The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Appropriations

BILL:	CS/CS/SB 1030
INTRODUCER:	Appropriations Committee; Health Policy Committee; and Senator Bradley and others
SUBJECT:	Low-THC Cannabis
DATE:	April 24, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Erickson	Cannon	CJ	**Favorable**
3.	Looke	Kynoch	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1030 creates s. 456.60, F.S., in order to allow the compassionate use of low-THC cannabis. The bill allows certain patients whose Florida-licensed physician registers them with the Department of Health (DOH) to use low-THC cannabis under limited circumstances. The bill defines low-THC cannabis as containing no more than 0.8 percent of tetrahydrocannabinol (THC) and at least 10 percent of cannabidiol (CBD).

The bill provides for patients who receive an order for low-THC cannabis by their physician to be added to a registry that is created and maintained by the DOH and to receive an identification card. Such a patient may purchase or acquire low-THC cannabis in an amount no greater than the physician's order and only from a dispensing organization that is approved by the DOH.

The bill exempts patients and their legal representatives from the legal restrictions on the purchase, acquisition, possession, and medical use of low-THC cannabis. Approved dispensing organizations, including owners, managers, and employees, are exempted from similar restrictions under certain parameters.

The bill encourages state universities with both medical and agricultural programs to develop or participate in Federal Food and Drug Administration-approved research on low-THC cannabis.

The bill has an indeterminate fiscal impact.

II. Present Situation:

Treatment of Marijuana in Florida

Florida law defines cannabis as "all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin"[1] and places it, along with other sources of THC, on the list of Schedule 1 controlled substances.[2] Schedule 1 controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States. As a Schedule 1 controlled substance, possession and trafficking in cannabis carry criminal penalties that vary from a first degree misdemeanor[3] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[4] Paraphernalia[5] that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.[6]

Medical Marijuana in Florida: The Necessity Defense

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State*[7] where the First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the First District found that the Jenks met the criteria for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

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[1] Section 893.02(c), F.S.
[2] Section 893.03(c)7. and 37., F.S.
[3] This penalty is applicable to possession or delivery of less than 20 grams of cannabis. See s. 893.13(3) and (6)(b), F.S.
[4] Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first degree felony with a mandatory minimum sentence that varies from 3 to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. See s. 893.135(1)(a), F.S.
[5] This term is defined in s. 893.145, F.S.
[6] Section 893.147, F.S.
[7] 582 So.2d 676 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991)

Medical Marijuana Laws in Other States

Currently, 20 states and the District of Columbia[8] have some form of law that permits the use of marijuana for medicinal purposes. These laws vary widely in detail but most are similar in that they touch on several recurring themes. Most state laws include the following in some form:

- A list of medical conditions for which a practitioner can recommend the use of medical marijuana to a patient.
  - Nearly every state that permits the use of marijuana for medicinal purposes has a list of applicable medical conditions, though the particular conditions vary from state to state. Most states also include a way to expand the list either by allowing a state agency or board to add medical conditions to the list or by including a "catch-all" phrase.[9] Most states require that the patient receive certification from at least one, but often two, physicians designating that the patient has a qualifying condition before the patient may be issued an identification card needed for the acquisition of medical marijuana.
- Provisions for the patient to designate one or more caregivers who can possess the medical marijuana and assist the patient in preparing and using the medical marijuana.
  - The number of caregivers allowed and the qualifications to become a caregiver vary from state to state. Most states allow one or two caregivers and require that they be at least 21 years of age and, typically, cannot be the patient's physician. Caregivers are generally allowed to purchase or grow marijuana for the patient, be in possession of the allowed quantity of marijuana, and aid the patient in using the marijuana, but are strictly prohibited from using the marijuana themselves.
- A required identification card for the patient, caregiver, or both that is typically issued by a state agency.
- A registry of people who have been issued an identification card.
- A method for registered patients and caregivers to obtain medical marijuana.
  - There are two general methods by which patients can obtain medical marijuana. They must either self-cultivate the marijuana in their homes or the state allows specified marijuana points-of-sale or dispensaries. The regulations governing such dispensaries vary widely.
- General restrictions on where medical marijuana may be used.
  - Typically, medical marijuana may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.

State Medical Marijuana Laws and Their Interaction with the Federal Government

The Federal Controlled Substances Act lists Marijuana as a schedule 1 drug with no accepted medical uses. Under federal law possession, manufacturing, and distribution of marijuana is a

[8] These states include Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois (effective 2014), Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and Illinois was the most recent state to pass medical marijuana legislation in August of 2013. Illinois legislation became effective in January, 2014. See http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx. (last visited on March 19, 2014).
[9] An example is California's law that includes "any other chronic or persistent medical symptom that either: 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, or if not alleviated, may cause serious harm to the patient's safety or physical or mental health."

crime.[10] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under the guidelines established in that state, such laws do not protect individuals from prosecution under federal law if the federal government enforces those laws.

In August of 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[11] This document details the federal government's current stance on low-level drug crimes and contains the following passage:

> … the Attorney General is announcing a change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels, will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins.

In addition, the USDOJ published on August 29, 2013, a memorandum with the subject "Guidance regarding Marijuana Enforcement." This memorandum makes clear that the USDOJ considers small-scale marijuana use to be a state matter which states may choose to punish or not, and, while larger operations would fall into the purview of the USDOJ, those operations that adhere to state laws legalizing marijuana in conjunction with robust regulatory systems would be far less likely to come under federal scrutiny.[12] These announcements generally indicate the USDOJ's current unwillingness to prosecute such cases and its inclination to leave such prosecutions largely up to state authorities.

Tetrahydrocannabinol

Tetrahydrocannabinol (THC) is the major psychoactive constituent of marijuana. The potency of marijuana, in terms of psychoactivity, is dependent on THC concentration and is usually expressed as percent of THC per dry weight of material.

Average THC concentration in marijuana is 1 - 5 percent and the form of marijuana known as *sinsemilla* is derived from the unpollinated female cannabis plant and is preferred for its high THC content (up to 17 percent THC). Recreational doses are highly variable and users often titer their own dose. A single intake of smoke from a pipe or joint is called a hit (approximately 1/20th of a gram). The lower the potency or THC content the more hits are needed to achieve the desired effects.[13]

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[10] The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. See http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm#cntlsbd. (last visited on March 19, 2014).
[11] See http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on March 19, 2014).
[12] See USDOJ memo on "Guidance Regarding Marijuana Enforcement," August 29, 2013, available at http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf (last visited on March 19, 2014).
[13] Drugs and Human Performance Fact Sheet for Cannabis / Marijuana, National Highway Traffic Safety Administration, available at http://www.nhtsa.gov/people/injury/research/job185drugs/cannabis.htm (last visited on March 19, 2014).

Marinol is a currently-approved drug[14] that consists of a man-made form of THC known as dornabinol.[15] Marinol is used to treat anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to adequately respond to conventional antiemetic treatments. Marinol has a variety of side-effects including a cannabinoid dose-related "high."[16]

Cannabidiol

Cannabidiol (CBD) is another cannabinoid that is found in marijuana and, although THC has psychoactive effects, CBD and other cannabinoids are not known to cause intoxication.[17] Some evidence shows that CBD is effective in treating seizure disorders,[18,19] although much of this evidence is anecdotal. Currently, the drug Epidiolex, which is a liquid form of highly purified CBD extract, was approved by the FDA in November 2013, as an orphan drug[20] that may be used to treat Dravet syndrome.[21,22]

Dravet Syndrome

Also known as Severe Myoclonic Epilepsy of Infancy (SMEI), Dravet syndrome is a rare form of intractable epilepsy that begins in infancy.[23] Initial seizures are most often prolonged events and, in the second year of life, other seizure types begin to emerge. Individuals with Dravet syndrome face a higher incidence of SUDEP (sudden unexplained death in epilepsy) and typically have associated conditions that also need to be properly treated and managed. These conditions include:

- Behavioral and developmental delays;
- Movement and balance issues;
- Orthopedic conditions;
- Delayed language and speech issues;
- Growth and nutrition issues;
- Sleeping difficulties;
- Chronic infections;
- Sensory integration disorders; and

[14] The drug is approved by the US Food and Drug Administration.
[15] See http://www.marinol.com/about-marinol.cfm (last visited on March 19, 2014).
[16] For Marinol prescribing information, see http://www.rxabbvie.com/pdf/marinol_PI.pdf (last visited on March 19, 2014).
[17] This information is from GW Pharmaceuticals, see http://www.gwpharm.com/FAQ.aspx (last visited on March 19, 2014).
[18] See http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/ (last visited on March 19, 2014).
[19] See also the presentation to the Florida House Criminal Justice Subcommittee on the Charlotte's Web strain of marijuana on January 9, 2014.
[20] An orphan drug is defined as a drug that is intended for the safe and effective treatment, diagnosis, or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. See http://www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions/default.htm. (last visited on March 19, 2014).
[21] See http://www.gwpharm.com/LGS%20Orphan%20Designation.aspx (last visited on March 19, 2014).
[22] Dravet syndrome is a rare form of childhood epilepsy. See http://www.ninds.nih.gov/disorders/dravet_syndrome/dravet_syndrome.htm (last visited on March 19, 2014).
[23] Dravet Syndrome Foundation, http://www.dravetfoundation.org/dravet-syndrome/what-is-dravet-syndrome (last visited on April 16, 2014).

- Disruptions of the autonomic nervous system (which regulates bodily functions such as temperature regulation and sweating).

Individuals with Dravet syndrome do not outgrow the condition. Current treatment options are extremely limited and constant care and supervision are typically required.

III. Effect of Proposed Changes:

Section 1 creates s. 456.60, F.S., to allow the compassionate use of low-THC cannabis. The bill:

- Defines the terms:
  - "Dispensing organization" to mean an organization approved by the Department of Health (DOH) to cultivate, process, and dispense low-THC cannabis;
  - "Low-THC cannabis" to mean a substance that contains no more than 0.8 percent of any THC and at least 10 percent of CBD and which is dispensed from a dispensing organization;
  - "Medical use" to mean the administration of the ordered amount of low-THC cannabis with the exception of possession, use, or administration by smoking and the transfer of low-THC cannabis to a person other than the qualified patient or his or her legal representative;
  - "Qualified patient" to mean a Florida resident who has been added to the compassionate use registry by a Florida-licensed physician; and
  - "Smoking" to mean burning or igniting a substance and inhaling the smoke. The term smoking does not include the use of a vaporizer.
- Effective January 1, 2015, allows Florida-licensed physicians to order low-THC cannabis for a patient suffering from a physical medical condition, or treatment for a medical condition, that chronically produces symptoms of seizure or severe and persistent muscle spasms. The physician may only order low-THC cannabis if:
  - The patient is a permanent resident of Florida;
  - The physician has treated the patient for his or her symptoms for at least two months;
  - The physician, along with a second physician for patients under the age of 18, determines the risk of ordering low-THC cannabis are reasonable;
  - The physician registers as the orderer for the named patient on the registry, updates the registry with the order's contents, and deactivates the patient's registration when treatment is discontinued;
  - The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis; and
  - The physician submits the treatment plan quarterly to the University of Florida's College of Pharmacy for research on the safety and efficacy of low-THC cannabis.
- Requires physicians to undergo eight hours of education, including passing an examination, offered by the Florida Medical Association relating to clinical indications, appropriate delivery mechanisms, contraindications, and relevant state and federal laws governing ordering, dispensing, and possessing low-THC cannabis. The bill requires the first course and examination to be presented by October 1, 2014, and at least annually thereafter, allows subsequent courses to be used to satisfy eight hours of continuing medical education. The bill allows the coursework to be offered in a distance learning format.

- Requires the DOH, by January 1, 2015, to:
  - Create a secure, electronic, and online registry for the registration of physicians and patients which must be able to be accessed by law enforcement and the dispensing organization in order to verify patient orders. The dispensing organization must be able to record the low-THC cannabis dispensed, and the registry must prevent an active registration of a patient by multiple physicians.
  - Authorize at least one, but no more than four, dispensing organizations to ensure reasonable statewide accessibility and availability of low-THC cannabis as necessary. The DOH must develop an application form and impose initial and biennial renewal fees that are sufficient to cover the costs of administering their responsibilities. An applicant for approval as a dispensing organization must be able to demonstrate:
    - The technical and technological ability to cultivate and produce low-THC cannabis;
    - The ability to secure the premises, resources, and personnel necessary to operate;
    - The ability to maintain accountability of all cannabis-related products and to prevent diversion of those substances;
    - An infrastructure reasonably located to dispense low-THC cannabis statewide or regionally as determined by the DOH;
    - The financial ability to maintain operations for the duration of the two-year licensure cycle;
    - That all owners, managers, and employees have been fingerprinted and passed a level II background screening;
    - Any additional criteria determined by the DOH as necessary to safely function as a dispensary; and
    - Monitor physician registration and ordering of low-THC cannabis in order to take disciplinary action as needed.
  - Implement a process for issuing identification cards to patients registered in the compassionate use registry which expire one year after the date issued. Once expired, a patient who continues to be registered and is being treated with low-THC cannabis may be issued a new card.
- Requires the DOH to monitor and inspect the activities of each approved dispensing organization for compliance with the requirements of this section of law.
- Allows the DOH to adopt rules pertaining to submission of patient information to the compassionate use registry for the issuance of identification cards and recordkeeping requirements in order to demonstrate compliance with the section. Specifically, the recordkeeping requirements must include production and finished product testing for quality.
- Requires a dispensing organization to maintain compliance with all listed criteria for approval at all times and to verify before dispensing any low-THC cannabis that a patient has an active registration and that the patient's order matches the one recorded on the registry and has not already been filled. When the dispensing organization dispenses any low-THC cannabis, it must record the date, time, quantity, and form of the cannabis dispensed. A dispensing organization must also make records, premises, resources, products, and vehicles available for inspection by the DOH and law enforcement agencies.

- Creates exceptions from all other sections of law to provide that:
  - Qualified patients and their legal representatives may purchase, acquire, and possess for that patient's medical use up to the ordered amount of low-THC cannabis; and
  - Dispensing organizations, including their owners, managers, and employees, may acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and possess, process, and dispense low-THC cannabis.
- Provides that dispensing organizations and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.
- Requires the DOH to establish an Office of Compassionate Use under the deputy state health officer to administer the act, including access to the compassionate use registry.

Section 2 creates s. 385.30, F.S., to encourage state universities with both medical and agricultural research programs to develop or participate in Federal Food and Drug Administration-approved studies and clinical research treatment plans using low-THC cannabis which are directed toward refractory or intractable epilepsy relief in pediatric patients. A participating university may request from the DOH a grant of up $100,000 annually. In order to be eligible for the grant, the participating university's medical college or medical school must submit a report to the DOH by January 1 of each year which contains, at minimum, the gender and age of each participating patient, the names of the participating physicians, and the level of seizure reduction in each participating patient. The bill exempts the DOH's grant award decisions from the requirements of ch. 120, F.S.

Section 3 creates s. 1004.441, F.S., to exempt universities conducting research on low-THC cannabis from the prohibitions in ch. 893, F.S. The bill specifies that the research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of low-THC cannabis for the treatment for refractory or intractable epilepsy and allows current state and privately obtained research funds to be used to support such research.

Section 4 allows the DOH to submit a budget amendment request using excess funds from the Biomedical Research Trust Fund to implement the act during fiscal year 2014-2015.

Section 5 establishes an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/CS/SB 1030 may have a positive fiscal impact on private sector organizations that are approved by the DOH to become dispensing organizations.

C. Government Sector Impact:

The Department of Health (DOH)

The DOH indicates the need for $120,000 to fund the creation of the compassionate use registry and will require further funds to maintain the registry, as well as to approve and monitor the dispensing organizations.[24] However, these costs should be fully offset by the revenue generated through initial license fees and renewal fees charged to the dispensing organizations.

The DOH will incur a recurring increase in workload associated with monitoring physician registration and ordering of low-THC cannabis. The impact is indeterminate.

The DOH may experience a recurring increase in workload associated with enforcement and regulation duties under the bill. The impact is indeterminate.

The DOH may experience an indeterminate negative fiscal impact to establish an Office of Compassionate Use.

The DOH will incur nonrecurring costs for rulemaking, which current budget authority is adequate to absorb.

The Florida Department of Law Enforcement (FDLE) and County Crime Labs

Section 1 of the bill may generate additional revenue for the FDLE due to an increase in the number of criminal history checks performed. The current cost for a state record check is $24.[25] The number of additional criminal history record checks is indeterminate.

VI. Technical Deficiencies:

None.

[24] Analysis of SB 1030 (July 1, 2014), Florida Department of Health (on file with Senate Committee on Health Policy and the Senate Committee on Criminal Justice). All information in the "Fiscal Impact" section of this analysis relevant to the DOH is from the DOH analysis.

[25] The cost for a state and national criminal history record check is $40.50 ($24 goes into the FDLE Operating Trust Fund and $16.50 from each request is forwarded to the Federal Bureau of Investigation).

VII. Related Issues:

Unless exempted from public records, the personal identifying information placed into the compassionate use registry will be available to the general public. SB 1700 creates that public records exemption.

Regarding the bill's requirements for fingerprints and background screening for owners, managers, and employees of dispensing organizations, the FDLE recommends participation in the state and federal fingerprint retention program to ensure that all arrests of individuals screened which occur after the initial criminal history screening, are made known to the DOH. Under that program, after the bill becomes effective, both the FDLE and the Federal Bureau of Investigation will retain the fingerprints, search the fingerprints against incoming arrests, and notify the DOH if the retained fingerprints match an incoming arrest.[26]

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 456.60, 385.30, and 1004.441.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on April 22, 2014:
The CS:

- Changes the name of "low-THC marijuana" to "low-THC cannabis" throughout the bill;
- Amends the amounts of THC and CBD required to qualify as low-THC cannabis from no more than .5 percent THC to no more than .8 percent THC and from at least 15 percent CBD to at least 10 percent CBD;
- Modifies patient eligibility to remove the requirement to exhaust all other treatment options and to reduce the period of time that the physician must have treated the patient for the medical conditions or symptoms from 6 months to 2 months;
- Requires a physician to undergo 8 hours of education, including passing an examination, relating to clinical indications for the appropriate use of low-THC cannabis, and other practice-related topics, prior to ordering low-THC cannabis for a patient;
- Requires the DOH to implement the compassionate use database, approve dispensing organizations, and establish an Office of Compassionate Use by January 1, 2015, so that physicians may begin ordering low-THC cannabis for appropriate patients by that date;
- Requires the DOH to implement a process for timely issuing identification cards, which expire one year after issued, to registered patients by January 1, 2015;
- Requires the DOH to monitor and inspect the activities of each dispensing organization to ensure compliance with the requirements of the section;

[26] Analysis of SB 1030 (March 3, 2014), Florida Department of Law Enforcement.

- Requires the dispensing organizations to make all records, premises, resources, finished product and byproducts, and vehicles available for inspection by the DOH and law enforcement;
- Encourages and authorizes state universities to develop or participate in US Food and Drug Administration approved studies and clinical research of low-THC cannabis directed toward refractory or intractable epilepsy relief in pediatric patients, notwithstanding ch. 893. Provides up to a $100,000 grant annually for this purpose; and
- Authorizes the DOH to submit a budget amendment, using excess funds in the Biomedical Research Trust Fund, to fund the program.

CS by Health Policy on March 11, 2014:
The CS:

- Changes the name of "medical-grade marijuana" to "low-THC marijuana" throughout the bill;
- Amends a typo in the definition of "low-THC marijuana"; and
- Changes "prescribe" to "order" throughout the bill to avoid a conflict with other statutes that define prescriptions as being filled at a pharmacy.

B. Amendments:

None.