter, with some modifications in how oversight functions are distributed, our position is that HB 1024 best reflects the current state of the science and represents a genuinely “yellow light” approach.

As a legislative matter, however, the changing landscape of federal enforcement makes it impossible for the Administration to support HB 1024 at this time. According to recent statements by U.S. attorneys, state employees would not be immune from federal prosecution even under this limited approach to marijuana for medical purposes. Assistant Attorney General Kathryn M. Rowe has stated that “there can be no doubt” that this legislation covers “activities that are illegal under the Controlled Substances Act.”

Referring to bills HB 1024 and HB 1158, she recently wrote that “the programs established under both bills involve conduct that could expose State employees to a <u>potentially significant risk of liability</u>.” (emphasis added). She also noted that in the case of prosecution, the Office of the Attorney General “may not represent or provide counsel for a State officer or State employee by a criminal law enforcement agency or in any criminal action in a court of this State or the United States.”

The Administration cannot support legislation that could lead to prosecution of state employees.

HB 1158 is also based on a proposal from the Workgroup. This legislation would permit individual doctors to obtain certification to recommend marijuana for a wide range of conditions and create a network of licensed dispensaries across the state.

The Department opposes HB 1158. The legislation would be very challenging and unwieldy to administer, is more expansive than justified by the state of scientific evidence, and would create an increased risk of diversion. In addition, the legislation is more expansive and poses even greater legal risk to state employees than the Delaware law that drew the attention of the Justice Department and the approach contemplated by HB 1024. In comparing HB 1158 to HB 1024, Maryland Assistant

Attorney General Kathryn M. Rowe stated, “House Bill 1158 encompasses a substantially wider range of activities that could at least potentially fit within the federal government’s announced enforcement priorities.”

Conclusion

The Department opposes HB 15 and HB 1158 both as policy and because of the risk of federal prosecution of state employees.

As policy, HB 1024 with some minor modifications represents a reasonable approach to the investigational use of marijuana for medical purposes. However, because of the potential for federal prosecution of state employees, we are unable to support HB 1024 at this time.