



## Memo

---

**To** Interested Parties

**From** Rob McKenna, Former Washington State Attorney General  
Brian Moran, Former Washington State Chief Deputy Attorney General  
Kay Winfree, Former Maryland Chief Deputy Attorney General

**Date** March 31, 2017

**Re** Opinion Regarding Compliance of BioTrackTHC Traceability System and API with Cole Memorandum

---

In November 2012, Washington State voters passed Initiative 502, authorizing the Washington State Liquor and Cannabis Board (WSLCB) to regulate and tax marijuana for persons 21 years of age and older. Initiative 502 requires the WSLCB to create a tightly-regulated, state-licensed system for marijuana producers, processors and retailers. Under federal law, however, marijuana production, processing, sale, and consumption remain illegal, raising concerns about potential criminal enforcement by the federal government.

On August 29, 2013, then-Deputy Attorney General James M. Cole issued a memorandum to all United States Attorneys to provide guidance regarding marijuana enforcement in light of state ballot initiatives, such as that in Washington State, that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing and sale. The Cole memorandum makes clear that “both the existence of a strong and effective state regulatory system, and an operation’s compliance with that system” are essential to meet the states’ obligations in regulating marijuana-related conduct so that federal intervention and enforcement are not necessary or appropriate.

Among other measures adopted to meet the I-502 mandate, the WSLCB requires marijuana licensees to track marijuana from seed to sale and to provide specific information on a system specified by the WSLCB. WAC 314-55-083(4). In 2013, the WSLCB contracted with Bio-Tech Medical Software, Inc. dba BioTrackTHC, to provide a web-based seed to sale inventory tracking system which enables the WSLCB to gather and track inventory, product harvesting, transfer and disposal, quality assurance, retail sales transaction data and tax information from all marijuana licensees. The BioTrackTHC system has been in place and operating since March 2014.

We have been engaged to evaluate whether the BioTrackTHC system is fully compliant with the federal guidance provided in the Cole memorandum. Pending legislation would require the WSLCB to contract for a new marijuana traceability system. Although that legislation has not yet passed, the WSLCB has already issued a Request for Proposals, RFP K907, for a system to replace the BioTrackTHC system.

As reflected in the attached opinion, we have thoroughly examined and evaluated the current BioTrackTHC marijuana traceability system and have concluded that it is fully compliant with the federal guidance provided in the Cole memorandum, as well as with all relevant Washington State laws and regulations. Indeed, the BioTrackTHC system appears to be the gold standard of marijuana traceability systems. By contrast, the system that the WSLCB seeks in the newly-issued RFP appears to be far less robust, may not satisfy the Cole memorandum’s requirements, and raises concerns about compliance with Washington State laws and regulations as well. While it is not clear why WSLCB is interested in moving to a less robust, possibly non-compliant, traceability system, such a move should raise serious concerns among Washington state lawmakers and law enforcement officials.



## Memo

---

**To** Interested Parties

**From** Rob McKenna, Former Washington State Attorney General  
Brian Moran, Former Washington State Chief Deputy Attorney General  
Kay Winfree, Former Maryland Chief Deputy Attorney General

**Date** March 31, 2017

**Re** Opinion Regarding Compliance of BioTrackTHC Traceability System and API with Cole Memorandum

---

### **I. Introduction**

In November 2012, Washington State voters passed Initiative 502, which authorizes the Washington State Liquor and Cannabis Board (WSLCB) to regulate and tax marijuana for persons 21 years of age and older. Initiative 502 requires the WSLCB to create a tightly-regulated, state-licensed system for marijuana producers, processors and retailers.

Among other measures adopted to meet this mandate, the WSLCB requires marijuana licensees to track marijuana from seed to sale and to provide specific information on a system specified by the WSLCB. WAC 314-55-083(4). In 2013, the WSLCB contracted with Bio-Tech Medical Software, Inc. dba BioTrackTHC, to provide a web-based seed to sale inventory tracking system which enables the WSLCB to gather and track inventory, product harvesting, transfer and disposal, quality assurance, retail sales transaction data and tax information from all marijuana licensees. The BioTrackTHC system has been in place and operating since March 2014.

We have been asked to opine on whether the BioTrackTHC traceability system utilized by the WSLCB complies with the federal guidance regarding marijuana enforcement provided by then U.S. Deputy Attorney General James M. Cole in his August 29, 2013 memorandum. As set forth below, we have concluded the BioTrackTHC seed-to-sale inventory tracking system fully complies with the requirements of the Cole memorandum.

### **II. Methodology**

We reviewed the following materials and documents to assist with our assessment:

1. Relevant Washington statutes and codes, including Initiative 502, RCW 69.50 and WAC 314-55-005 through 314-55-540;
2. August 29, 2013, Memorandum from then-Deputy Attorney General James M. Cole to All United States Attorneys re: Guidance Regarding Marijuana Enforcement;
3. WSLCB Request for Proposals for K456 Seed to Sale Inventory Tracking System;
4. BioTrackTHC RFP K456 Submittal Document;



March 31, 2017

Page 2

5. WSLCB Contract K456 with Exhibits;
6. WSLCB Contract K456 Seed to Sale Tracking System Project Charter, Project Management Plan and Communications Plan Diagram;
7. Compliance scripts and manuals for marijuana producers, marijuana processors, marijuana producer/processors and marijuana retailers;
8. WSLCB training materials, including manual and original training agendas;
9. September 17, 2014, API Testing and Validation functional audit report from KirkpatrickPrice;
10. November 8, 2016, API Testing and Validation functional audit report from KirkpatrickPrice;
11. U.S. Government Accountability Office Report to Congressional Requesters on State Marijuana Legalization, dated December 2015;
12. Email from USDOJ, dated December 16, 2014, regarding request for information about total weight of marijuana produced, processed and sold since implementation of Initiative 502, and emails to and from WSLCB and BioTrackTHC, dated December 16 and 17, 2014, regarding that request;
13. The WSLCB website and information available thereon related to the regulation and enforcement of marijuana-related conduct;
14. 2017 Washington Legislative Session Senate Bill 5130 and House Bill 1858; and
15. A 90-minute online demonstration of the BioTrackTHC traceability system, including the interface capabilities for both licensees and the WSLCB.

### **III. The Cole Memorandum**

On August 29, 2013, then-Deputy Attorney General James M. Cole issued a memorandum to all United States Attorneys to provide guidance regarding marijuana enforcement in light of state ballot initiatives, such as that in Washington State, that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing and sale. The "memorandum serves as guidance to Department [of Justice] attorneys and federal law enforcement to focus their enforcement resources and efforts, including prosecution, on persons or organizations whose



March 31, 2017

Page 3

[marijuana-related] conduct interferes with any one or more of [eight enumerated] priorities, regardless of state law.” Those eight priorities include:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for trafficking of other illegal drugs or illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

The Cole memorandum further provides:

The Department’s guidance in this memorandum rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice. Jurisdictions that have implemented systems that provide for regulation of marijuana activity must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with

those laws and regulations is less likely to threaten the federal priorities set forth above. Indeed, a robust system may affirmatively address those priorities by, for example, implementing effective measures to prevent the diversion of marijuana outside of the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity.

Thus, the memorandum makes clear that “both the existence of a strong and effective state regulatory system, and an operation’s compliance with that system” are essential to meet the states’ obligations in regulating marijuana-related conduct so that federal intervention and enforcement are not necessary or appropriate.

#### **IV. The Washington State Marijuana Regulatory Scheme**

Passed in November 2012, Initiative 502 was intended to take “marijuana out of the hands of illegal drug organizations and bring[] it under a tightly regulated, state-licensed system similar to that for controlling hard alcohol.” See notes following RCW 69.50.101. Thus, it removes state-law prohibitions against producing, processing, and selling marijuana, subject to licensing and regulation by the liquor control board;<sup>1</sup> allows limited possession of marijuana by persons aged twenty-one and over; and imposes excise taxes on wholesale and retail sales of marijuana, earmarking revenue for purposes that include substance-abuse prevention, research, education, and healthcare.<sup>2</sup>

Washington has enacted a robust regulatory scheme to implement Initiative Measure 502. For example, Washington statutes provide for the issuance of state licenses for marijuana producers, processors and retailers (see RCW 69.50.325) and classify as lawful certain marijuana-related activities so long as they are conducted by licensed producers, processor and

---

<sup>1</sup> Pursuant to 2015 legislation, the name of the Washington Liquor Control Board was changed to the Washington Liquor and Cannabis Board. See <http://lcb.wa.gov/pressreleases/new-legislation-concerning-alcohol-and-marijuana>.

<sup>2</sup> In addition, laws prohibiting driving under the influence were amended to include maximum thresholds for THC blood concentration.

March 31, 2017

Page 5

retailers. The law strictly prohibits the delivery, distribution and sale of marijuana or marijuana products to any person under the age of 21. See RCW 69.50.360.

Under statutory law, the WSCLB is required to adopt rules that establish the procedures and criteria necessary to implement a number of specific functions, including the licensing of marijuana producers, processors and retailers; determining the maximum number of retail outlets that can be licensed in each county; determining the maximum quantity of marijuana and/or marijuana products a producer, processor or retailer may have on the premises of a licensed location; determining the proper containers to be used by licensees; establishing reasonable advertising restrictions; specifying and regulating time, manner, method and means of marijuana transport and delivery; establishing accreditation requirements for testing laboratories used by licensees; and specifying procedures for identifying, seizing and confiscating for law enforcement training purposes marijuana and marijuana products that do not conform with legal standards. See RCW 69.50.345.

In response, the WSCLB has promulgated a strong set of regulatory measures that govern every aspect of the Washington State marijuana industry, including the licensing application process; security and insurance requirements; transportation requirements; tax and reporting requirements; sampling protocols; product compliance; advertising; packaging and labelling requirements; and destruction and disposal procures. See Chapter 314-55 WAC.

#### **V. The WSCLB's Seed to Sale Inventory Tracking System**

In order to enable effective enforcement of the laws and to "prevent diversion and to promote public safety," WSCLB requires marijuana licensees to track marijuana from seed to sale. Licensees must collect specific information and record it using a traceability system specified by the agency. WAC 314-55-083(4)(a)-(s). This record keeping requirement is quite comprehensive, and includes:

- (a) Key notification of events, such as when a plant enters the system (moved from the seedling or clone area to the vegetation production area at a young age);
- (b) When plants are to be partially or fully harvested or destroyed;
- (c) When a lot or batch of marijuana, marijuana extract, marijuana concentrates, marijuana-infused product, or marijuana waste is to be destroyed;
- (d) When usable marijuana, marijuana concentrates, or marijuana-infused products are transported;



March 31, 2017  
Page 6

(e) Any theft of usable marijuana, marijuana seedlings, clones, plants, trim or other plant material, extract, infused product, seed, plant tissue or other item containing marijuana;

(f) There is a seventy-two hour mandatory waiting period after the notification described in this subsection is given before any plant may be destroyed, a lot or batch of marijuana, marijuana extract, marijuana-infused product, or marijuana waste may be destroyed;

(g) There is a twenty-four hour mandatory waiting period after the notification described in this subsection to allow for inspection before marijuana plants, seeds, plant tissue cultures, or lots of marijuana are transported from a producer to another producer or to a processor;

(h) There is a twenty-four hour mandatory waiting period after the notification described in this subsection to allow for inspection before usable marijuana, marijuana concentrates, or marijuana-infused products are transported from a processor to another processor or to a retailer;

(i) All marijuana plants eight or more inches in height or width must be physically tagged and tracked individually;

(j) A complete inventory of all marijuana, seeds, plant tissue, seedlings, clones, all plants, lots of usable marijuana or trim, leaves, and other plant matter, batches of extract, marijuana concentrates, marijuana-infused products, and marijuana waste;

(k) All marijuana, usable marijuana, marijuana-infused products, marijuana concentrates, seeds, plant tissue, clone lots, and marijuana waste must be physically tagged with the sixteen digit identification number generated by the traceability system and tracked;

(l) All point of sale records;

(m) Marijuana excise tax records;

(n) All samples sent to an independent testing lab, any sample of unused portion of a sample returned to a licensee, and the quality assurance test results;

(o) All free samples provided to another licensee for purposes of negotiating a sale;



March 31, 2017  
Page 7

- (p) All samples used for testing for quality by the producer or processor;
- (q) Samples containing usable marijuana provided to retailers;
- (r) Samples provided to the WSLCB or their designee for quality assurance compliance checks; and
- (s) Other information specified by the board.

In 2013, the WSLCB issued a Request for Proposals to contract for the implementation and support of a web-based Seed to Sale Inventory Tracking System to assist with implementation of Initiative 502 and to meet the requirements set forth in the agency's regulations. Bio-Tech Medical Software, Inc. dba BioTrackTHC (hereinafter, "BioTrackTHC") submitted a proposal and was awarded the contract. That contract had very detailed and specific component requirements for the system, including:

- Ability to trace product from initial plant growth to sale, using a Unique Plant Identifier;
- Track plant cultivation, including germinating plant inventory, plant transfer to vegetative growth areas, plant harvest, plant processing, and packaging;
- Track inventory transactions, including inventory receipt and add, product assembly/bill materials, location transfer, inventory disposal and adjustments;
- Track plant, lot, and batch disposal and/or destruction;
- Track transfer of marijuana products between marijuana licensee facilities and locations;
- Track transfer of marijuana products between marijuana licensees;
- A web-based user interface for data entry by marijuana licensees;
- Ability to generate tax reports;
- Ability to track quality assurance testing;
- Reporting functionality for WSLCB personnel to determine licensees' compliance with state statutes and rules; and
- Internal software security to prevent unauthorized access to programs and data.

To ensure BioTrackTHC's software system design and Application Programming Interface ("API") met these contract requirements prior to deployment, testing was coordinated with WSLCB staff in December 2013 and January 2014. In addition, training of the agency's staff was conducted from January to March 2014. Entry of live data commenced on March 11, 2014. Since that time, WSLCB has requested two separate independent testing and validation audits of the API's functionality, one in 2014 and one in 2016. In both instances, the auditor concluded that all functions worked as documented in BioTrackTHC's XML API documentation.

#### **A. Security Features**

In addition to its tracking and tax reporting capabilities, BioTrackTHC's Seed to Sale Inventory Tracking System and API, utilized by the WSLCB and licensees, has a number of core security features, including the following:

1. Unique Identifier. The system utilizes a unique sixteen (16) digit traceability identifier for each inventory item. The system generates and issues the identifier, which prevents unintentional duplication and intentional counterfeiting. Every time inventory needs to be separately identifiable (for example, converting marijuana infused butter into baked goods), the system issues a new traceability identifier. This feature allows for the backwards-tracing of individual items from point-of-sale or destruction all the way back to the original plant, and allows for the forward-tracing of an individual plant to every single item that contains its material all the way to point-of-sale or destruction.

2. Permanent Retention of Data. The creation of, modification or deletion of any record or transaction is permanently recorded. Although records may be "deleted" and events or transactions "undone," they are retained by the system. This creates an audit trail by which the system's data can be reconstructed at any time for any time.

3. Closed System. Each marijuana licensee can enter only its own information. Licensees are completely separate from one another, with no vertical integration.

#### **B. Enforcement Features**

The BioTrackTHC API also has capabilities that enable and enhance enforcement of the applicable laws, including the following:

##### 1. Automatic Enforcement on Marijuana Licensees' Interface

The system has a number of features that automatically enforce the law by restricting marijuana licensee data entry for actions that are not legally permissible. For example, a

March 31, 2017

Page 9

marijuana processor can only convert marijuana into a product that is lawful. Likewise, a processor is permitted to transfer to a retailer only marijuana or a marijuana product that is legal to sell and that has been tested for quality assurance. Also, a licensee can only transfer a sample for testing to a licensed laboratory. No marijuana licensee can transfer marijuana or marijuana products outside of Washington State. Unless transactions are permitted by law, the system will not populate and record the entry being attempted. The system populates and allows data entry only for actions and events that are permitted by the law.

The API automatically enforces the legal limits on size on all marijuana products. For example, Washington law limits the quantities of marijuana and marijuana products that can be delivered, distributed and sold by licensed retailers. See RCW 69.50.360(3)(a)-(d). The system will not permit a marijuana retailer to distribute or sell a product in excess of those allowable limits.

In addition, the system automatically enforces the “waiting periods” required by the regulations. As noted above, the WSLCB mandates a 72-hour waiting period after a licensee has made an entry for destruction of product. WAC 314-055(4)(f). There is also a mandatory 24-hour waiting period after notification to allow for inspection before marijuana plants and seeds can be transported from a producer to another producer or to a processor, and before marijuana products can be transported from a processor to another processor or to a retailer. WAC 314-055(4)(g) and (h). After a licensee has made the required notification on the system, the system will not allow the licensee to actually carry out the event until the mandatory waiting periods have expired.

## 2. Enforcement through the WSLCB Interface

The WSCLB interface is designed to facilitate and enhance the ability of the WSLCB to enforce the law, including the following features:

- **Event/Tasks Live Feed.** When a WSLCB employee logs in, the default screen is the Live Dashboard that provides a snapshot of real-time activity of four event types—a harvesting plant, transporting, destroying plant, destroying inventory—as reported by licensees. The live feed provides details about the event or task, including the enforcement district, the day and time the event was reported and the traceability identifier. This allows enforcement to select events to investigate.

- **Travel Planner.** This feature allows the user to create a list of licensees to visit for inspection.

- **Spot Check.** The user can remove inventory from a licensee for the purpose of a WSLCB quality assurance or for WSLCB seizure.

- **State Map.** Every licensee that has any of the four event types outstanding (harvesting, transporting, destroying plant and/or destroying inventory) will have a pin placed on its location on the Dashboard map. This allows the WSLCB user to see a visual representation of the state's activity as reported in the traceability system.

- **System-wide alerts.** This feature allows the user to post an alert that will be visible to other WSLCB users viewing the dashboard. Such alerts might include the location of a vehicle crash involving a marijuana transport or a fire at a licensee's facility.

- **Manifest Lookup.** A transport manifest is automatically generated by the system and a paper copy accompanies the product being transported. The user can verify the authenticity of a printed manifest by looking in the Manifests feature of the system. Also, each time a manifest is automatically generated by the system, the Washington State Police get an exact digital copy, which enables them to verify the legality of a transport in the field.

- **Reports.** The WSLCB user can generate reports for every licensee in a variety of categories, including events; existing inventory; financial and tax information; inventory adjustments; red flag reports; samples; and technical information. These reports can be used to help the agency focus on licensee activity that warrants investigation, for example, to look for anomalies in inventory or sales. In addition, the system can generate reports that respond to requests from federal enforcement authorities, such as the December 16, 2014 email request from the USDOJ for information about total weight of marijuana produced, processed and sold since implementation of Initiative 502.

## **VI. Conclusion**

The key to meeting the requirements of the Cole memorandum is “both the existence of a strong and effective state regulatory system, and an operation’s compliance with that system.” As described above, Washington State has a robust, comprehensive regulatory scheme that controls the entire marijuana supply chain. The flagship component of this regulatory scheme is the WSLCB’s seed to sale inventory system, the BioTrackTHC Traceability System. The BioTrackTHC system has both significant security and enforcement features, including many that are automatic, which facilitate real-time enforcement by the WSLCB and Washington State Police. As such, it is not a passive monitoring system but rather a proactive and preventative system. It is our opinion that the BioTrackTHC seed to sale inventory system is fully compliant with the requirements of the Cole memorandum.