



STATE OF MARYLAND

**DHMH**

**Maryland Department of Health and Mental Hygiene**

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

Joshua M. Sharfstein, M.D., Secretary

**Testimony on HB 302, HB 1100, and HB 1101 Related to Medical Use of Marijuana  
Joint Hearing of the Health and Government Operations Committee and the Judiciary Committee**

**March 8, 2013**

**Joshua M. Sharfstein, M.D.**

**Secretary, Maryland Department of Health and Mental Hygiene**

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

In 2011, a workgroup that was convened as a result of legislation developed two alternate proposals for legislative consideration. These proposals are reflected in HB 1100 and HB 1101. In my testimony, I will review these two proposals and HB 302.

The Department supports HB 1101 with amendments and opposes HB 302 and HB 1100.

**Background**

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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 in 2011 and 2012, the Department described three approaches to the use of the marijuana plant for medical purposes.<sup>1</sup>

- 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.”

The Department has taken 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, based on the Institute of Medicine recommendations.

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<sup>1</sup> 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>.

## Recent Developments – Science

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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.”<sup>2</sup>

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 12<sup>th</sup> 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 12<sup>th</sup> graders’ perception of risk from marijuana use.<sup>3</sup> Marijuana poses a wide range of health threats to teenagers, including impairment of judgment, addiction, and exacerbation of mental health disorders.

## The Workgroup

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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;
- 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;

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<sup>2</sup> See Federal Register, 8 July 2011, 40552-40589.

<sup>3</sup> 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>.

- 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.<sup>4</sup>

The first proposal is the basis for HB 1101. 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. Eleven workgroup members supported this proposal, including the oncologist, rehabilitation medicine specialist, and addiction medicine specialist on the panel.

The second proposal is the basis for HB 1100. 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.

### **Proposed Legislation**

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**HB 302** 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 302. 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.

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<sup>4</sup> Medical Marijuana Model Program Workgroup. Report to the Legislature. 9 December 2011.

**HB 1101** is based on the first proposal mentioned above from the Workgroup. Our position is that HB 1101 best reflects the current state of the science and represents a genuinely “yellow light” approach. We recommend the following 4 policy amendments:

1. The bill should assign all regulatory functions to the Commission, to centralize authority and oversight.
2. The bill should establish a special fund for contributions and grants that can fund the start-up of the program.
3. The bill should reserve the first year to develop policies and prepare for implementation.
4. The bill should require by December 1 a plan for fees to support the operation of the program in future fiscal years.

**HB 1100** is based on the second proposal discussed above 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.

For reasons discussed at length in previous testimony, the Department continues to oppose HB 1100. 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. If this legislation were to pass, it is critically important that resources not be diverted from ongoing public health efforts at the Department to fund its implementation.

### **The Legal Environment**

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Last year, we testified about concerns that state law on the medical use of marijuana does not shield state residents – or state employees – from potential criminal prosecution. Indeed, when asked to review proposed legislation that is essentially the same as HB 302, HB 1100, and HB 1101, Maryland’s Attorney General found a “potentially significant risk of liability” to state employees.

Since last year, the federal government has conducted some additional enforcement, but not against state employees. New Jersey and the District of Columbia have initiated programs for the medicinal use of marijuana without interference by the Department of Justice.

The legal environment for state regulation of marijuana for medical purposes remains clouded. The Administration’s position is that the legal issues should be considered at the stage of implementation. If the legislature is interested in pursuing legislation this session, we support two additional amendments:

5. The bill should allow the state to support the defense of any state employees charged with violations of federal law for implementation of this act;
6. The bill should permit the Governor to suspend implementation in the event that there is a reasonable concern that state employees may face criminal prosecution.

## **Conclusion**

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The Department opposes HB 302 and HB 1100.

With amendments, HB 1101 represents a reasonable approach to the investigational use of marijuana for medical purposes.