RFP K430 SUBMITTAL DOCUMENT

Proposer must complete and submit all sections of this Submittal Document as listed below:

- Proposer's Authorized Offer
- Proposer Information
- Subcontractor Information
- Letter of Submittal
- Non-Cost Proposal
- Cost Proposal

SUBMITTAL INSTRUCTIONS

Complete Proposals must be received electronically on or before **February 15, 2013 at 2:00PM (PT).** Proposer must complete and submit all sections of this Submittal Document. Proposer may attach additional sheets as necessary. Proposer should:

- Attach the completed submittal document to a single email message and send it to **lcbbids@liq.wa.gov**.
- Clearly mark the subject line of the email: RFP– K430, Vendor Name (e.g. RFP- K430, ABC Company).
- The preferred software formats are Microsoft Word 2000 (or more recent version) and PDF. If this presents any problem or issue, contact the Procurement Coordinator immediately. To keep file sizes to a minimum, Proposers are cautioned not to use unnecessary graphics in their proposals.
- It is preferred that electronic signatures appear on all documents requiring signature. However, an email date stamp will be accepted as signed by the legally authorized representative of the firm for the purpose of this Proposal only.

Time of receipt will be determined by the e-mail date and time **received** at the WSLCB's mail server in the lcbbids@liq.wa.gov inbox. The "receive date/time" posted by the WSLCB's email system will be used as the official time stamp. The WSLCB is not responsible for problems or delays with e-mail when the WSLCB's systems are operational. If a Proposal is late, it may be rejected.

Proposals should be submitted in the format described in this solicitation. All Proposals and any accompanying documentation become the property of the WSLCB and will not be returned. Incomplete Proposals may be rejected. Proposals submitted by fax, will not be accepted and will be considered non-responsive.

SUBMITTAL CHECKLIST

This checklist is provided for Proposer's convenience only and identifies the sections of this submittal document to be completed and submitted with each Response. Any response received without any one or more of these sections may be rejected as being non-responsive.

Proposer's Authorized Offer (see page 2)	☒
Proposer Information (see page 3)	☒
Subcontractor Information (see page 4)	☒
Letter of Submittal (see page 5)	☒
Non-Cost Proposal (see page 6)	☒
Cost Proposal (see page 8)	☒

Note: The WSLCB understands that potential Proposers may have limited experience in providing the expertise required in all Categories described in RFP K430. In order to better leverage resources available for performing the Services required herein, the WSLCB recommends that potential Proposers may form teams that combine their knowledge, skills, and abilities into one (1) Proposal to meet the requirements as stated in RFP K430.

PROPOSER'S AUTHORIZED OFFER

(PROPOSAL SIGNATURE PAGE)

Initiative 502 Consulting Services – RFP K430

Issued by the Washington State Liquor Control Board

Certifications and Assurances

We make the following certifications and assurances as a required element of the Response, to which it is attached, affirming the truthfulness of the facts declared here and acknowledging that the continuing compliance with these statements and all requirements of the RFP are conditions precedent to the award or continuation of the resulting Contract.

1. The prices in this Response have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered. The prices in this Response have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before Contract award unless otherwise required by law. No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition. However, we may freely join with other persons or organizations for the purpose of presenting a single Proposal.
2. The attached Response is a firm offer for a period of 120 days following the Response Due Date specified in the RFP, and it may be accepted by the Washington State Liquor Control Board (WSLCB) without further negotiation (except where obviously required by lack of certainty in key terms) at any time within the 120 day period. In the case of protest, our Response will remain valid for 180 days or until the protest and any related court action is resolved, whichever is later.
3. In preparing this Response, we have not been assisted by any current or former employee of the state of Washington whose duties relate (or did relate) to this solicitation, or prospective Contract, and who was assisting in other than his or her official, public capacity. Neither does such a person nor any member of his or her immediate family have any financial interest in the outcome of this Response. Any exceptions to these assurances are to be described in full detail on a separate page and attached to the Proposer's Response.
4. We understand that the Washington State Liquor Control Board (WSLCB) will not reimburse us for any costs incurred in the preparation of this Response. All Responses become the property of the WSLCB, and we claim no proprietary right to the ideas, writings, items or samples unless so stated in the Response. Submission of the attached Response constitutes an acceptance of the evaluation criteria and an agreement to abide by the procedures and all other administrative requirements described in the solicitation document.
5. We understand that any Contract awarded, as a result of this RFP will incorporate all the solicitation requirements. Submission of a Response and execution of this Certifications and Assurances document certify our willingness to comply with the Contract terms and conditions appearing in Appendix B, [or substantially similar terms], if selected as a contractor. It is further understood that our standard contract will not be considered as a replacement for the terms and conditions appearing in Appendix B of this solicitation.
6. We (circle one) ~~are~~ / **ARE NOT** submitting proposed Contract exceptions.
7. The authorized signatory below acknowledges having read and understood the entire solicitation and agrees to comply with the terms and conditions of the solicitation in submitting and fulfilling the offer made in its Proposal.
8. By submitting this Proposal, Proposer hereby offers to furnish materials, supplies, services and/or equipment in compliance with all terms, conditions, and specifications contained in this solicitation.
9. Proposer has read and understands the requirements of the WSLCB set forth in and pertaining to Initiative 502.

The signatory below represents that he/she has the authority to bind the company named below to the Proposal submitted and any contract awarded as a result of this solicitation.

Mark A. R. Kleiman	BOTEC Analysis Corporation
Proposer Signature	Company Name
CEO / Chairman of the Board	February 15, 2013
Title	Date

PROPOSER INFORMATION

Proposer Profile:

Firm Name	BOTEC Analysis Corporation
Street Address	73 Fayerweather St
City, State, Zip	Cambridge, MA 02138
Federal Tax ID Number	PersonalInfo
UBI	
Website URL	

Proposer Authorized Representative:

Proposer must designate an Authorized Representative who will be the principal point of contact for the WSLCB Contract Administrator for the duration of this RFP process. Proposer's Authorized Representative will serve as the focal point for business matters and administrative activities.

Representative Name:	Steven Davenport
Telephone:	(510) 552-0575
Email:	davenport@botecanalysis.com

Payment Options:

☒ **YES** ☐ **NO** Do you offer a Prompt Payment Discount? If yes, please provide below.

Prompt Payment Discount 0.5% if received within 10 days.

☐ **YES** ☒ **NO** Will you accept the State's Purchasing Card (P-Card)?

☐ **YES** ☒ **NO** Will you accept Electronic Funds Transfer (EFT)?

Categories of Service:

Proposer must designate the Category(ies) of service for which this Response applies. Please check the appropriate box(es) below:

Category	Description	Response Applies this Category
All	ALL Categories (1-4) listed below	☒
1	Product and Industry Knowledge	☒
2	Product Quality Standards and Testing	☒
3	Product Usage and Consumption Validation	☒
4	Product Regulation	☒

SUBCONTRACTOR INFORMATION

Check the applicable box:

☒Yes ☐No Your firm intends on utilizing subcontractors to fulfill the service requirements outlined in RFP K430, Initiative 502 Consulting Services.

Contractor will be required to perform all work under this contract using his/her own employees carried on payroll or by using approved subcontractors. Where subcontractors are used in the performance of the contract, proposers will indicate as required with their response to seek approval. Contractor will be held responsible for all work performed or not performed by the subcontractor(s). Subcontractors will be required to bill through the Contractor.

If revisions are required in the subcontract assignment, new parties are to be proposed in advance of assignment, in writing to the WSLCB and the Contract Administrator.

All subcontractors are to submit a letter on company letterhead indicating the contract has been read, the standard terms and conditions reviewed and agreeing to all requirements presented. The subcontractors shall be required to meet all requirements established for Contractor staff.

If applicable, Proposer shall identify below all subcontractors who will perform services in fulfillment of contract requirements, including their name, the nature of services to be performed, address, telephone, facsimile, email, federal tax identification number (TIN), Washington State Uniform Business Identifier (UBI), and expected work to be performed of each subcontract:

Subcontractor 1

Name:	RAND Corporation
Services:	Research & Analysis
Address:	1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407
Telephone	310-393-0411x6625
Email:	byone@rand.org
Fed ID:	[redacted] PersonalInfo
UBI:	
Work to be Performed:	Report: Size of marijuana market in WA State
OMWBE certified:	___Yes _X__No

Subcontractor 2

Name:	National Medical Services, Inc (dba NMS Labs)
Services:	Clinical and Forensic Tests
Address:	3701 Welsh Rd, Willow Grove, PA 19090
Telephone:	800.522.6671
Email:	Pat.haneman@nmslabs.com
Fed ID:	[redacted] PersonalInfo
UBI:	N/A
Work to be Performed:	Toxicology and Cannabis Testing Consultation
OMWBE certified:	___Yes _X__No

Subcontractor 3

Name:	Donald I. Abrams, MD
Services:	San Francisco General Hospital
Address:	Ward 84, 995 Potrero, San Francisco, CA 94110
Telephone	(415) 206-4919
Email:	dabrams@hemeonc.ucsf.edu
Fed ID:	Not given
UBI:	N/A
Work to be Performed:	Medical Cannabis Consultation
OMWBE certified:	___Yes _X__**No**

Subcontractor 4

Name:	Steep Hill Lab
Services:	Medical marijuana testing
Address:	473 Roland Way Oakland CA 94621
Telephone:	510-562-7400
Email:	david@steephilllab.com
Fed ID:	[redacted] PersonalInfo
UBI:	N/A
Work to be Performed:	Cannabis Testing Consultation
OMWBE certified:	___Yes _X__No

LETTER OF SUBMITTAL

The Proposer's Letter of Submittal must be signed by the individual within the organization authorized to bind the bidder to the offer. Along with introductory remarks, the Letter of Submittal is to include by attachment the following information about the Proposer and any proposed subcontractors:

- Name, address, principal place of business, telephone number, and fax number/e-mail address of legal entity or individual with whom contract would be written.
- Name, address, and telephone number of each principal officer (President, Vice President, Treasurer, Chairperson of the Board of Directors, etc.)
- Location of the facility from which the Proposer would operate.
- Statement of which of the following Categories Proposer is responding to:
  - Category 1: Product and Industry Knowledge
  - Category 2: Product Quality Standards and Testing
  - Category 3: Product Usage and Consumption Validation
  - Category 4: Product Regulation
- Identify any state employees or former state employees employed or on the firm's governing board as of the date of the proposal. Include their position and responsibilities within the Proposer's organization. If following a review of this information, it is determined by the WSLCB that a conflict of interest exists, the Proposer may be disqualified from further consideration for the award of a contract.

NON-COST PROPOSAL

Please refrain from using company name or other information that will identify your company while preparing your response for the Non-Cost Submittal. The Washington State Liquor Control Board (WSLCB) reserves the right to modify proposals in order to eliminate company names or any other information that may identify a specific company brand.

CATEGORY 1 – PRODUCT AND INDUSTRY KNOWLEDGE

Please answer the questions listed below, attaching additional pages as necessary:

1. **Ability, Capacity and Skills.** In two (2) pages or less, please describe your firm's ability, capacity, skills and/or other expertise in Product and Industry Knowledge, including but not limited to the following:
    a. How Marijuana and/or Agricultural products are grown, cultivated, harvested, cured, and processed
    b. How Marijuana is infused into food and beverages
    c. How Marijuana should be packaged, labeled, transported, and sold at retail level
    d. How wholesale and retail Product should be recalled and accounted for
    e. How Marijuana should be destroyed if overproduced, contaminated, or recalled

In formulating its regulatory strategy, the Board faces trade-offs between the objectives of consumer safety and health, tax revenue, and the size of the remaining illicit market. Tighter regulations can help protect health, but also impose costs on the licit industry. Higher costs will tend to lead to higher prices (net of tax) thus reducing the revenues the state can collect without pushing licit prices so high that illicit dealers—not paying taxes or subject to regulation—enjoy a price advantage in the competition for consumers.

Making sound choices therefore requires detailed knowledge both of production processes and of licit and illicit marijuana markets. Our team offers outstanding expertise in all these areas. A former CEO of a regulated cannabis producer brings expertise in the industrial-scale production of standardized cannabis and cannabis products and has strong practical experience in the means of producing pharmaceutical-grade marijuana free of hazardous impurities and with measured and consistent levels of THC and CBD, the two chemicals in marijuana whose psychoactivity is best understood scientifically. The operators of our two medical marijuana testing labs (one of whom doubles as our chemist specializing in extracts) have worked with producers in the medical-marijuana industry, and have strong experience with product testing and labeling. An extracts specialist has expert knowledge infusing foods and drinks with cannabis and its extracts. A clinical research and forensic toxicology lab offers proven competence in legally compliant marijuana handling, accounting, and testing, as their ISO 17025 certification and DEA-license attest. The cannabis production manager, our extracts specialist, and the operator of our primary medical marijuana testing lab all have experience with industry practice and behavior under a variety of regulatory regimes. A Colorado-based policy analyst has expertise in the general mechanics of legally compliant marijuana businesses, particularly in the newly licit market of Colorado. A CPA servicing the medical marijuana industry and former dispensary CFO delivers expertise in product accounting and retail operations. A former dispensary operator and quality standards specialist also bring retail experience. Our operations management specialist and two colleagues from RAND have produced pathbreaking studies of the costs of producing marijuana under semi-licit conditions (legal under state but not federal law) similar to those that will prevail in Washington unless the federal government elects to respect the State's policy of licit availability.

The DEA-licensed forensic toxicology laboratory complements the rest of the team by offering expertise with forensic and toxicological analysis of marijuana seized by law enforcement, and has extensive expertise with respect to the effects of alternative growing and processing techniques on the chemical composition of the final product. They have a rare expertise in dangerous compounds related to cannabinoids, such as "bath salt compounds" and "synthetic marijuana," which could potentially be chemically altered to classify as a legal cannabinoid while retaining their relatively dangerous psychoactive effects.

The Board will need to establish standards for production and processing.

Regardless of whether marijuana is grown solely under artificial lighting, in a greenhouse or in an open plot, the manufacturing process can be divided into five phases: the vegetative phase, the generative phase, harvesting and drying, processing and sterilization, and batch testing. Each phase presents its own production and quality-assurance challenges, and the Board's regulatory processes need to ensure that producers handle each phase in ways designed to protect consumers. For example, the whole flowers usually sold in both medical and purely illicit markets today have aesthetic appeal to some consumers, but—compared to blended, granulated product—complicate the task of ensuring accurate labeling and lot-to-lot consistency in chemical content. Gamma-irradiation, the standard required for the sterilization of pharmaceutical marijuana in the Netherlands and in Canada, is banned in the United States, leaving the question of what sterilization practices to require and how to monitor the product for freedom from microbial contamination.

The infusion of marijuana into foods and beverages poses its own set of production, quality-assurance, and regulatory challenges. The choice of solvents, the measurement of extracts, and the selection of a matrix (e.g., baked goods versus consumption of an infused liquid) are all significant, and our extracts chemist offers extensive experience with the relevant technologies and in regulatory practices with respect to them.

The conversion of THC-acid to THC by heat means that products need to be labeled according to how they have been processed. The risks of unintentional overdose from food products—due both to the long and variable lag between ingestion and the diffusion of the active agents through the blood-brain barrier and to the phenomenon of "munchies" (appetite stimulation, especially for sweet and salty foods) that can make eating additional infused products seem very attractive—suggest the need for appropriate labeling. In addition, the difference in bioavailability and speed of onset between inhaled and ingested marijuana should be reflected in how product potency is reflected on labels: 40 milligrams of inhaled THC is effectively a larger dose than 40 milligrams of ingested THC, and consumers used to the effects of marijuana in one form may need guidance as to its likely effects in the other form.

To guarantee product stability, product should be sealed in airtight inert packages. Our testing, packaging, and labeling expert (also the operator of our primary commercial testing lab) has innovated multiple products aimed at enhancing the credibility and effectiveness of these processes for the medical marijuana market in California. He has developed the industry's first safe packaging system, which tests batches of marijuana for contaminants and posts results on an identifiable tamper-proof, nitrogen-sealed package. He has experience in constructing voluntary quality-certification systems from the ground up and in soliciting buy-in and compliance from other firms.

Accounting for product is essential to guarantee it is cultivated and processed instate and ultimately consumed instate. Accounting can begin as early as the point of planting, similar to Mendocino County's program, with a zip tie officially identifying the plant. Further controls should be performed at point of wholesale purchase, with responsibility of the purchaser to verify the identity of the seller. At this point in the distribution chain, the control shifts from being per-plant to being based upon the weight of the product. These controls should continue after the curing process and until point of sale at retail. After that stage, diversion may be prevented via a registry of buyers, perhaps using a state identification number to track retail purchases by a buyer over time.

NMS Labs is required to receive, store and discard controlled substances (including Marijuana) at its facility under the regulatory authority of DEA and ASCLD-LAB ISO 17025, in addition to local regulatory environments. Successful long term maintenance of these accreditations requires NMS Labs to have knowledge of handling of Marijuana, secured storage, building security, transportation security, discard control and extensive documentation of all of these challenging areas. Their experience in executing these activities under existing regulatory environments will be useful in evaluating operational processes, record keeping, archiving and retrieving and tracking inventory.

Our team also has expertise in destruction of product from several perspectives: as manager of the entire project of cannabis processing and ensuring legal compliance, as operator of a lab that regularly destroys contaminated product, and as a DEA-licensed facility that regularly oversees disposition of marijuana according to the regulatory authority of DEA and ASCLD-LAB International ISO 17025.

2. **Experience.** In two (2) pages or less, please describe your firm's experience in Product and Industry Knowledge as it relates to Marijuana.

Our team brings considerable experience in marijuana cultivation, processing, and product innovation. Our horticultural production manager served as CEO of Bedrocan International, Inc. (BI, California, USA) for two years, where he gained an in-depth understanding of how to produce standardized cannabis products on an industrial scale and in a fully regulated environment. Our infusions expert and secondary cannabis testing laboratory operator is a chemist with four years of experience in executing cannabinoid extraction and food and beverage infusion, and over 20 years of experience working in regulated laboratory facilities, including industrial food production and nutritional supplement contract manufacturing (both overseen by the FDA). One of our commercial testing labs has brought to the industry a number of new products and services, including the first safe packaging system (using a nitrogen-sealed tamper proof bag), a contaminant-free certification system folding together various technologies in testing, packaging, and labeling, and the industry's first remotely-operated testing modules.

Our team brings experience in operating marijuana businesses, including administering retail, legal compliance, financial affairs, and large-scale production. Our financial expert has spent two years as the CFO of Harborside and currently operates a tax consulting business that primarily services marijuana-related businesses of all varieties. Famously, he brought Internal Revenue Code 280e to the attention of the cannabis industry at a time when many operators were out of compliance with the law and were not even aware that it applied to their businesses. A Colorado-based policy expert has received advanced training from Oaksterdam University.

Our experts have strong ties to industry and regulatory bodies throughout California, Colorado, and Montana. Many of those regulatory environments are much more rigorously regulated than Washington may be, and thus pose additional challenge and opportunities for learning to our experts.

Our team brings impressive industry and product knowledge of marijuana from an academic perspective, as attested by their publications. Books published on the subject by our experts include *Marijuana Legalization: What Everyone Needs to Know*, *Drugs and Drug Policy*, and *Against Excess: Drug Policy for Results*. A small sample of our Team's research includes studies on the effects of California's Prop 19 failed legalization bill on prices in California and Mexican drug trafficking organization revenue as well as estimates of the size of the illicit market in America and abroad.

As mentioned above, our horticultural production manager served as CEO of Bedrocan International, Inc. (BI, California, USA). BI operated as the international affiliate of Bedrocan BV (Netherlands), the only company in the world licensed to produce multiple, diverse cannabis varieties for patients under a national program. Regulated by the Dutch Ministry of Health's Office of Medicinal Cannabis (OMC), Bedrocan's botanical products are manufactured in accordance with Good Agricultural Practices (GAP) and adhere to World Health Organization (WHO) standards for the production of botanical drugs. Bedrocan is the single licensed supplier of medical marijuana in the Netherlands and developer of perhaps the precise, effective, and tested cultivation and processing techniques. Bedrocan's pharmaceutical-grade cannabis has been sold in Dutch pharmacies on a prescription basis since 2003, and its manufacturing processes are recognized the world over as the finest in precision and purity. His work in management builds on his M.A. in International Administration and years of experience managing the production of cashmere and other fine fibers.

As mentioned above, our infusions expert and secondary cannabis testing laboratory operator is a chemist with extensive experience in executing cannabinoid extraction and food and beverage infusion as well as working in regulated laboratory facilities, including industrial food production and nutritional supplement contract manufacturing (both overseen by the FDA). She has operated a Cannabis processing facility and testing laboratory for nearly four years, where as head chemist she regularly produces food products and tinctures infused with precise doses of THC. Her methods are informed by the knowledge of Standard Operating Procedures (SOP) and current Good Manufacturing Practices (cGMP) as she has learned them after decades in regulated laboratory environments; additionally, her processes benefit from years of extensive customer feedback. To ensure proper practice, she has developed forms for tracking extracts and extracted material, and infused product production logbooks. Accordingly, her products boast distinctly precise and quantified doses, exceptional product stability (via appropriate use of

matrices, packaging, and storage). She has offered pro bono consulting on extraction for producers operating on a small scale for personal needs. With her experience in consulting and applying SOPs and cGMPs, she is qualified to disseminate these processes so that other producers may achieve the same outcomes.

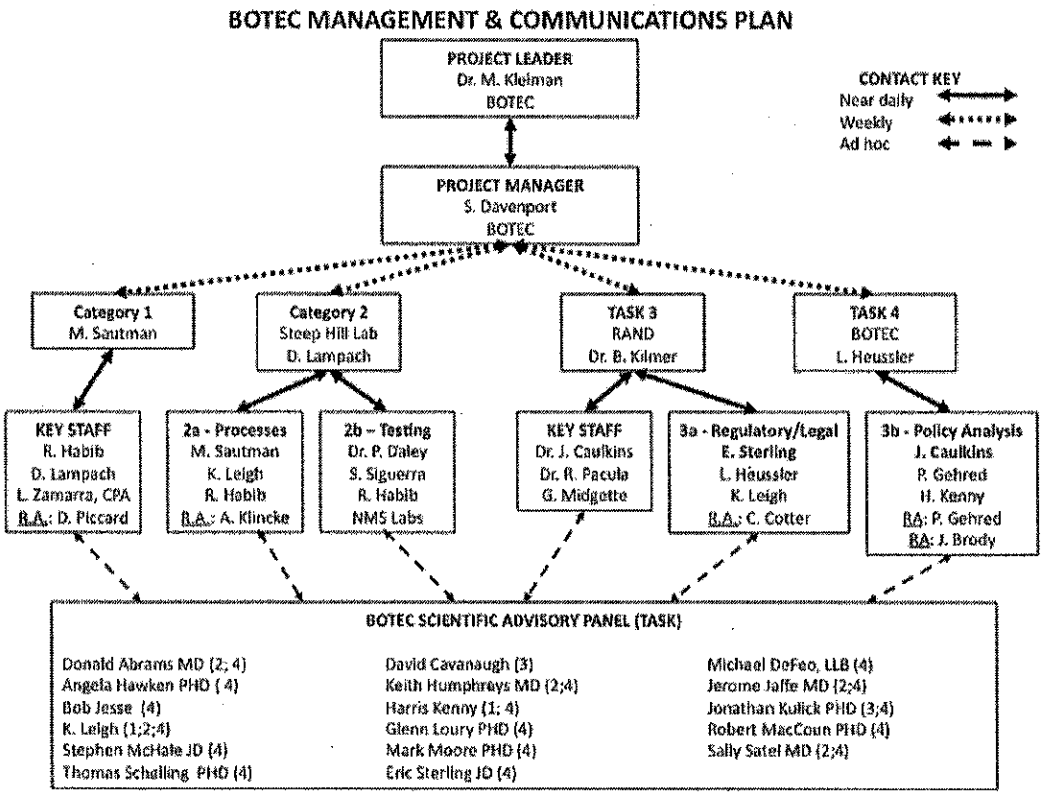
Our primary commercial medical marijuana testing lab was California's first, founded in 2007. They have contributed various innovations and acts of regulatory assistance to the medical marijuana market in California.

- **Safe Packaging:** The first safe packaging program in the country for bulk medical cannabis. This includes a product labeling and tracking component for all lots.
- **Remotely operated testing:** The only remotely operated instant (80 second) cannabinoid testing system in the medical cannabis market. Less accurate than conventional chromatography tests but quicker and cheaper per test, the Quantacann system uses ultra infrared technology to identify and analyze the moisture content of a cannabis sample. The system also provides a real time window into the state of cannabis within the network of testing machines.
- **Mendocino County Sheriff's 3rd Party Inspector:** Personnel of the lab engaged in over 50 hours of training with the Mendocino County Sheriffs Department, as a third party inspector to help implement the 9.31 exemption program. The personnel were given Sheriff ID cards in order to help large commercial producers become compliant with county ordinances.

Our forensic toxicology and clinical research laboratory has been performing the testing of controlled substances, including marijuana, for over 40 years. For most of this time, marijuana has been a Federally scheduled drug; accordingly, the majority of our forensic lab's experience has been with confiscated marijuana plants, processed marijuana for distribution, and various marijuana infused products and paraphernalia used to support marijuana usage. Due to their national and international experience with a wide variety of clients and materials, our forensic lab's staff has seen and tested a broad range of "packaging" of marijuana, from hundreds of kilo's of plant materials, to marijuana cigarettes, infused marijuana products, baked goods, oils, and all types of smoking and other drug paraphernalia. Their additional experience with other controlled substances, synthetic marijuana and pharmaceutical products gives us an understanding and vision of additional considerations that may be helpful to the Board.

In 2012 our DEA, ASCLD-LAB ISO 17025 regulated laboratory tested over 15,000 controlled substances and product containing controlled substances for law enforcement, defense community, hospitals, researchers, pharmaceutical companies and other clients. It is estimated that over 50% of these tests were to identify marijuana, marijuana infused products and paraphernalia used to support the use of marijuana. This experience in handling marijuana and associated products as well as other controlled substances and synthetic cannabinoids, gives our scientific staff substantial experience in understanding these products and handling them in a safe and regulated environment.

3. **Team Structure and Internal Controls.** In two (2) pages or less, please describe the proposed project team structure and internal controls to be used during the course of the project, including any subcontractors. Please define how the firm will establish lines of authority for personnel who might be involved in performance of this potential contract and relationships of this staff to other programs or functions of the firm.



Mark Kleiman, the CEO of BOTEC, will have overall project direction, with BOTEC managing director Steven Davenport coordinating administratively among teams and with WSLCB. Each of the four categories of activity identified in the RFP will have its assigned team with a designated team leader (Michael Sautman for Category 1, David Lampach for Category 2, Beau Kilmer for Category 3, and Lowry Heussler for Category 4, and in some cases sub-teams assigned to specific tasks. A preliminary set of assignments is reflected in the organization chart above. Each team will be able to draw on the extensive expertise of the scientific and legal advisory panel. For each member of that panel, the chart above lists the categories to which that person is mostly likely to contribute.

Our team will use a variant of "agile" project development (so named because it derives from agile software development) because expectation of client- and environment-driven requirements changes makes typical hierarchical or "waterfall" approaches impractical. The exception would be if and when there are primary data collection efforts, such as running focus groups with customers and/or potential store owners. Those activities will be run using the standard methods employed for management of field data collection, something in which our subcontractor RAND excels.

We refer to our particular instantiation as "task-oriented team management." It draws on the blackboard metaphor for virtual team coordination, and has been tried and tested in the production of several major products. Importantly, most of the core team members have worked with most of the other team members before on projects at BOTEC (notably an ongoing effort to analyze policy concerning menthol cigarette markets and structural policy changes), RAND (e.g., a current effort to estimate the size of the marijuana, cocaine, heroin, and illicit methamphetamine markets), and writing

books (Caulkins, Hawken, Kilmer, and Kleiman used task-oriented team management to produce two full-length books published by Oxford University Press).

The blackboard metaphor refers to a common cloud-based artifact that identifies deliverables with (1) due dates, (2) owners or "pigs" in the argot, (3) versions, and (4) version control. This applies to both small deliverables to the client (e.g., memos and white papers of up to 3,000 words) and also "internal" deliverables to be combined with other internal deliverables to create an external deliverable. A key is to slice bigger deliverables into modules that can be comprehended in a single sitting, so each time someone takes ownership of a module it is possible to accomplish a discrete task and pass it on to someone else.

The owner is essentially the "project manager" for that module. In the spirit of open source software development, "all eyes" (everyone on the team) observe the blackboard, and the syntax of the versioning makes progress transparent without even opening the underlying documents. (Our usual syntax is "filename" & version number & date followed by a chronological list of the initials of those making iterative improvement passes on that version. E.g., "user survey question, v3, Feb 12 jpc mk ah" would indicate that Jon (Paul) Caulkins posted version 3 of the questionnaire design on February 12th, and that document was subsequently edited by Mark Kleiman and Angela Hawken." When someone wants to "take down" a document from the public bulletin board to work on it, they announce that they are taking version control for the coming hours or day.

Closer to deadlines, the module owner may schedule a series of control windows and hand-offs. (E.g., a night own on the west coast takes version control from 10 PM – 2 AM Pacific time before passing the document to an early riser on the east coast who takes version control from 2 AM – 6 AM Pacific time (5 – 9 AM east coast), who passes it to someone on the west coast who will work on it during normal working hours.)

Our experience is that this rapid sequencing of sole ownership, akin to open-source software development, produces greater reliability of technical analysis than does the "Google docs" approach of simultaneous collaboration on a single cloud-based artifact.

The key is public accountability with respect to authorship (identified via versioning conventions) and timeliness; delays in a module are visible in real-time, so adjustments can be made before there are serious threats to timely completion relative to the (publically visible) due date.

The remaining points to make concerning the project management are assignment of "owners" and quality control.

Most assignments of owners to modules happen via self-selection. The overall project manager (Mark Kleiman) posts the spec to the blackboard, and someone volunteers to take ownership (responsibility) of delivering that module by the due date. Self-selection of responsibility enjoys many obvious advantages; each team member knows best his or her comparative advantages and schedules.

Nevertheless, each module falls within a domain that has a "chief engineer" (designated in the chart above) responsible for seeing that someone takes ownership if no volunteers emerge. Likewise, the chief engineer has the ultimate responsibility for making sure that a module stays on track and on time even if as a practical matter the "all eyes" approach means it is rarely necessary for a chief engineer to intervene overtly.

We will start with one chief engineer for each category described in the RFP. It is plausible that a juggling of the "boundaries" of the chief engineers' responsibilities may make sense depending how the flow of work develops, but until the initial assignment is clarified, our team cannot identify task managers with certainty. However, at this time it appears that Category 1 will fall under the responsibility of Michael Sautman; Category 2 will recruit the strengths of Steep Hill Lab, NMS Labs, Jonathan Caulkins, and a mix of regulatory experts; Category 3 will draw heavily on the RAND team; and Category 4 (as well as the project as a whole) will be headed by Mark Kleiman. However, those task managers' work need not be confined to those tasks. For instance, that structure would not preclude Mr. Sautman from contributing to a sub-task in Category 4, or recruiting Dr. Kleiman to write a sub-section of Category 1. Since the system is task-oriented rather than status-oriented, task hierarchy (with a task manager exercising supervision over team members) need not reflect "seniority" in the usual sense.

4. **Staff Qualifications and Capabilities.** Please identify staff by name and title, including subcontractors, who would be assigned to the potential contract, indicating their normal responsibilities in your firm. Provide qualifications information on the named staff, including the individuals' particular skills related to this project, education, experience, significant accomplishments and any other pertinent information.

Our team is headed by BOTEC Analysis Corporation, a think-tank specializing in crime and drug policy and acting as the primary contractor on the proposal. BOTEC has thirty years of experience contributing research and government advisory focusing on methods to maximize the effectiveness of crime and drug control policies while minimizing their attendant costs. Previous projects include analyses of the volume and danger of illicit cigarette markets, advising the implementation of criminal supervision programs intended to reduce drug abuse among parolees, and Federal research grants aiming to reduce incarceration and to explore the connection between crime and drugs. BOTEC CEO Mark Kleiman offers the Board his core staff of analysts, researchers, and evaluators, to be complemented by a highly selective and tight-knit network of experts. The group is assembled to provide a broad range of options and a depth of resources from which the Board may draw according to its particular needs.

BOTEC Analysis' core staff consists of Dr. Mark Kleiman (PhD Public Policy, Harvard Kennedy School), senior researchers Dr. Jonathan P. Caulkins (PhD Operations Science, MIT) and Dr. Angela Hawken (PhD Public Policy, RAND), general counsel Lowry Heussler, JD, and managing director Steven Davenport. Dr. Caulkins and Dr. Hawken are both professors of public policy and highly regarded contributors to the study of illicit markets, crime, and drug abuse. While Dr. Kleiman is tasked with overseeing the entire project team, Mr. Davenport's focus is to coordinate project activity.

BOTEC offers the WSCLB a wealth of experts in formalized marijuana cultivation and testing, quality standards, statistical modeling, policy analysis, dynamics of illicit markets, law enforcement, drug control, drug dependency, game theory, economics, and rule-making. They've occupied prestige positions ranging from Presidential Advisors to Nobel Laureate. The experts particular to this category include:

Michael Sautman, former CEO, Bedrocan International. M.A. International Administration.
As CEO of Bedrocan International, Inc. (BI, California, USA), Mr. Sautman is a leading expert in producing standardized cannabis products on an industrial scale in a regulated environment. His experience with BI is detailed above in question two.

In addition, Mr. Sautman has over 25 years of experience in natural product manufacturing. As CEO of California Cashmere Co., Inc., (1990–2005) he became a recognized expert in production of rare animal fiber products like cashmere, silk and camelhair. He founded manufacturing operations in Mongolia, China and the U.S. that provided rare fiber products to manufacturers and finished products to major department stores and designers. In 2007, he began negotiations with Bedrocan BV to bring their manufacturing system to the U.S. and other countries. After BI was formed in 2009, he has consulted lawmakers and regulators in Canada, Israel and several U.S. states regarding how medical marijuana is produced and distributed in the Netherlands. At BI, he initiated Bedrocan's medical marijuana drug approval program with Health Canada, the Canadian Ministry of Health. Mr. Sautman has a comprehensive understanding of how cannabis is manufactured around the world.

Luigi Zamarra, CPA
Formerly employed by Ernst & Young and PriceWaterHouse Coopers, Mr. Zamarra became the first CFO of Harborside Health Center. For the next two years Luigi was instrumental in making Harborside the model for transparency in the medical marijuana trade. He is credited with being the reason the federal enforcement officials have never raided HHC, as his work helped to ensure they were compliant with all state and local laws. He tightened their systems of internal controls and advised on how to track inventory from purchase or cultivation all the way to sale. He was involved in all aspects of the retail dispensary operation, from conducting meetings with patient-vendors, to helping to identify losses in inventory, to addressing complaints from patient-customers.

Currently, Luigi is a CPA for the Northern California medical marijuana industry through Henry Levy & Co., with clients all over California and Arizona, as well as clients in several other states. He handles roughly 50 to 70 clients in

all facets of the distribution chain, including: clone manufacturers, cultivators, farms, edible manufacturers, concentrate manufacturers, grow-equipment retailers, dispensary operators, delivery companies and testing labs.

Rose Habib, Chemist, CannabAnalysis. B.S. Chemistry
Rose Habib is lead chemist at CannabAnalysis, a Cannabis laboratory specializing in testing and infusions and extracts. Her laboratory works with both large and small-scale producers and retailers, offering testing and processing services to convert plant material into safe, consistently dosed edibles and extracts.

Ms. Habib has over twenty years of experience in regulatory laboratory facilities in multiple industries, including industrial food production and nutritional supplement contract manufacturing. She is a forceful advocate for proper protocols and recommended practices for laboratory testing and infused product manufacturing, for instance in her capacity as advisor to AHPA's efforts to develop proper quality standards. Ms. Habib successfully combines her technical skills from regulated laboratory work and her management skills implicit in her success as a small business owner and transfers these to her laboratory and advisory work. She collects extensive customer feedback from clientele and strictly uses extracting, infusion, and packaging methods that have been formally tested and approved by regulatory bodies such as AHPA.

David Lampach, President, Technological development, Steep Hill Lab.
As a co-founder of Steep Hill Lab, Mr. Lampach has played central roles in his laboratory's innovations in the marijuana testing industry, including the development of QuantaCann, SafeCannabis, and the first cannabis safe packaging and labeling protocol in the U.S. He is an expert in applying technology and analytical instruments most appropriate for analyzing cannabis samples (GC-FID, GC-MS, HPLC, HPLC-MS, NIR Reflectance Spectroscopy). He has also developed software to make the cannabis distribution chain more efficient and transparent. Mr. Lampach was selected by the Mendocino County Sheriff's department to implement the county's 9.31 program, in which he inspected and assisted large commercial producers in their compliance with county law. In addition, he is a skilled cannabis producer and has consulted dozens of producer on proper technique and problem mitigation.

NMS Labs
NMS Labs features a robust staff with superlative scientific pedigrees, including over 10 PhD's in Forensic Toxicology, Pharmacology, Analytical Chemistry, Molecular Biology and Mathematics. It is the first private laboratory to receive American Board of Toxicology laboratory accreditation for forensic toxicology analysis. It participates in over 20 mandatory and voluntary proficiency tests to assure the accuracy of testing required in the scientific community. NMS Labs holds certifications to identify and test marijuana (ASCLD-LAB International ISO 17025), to test biological substances (ISO 15189), and to handle and dispose marijuana (DEA-licensed). Its staff include members of the Board of Directors for the American Board of Forensic Toxicology, a recipient of the National Safety Council's Robert F. Borkenstein Award and of the American Academy of Forensic Sciences' (AAFS) Rolla N. Harger Award, and many other top honors.

Harris Kenny, Policy Analyst, Reason Foundation
Mr. Kenny serves on the Amendment 64 task force on the Local Authority and Control Working Group, and works as a policy analyst at Reason Foundation, a non-profit think tank. He is also on track to complete his Basic and Advanced Certificates of Completion from Oaksterdam University, the first and premiere cannabis-centric educational institution in the United States, by February 28, 2013. His courses cover the entire production and retail processes.

Dr. Mark Kleiman, CEO, BOTEC Analysis Corporation. Ph.D. Public Policy, Harvard.
Dr. Kleiman teaches public policy at UCLA, and is an expert in many aspects of criminal and drug policy, including probation and parole, incarceration, and marijuana policy. Recent author of *Marijuana Legalization: What Everyone Needs To Know* co-authored with Jonathan Caulkins, Angela Hawken, and Beau Kilmer, and *When Brute Force Fails.* Other publications include:

- M. Kleiman, *Marijuana: Costs of Abuse, Costs of Control* (Greenwood, 1979)
- M. Kleiman, *Against Excess: Drug Policy for Results* (Basic Books, 1993)

Dr. Beau Kilmer (PhD in Public Policy, Harvard University) is Senior Policy Researcher at the RAND Corporation, Co-Director of the RAND Drug Policy Research Center, and Professor at Pardee RAND Graduate School.

Dr. Jonathan Caulkins (PhD in Electrical Engineering and Computer Science, MIT) is H. Guyford Stever Professorship of Operations Research and Public Policy at Carnegie Mellon University and former Co-Director of the RAND Drug Policy Research Center.

Dr. Rosalie Liccardo Pacula (PhD in Economics, Duke University) is Senior Economist at the RAND Corporation, Co-Director of the RAND Drug Policy Research Center, Professor at Pardee RAND Graduate School, and Director of RAND Health's Program on Economics, Finance, and Organization.

CATEGORY 2 – PRODUCT QUALITY STANDARDS AND TESTING

Please answer the questions listed below, attaching additional pages as necessary:

5. **Ability, Capacity and Skills.** In two (2) pages or less, please describe your firm's ability, capacity, skills and/or expertise in Product Quality Standards and Testing, including but not limited to the following:
    a. Knowledge of the infrastructure required to test Marijuana to ensure product quality, content, ingredients and consumer safety considerations
    b. Assisting the WSLCB with establishing quality standards for testing Marijuana

Introduction

Our Category 2 (Product Quality Standards and Testing) team is composed of a wide-ranging group of experts on proper marijuana testing procedures, on establishing Product quality standards, and on the variety of testing standards and quality control measures in use on both a local and international scale. The team can combines the knowledge and skills of three leading laboratories with those of experts who have conducted production processes involving marijuana products in highly regulated environments and are familiar with the practical demands of quality assurance and standards compliance, and with the impacts of regulations on production costs.

The testing sub-team boasts three highly regarded laboratories: Steep Hill Lab, a commercial marijuana testing lab at the forefront of cannabis-related consumer safety since its founding in 2007 and a standard-bearer for rigorous testing and certification of marijuana; CannabAnalysis, a Montana-based commercial lab of a smaller scale and known for its exceptional precision, operated by our expert in infusions; and NMS Labs, a DEA-licensed forensic toxicology lab with forty years of experience handling and testing controlled substances, including marijuana. Our range of laboratory partners is designed to offer the WSCLB complementary skills; together they possess expertise and experience with marijuana in all of its forms from flower, extract, ingested, or "synthetic", and all its phases, from "seed to sale."

The sub-team focused on standard operating procedures and regulations brings together experts with diverse experiences: a former CEO of Bedrocan International, the world's sole producer of entirely licit cannabis for sale to end-users, who managed of its cannabis production practices; a chemist at CannabAnalysis with decades of experience operating in regulated laboratory environments and years of experience contributing regulatory advice to the American Herbal Products Association (AHPA); a Colorado attorney with extensive experience shaping regulations in Colorado; and a professor of Operations Science at Carnegie Mellon.

To complement this technical background, the product quality and testing team will have access to the expertise of BO Tec's array of senior scientists, policy analysts, physicians, and attorneys, including experts on marijuana use and abuse and on the economic analysis of both licit and illicit drug markets and on the regulatory issues involved in crafting and enforcing product quality and testing standards.

The combination will allow the team to provide WSLCB with state-of-the-art advice on how to design and enforce quality standards and testing and labeling requirements, within the capacity of cost-effective laboratory technology. The goal is to ensure that buyers have access to marijuana not only free of excess contaminants but also accurately labeled as to its content of active agents, thus reducing the risks of unintentional over-intoxication, anxiety, and panic attacks. Reducing these risks might reduce health-care utilization, including expensive emergency room visits. It is possible that accurate and clear labeling might "nudge" the market towards products with lower THC content and lower THC:CBD ratios; research suggests that such products might be less risky with respect both to acute bad experiences and to developing substance abuse disorders.

Knowledge of the infrastructure required to test marijuana to ensure product quality, content, ingredients and consumer safety considerations

The team consists of labs and credentialed members that include those at the forefront of marijuana standard development, testing, and certification. The team will help WSLCB with:

- Establishing minimum standards for testing and confirming product safety from microbiological contaminants (i.e., molds, bacteria, yeast) and pesticides in order to protect the health and safety of users.
- Creating testing standards and protocols for Product testing of THC/CBD levels and ratios.

- Formulating labeling standards, consistent with State law, so that the consumers can make choices appropriate to their needs.

Our labs and testing experts use methodologies compliant with a wide range of standards appropriate to their operating processes. Our forensic toxicology lab is qualified to identify and test marijuana for introduction as evidence (ASCLD-LAB International ISO 17025 certified) and trusted and required by the Federal government to perform handling and disposition of marijuana (DEA licensed). The mold, yeast, and bacteria testing programs of our larger commercial lab comply with the standards set forth by the United States Pharmacopoeia, The World Health Organization, and the American Herbal Products Association (AHPA). That lab's internal sample handling and storage procedures are based on DEA protocol for Schedule I controlled substances, requiring a secure chain of custody for sample handling, secure methods of storage, proper sample destruction, and efforts to prevent sample diversion into the black market.

Compliance with these standards and credentials requires fluency in appropriate laboratory equipment and infrastructure. Our forensic laboratory's ISO 17025 certification requires proper implementation of rigorous quality management systems, exceptional testing accuracy and maintenance of testing equipment. (No commercial marijuana testing lab in the country holds these credentials.) Our larger commercial lab regularly performs tests on cannabis samples with a wide range of appropriate methods, including GC-FID, GC-MS, HPLC, HPLC-MS, and NIR Reflectance Spectroscopy.

Assisting the WSLCB with establishing Product Quality Standards

The team consists of labs and individual experts with valuable and complementary experiences dealing with quality standards, formalizing operations, and certified laboratory work and understand all aspects of Marijuana—from seed, to growing practices, cultivation, harvesting, curing, and processing—and the variable effects each has on maintaining quality of Product.

Our experts have familiarity with operating under distinctly different pharmaceutical and manufacturing standards across the world. Our cannabis cultivation manager has worked to earn methods of cannabis production FDA approval and Canadian medicinal approval. He has operated under the standards set by the Dutch Ministry of Health's Office of Medicinal Cannabis, providing services in production consulting including Canada, Israel, Oregon, Brazil, and the U.S. Our infusions expert brings twenty years of experience producing nutritional supplements and four years of experience extracting and infusing THC in Montana.

Our experts are skilled in the art of formalizing manufacturing processes – horticultural and chemical – and operating under and verifying those formalizations. One expert helped create a Common Technical Document for a cannabis manufacturing process for use in clinical trial applications and has used this material to apply for approval as a regulated drug. The same expert is a skilled manager of manufacturing processes of rare fiber and finished products. Our extracts chemist has skills in precise formations harnessed through decades in industrial food production and nutritional supplement contract manufacturing. One of our labs is a frequent innovator of new methods in cannabis testing and handling, including testing-and-packaging certification systems and low-cost remote chemical identification of Marijuana modules.

Our experts are well-informed, articulate, and active proponents of the need for Product quality standards and actively engage other firms, labs and associations in this regard. One of our labs is a founding member of the Association of California Cannabis Laboratories, a body designed to encourage the widespread adoption of tested and effective quality standards in commercial testing. One of our experts has advised the American Herbal Products Association (AHPA) on formalizing proper methods of extraction. Our forensic toxicology lab staff includes trained laboratory inspectors for regulatory agencies and scientific organizations and are fluent in the best and worst practices in laboratory quality, certifications, and validation mechanisms.

Our forensic toxicology lab has a unique understanding of, and experience with, potentially dangerous strains of cannabinoids and related chemicals, which may fall beyond the current perspective of commercial marijuana testing labs. The lab is trained to detect other contaminants and "enhancing drugs" that may be added to Marijuana products to increase their desirability to users and abusers, any of which may increase risks for dependency and social costs of intoxication. The lab's experience in testing for related chemicals such as "Synthetic Marijuana" and Bath Salt

Compounds informs this expertise. In the case that these related compounds are altered to legally classify as cannabinoids – thereby ushered into the licit market – their expertise will be essential to promptly responding to associated issues of public safety. The forensic toxicology lab currently has a dedicated Center of Innovation devoted to research and development for laboratory testing of synthetic cannabinoids and continuing education of the scientific, health and law enforcement communities.

6. **Experience.** In two (2) pages or less, please describe your firm's experience in the Product Quality Standards and Testing field, as it relates to Marijuana.

The primary contractor, a research and government consulting and advisory firm that has managed, overseen, and performed projects in the field of criminal and drug policy for the past 30 years, has brought a number of highly qualified testing and quality standards experts onto our team. Our team offers the oldest commercial marijuana testing lab in California, a DEA-licensed clinical research and forensic toxicology lab which has dealt with marijuana ever since it has become a Federally-controlled substance, and a Montana-based commercial testing lab which has operated since that state's legalization of medical marijuana.

Our labs have tested an immense number of samples, from both a commercial and forensic perspective. One of our commercial labs was the country's first medical marijuana lab and has tested over 60,000 samples and may be the largest testing lab in the country. In 2012 alone, our forensic toxicology lab performed laboratory testing of over 15,000 drug samples, with more than half of this testing performed for Cannabinoid identification in botanicals and various Marijuana Products.

Our labs have worked in compliance with and/or cooperation with government bodies. Our forensic toxicology lab complies fully with regulations imposed by Federal enforcement authorities, a central stakeholder in Initiative 502's implementation. One of our commercial testing labs is a certified Mendocino County Third Party Inspector for collective cooperative producers seeking to expand the scope of their operations as permissible under Mendocino County Code 9.31. (This includes the zip tie program, intended to prevent diversion into the illicit market by tracking all product as it moves through the supply chain.)

Our labs have been active at the forefront of cannabis-related consumer safety and have been central to the movement to apply to medical cannabis the same standards as other herbal products and drugs. One of our commercial labs has made advisory contributions to AHPA in shaping its standards. Another of our commercial labs is a member of the ACCL (Association of California Cannabis Laboratories), has worked to encourage other labs to adapt similar protections and will be instrumental in helping develop infrastructure for Washington-based labs. They have pioneered several products and methodologies:

- The nation's first non-federal cannabis potency testing program.
- The nation's first cannabis testing program for mold, yeast, and bacteria.
- Testing programs for pesticides, terpenoids and minor components, and trace VOC residue in concentrates.
- An independent certification system to assure customers that the product is pure, pesticide-free, and properly measured for potency. The certification seal is awarded at the end of a testing and packaging process. Product is loaded into nitrogen-sealed 1-pound bags, from which 4-gram samples are extracted and tested for excessive levels of microbiological contaminants and pesticide residues. Upon passing the test, the seal is affixed to the sealed package, assuring the purity of the cannabis and the quality of the packaging.
- The first inert gas safe packaging and labeling protocol for medical cannabis in California. This proprietary packaging provides a standardized tamper-proof nitrogen packaging, to keep the cannabis fresh, reduce opportunities for mold and bacterial growth, prevent degradation, and ensure product safety, quality, and labeled potency.
- The first instant cannabis potency testing program, which also allows testers and regulators new tools to track and trace products through the supply chain. Operating with near infrared (NIR) technology and RFID tags, the system is designed with the potential to provide central authorities a real time window into the character of medical cannabis samples tested within its instrument network. If pursued, the system may offer benefits to inventory tracking and diversion control. The product also has the distinction of being the only truly "green" cannabis testing system available, using no harmful chemicals.

Our labs and experts have made valuable contributions to existing quality standards and trade associations supporting such standards. One of our labs is a founding member of the Association of California Cannabis Laboratories (ACCL), which works to disseminate and popularize appropriate procedures and consumer safeguards.

Our commercial testing lab has implemented testing program for mold, yeast, and bacteria in compliance with the standards set forth by the United States Pharmacopoeia, The World Health Organization, and the American Herbal

Products Association. The lab's internal sample handling and storage procedures are based on DEA protocol for Schedule I controlled substances; the procedures require a secure chain of custody for sample handling, secure methods of storage, proper sample destruction, and efforts to prevent sample diversion into the black market.

7. **Staff Qualifications and Capabilities.** Please identify staff by name and title, including subcontractors, who would be assigned to the potential contract, indicating their normal responsibilities in your firm. Provide qualifications information on the named staff, including the individuals' particular skills related to this project, education, experience, significant accomplishments and any other pertinent information.

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Dr. Kleiman teaches public policy at UCLA, and is an expert in many aspects of criminal and drug policy, including probation and parole, incarceration, and marijuana policy. Recent author of *Marijuana Legalization: What Everyone Needs To Know* co-authored with Jonathan Caulkins, Angela Hawken, and Beau Kilmer, and *When Brute Force Fails.* Other publications include:

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Michael Sautman, former CEO, Bedrocan International. M.A. International Administration.
As CEO of Bedrocan International, Inc. (BI, California, USA), Mr. Sautman is a leading expert in producing standardized cannabis products on an industrial scale in a regulated environment. BI operated as the international affiliate of Bedrocan BV (Netherlands), the only company in the world licensed to produce multiple, diverse cannabis varieties for patients under a national program. Regulated by the Dutch Ministry of Health's Office of Medicinal

Cannabis (OMC), Bedrocan's botanical products are manufactured in accordance with Good Agricultural Practices (GAP) and adhere to World Health Organization (WHO) standards for the production of botanical drugs. Bedrocan's pharmaceutical-grade cannabis has been sold in Dutch pharmacies on a prescription basis since 2003, and its manufacturing processes are recognized the world over as the finest in precision and purity.

Mr. Sautman has over 25 years of experience in natural product manufacturing. As CEO of California Cashmere Co., Inc., (1990-2005) he became a recognized expert in production of rare animal fiber products like cashmere, silk and camelhair. He founded manufacturing operations in Mongolia, China and the U.S. which provided rare fiber products to manufacturers and finished products to major department stores and designers. In 2007, he began negotiations with Bedrocan BV to bring their manufacturing system to the U.S. and other countries. After BI was formed in 2009, he has consulted lawmakers and regulators in Canada, Israel and several U.S. states regarding how medical marijuana is produced and distributed in The Netherlands. At BI, he initiated Bedrocan's medical marijuana drug approval program with Health Canada, the Canadian Ministry of Health. Mr. Sautman has a comprehensive understanding of how cannabis is manufactured around the world.

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Paul Daley, Research Chemist, Steep Hill Lab. PhD, Entomology, UC Berkeley; M.S. Entomology, B.S. Environmental Toxicology, UC Davis.
Dr. Daley has over 30 years experience in a variety of environmental and analytical disciplines. He has published research in integrated pest management, plant photosynthesis, and environmental chemistry. He has assisted SHL in method development for cannabinoids in medical cannabis strains, method validation, troubleshooting instrumentation, and isolation of rare cannabinoids for use as analytical reference materials. He is also the Resident Chemist at the Alexander Shulgin Research Institute in Lafayette, CA, where his work focuses on the chemistry and pharmacology of psychoactive drugs, particularly the psychedelics.

Savino Sguerra, Lab Director, Steep Hill Lab. B.S. Columbia University.
Mr. Sguerra oversees the day-to-day management of the lab and tests thousands of samples of cannabis a month for potency, mold and bacterial counts, pesticides, terpenoids, moisture content, and various other types of analysis.

NMS Labs
NMS Labs features a robust staff with superlative scientific pedigrees, including over 10 PhD's in Forensic Toxicology, Pharmacology, Analytical Chemistry, Molecular Biology and Mathematics. It is the first private laboratory to receive American Board of Toxicology laboratory accreditation for forensic toxicology analysis. It participates in over 20 mandatory and voluntary proficiency tests to assure the accuracy of testing required in the scientific community. NMS Labs holds certifications to identify and test marijuana (ASCLD-LAB International ISO 17025), to test biological substances (ISO 15189), and to handle and dispose marijuana (DEA-licensed). Its staff include members of the Board of Directors for the American Board of Forensic Toxicology, a recipient of the National Safety Council's Robert F. Borkenstein Award and of the American Academy of Forensic Sciences' (AAFS) Rolla N. Harger Award, and many other top honors.

8. **Approach and Methodology.** In two (2) pages or less, please provide a complete description of your firms' proposed approach and methodology to be used in assisting the WSLCB to develop a reputable protocol for Product Quality Standards and Testing as requested in this RFP, to determine TCH/CBD levels and/or ratios, mold or chemical contaminates, and Product strain.

The complexity and expense of marijuana testing would make it virtually impossible for the WSLCB to staff and equip itself to perform testing in-house. That task will be delegated to outside laboratories, either public or private, acting under contract to producers and processors. The WSLCB's decisions will involve creating and enforcing standards for testing and labeling, certifying laboratories, and developing and executing an inspections process designed to verify that test results are produced and reported accurately and that product labels properly reflect package contents. The WSLCB needs to determine: (1) maximum levels of harmful contaminants; (2) statistical error tolerances for the measurement of active agents; (3) certification processes for laboratories; (4) an inspections process; and (5) a recall process for contaminated or mislabeled product. The Board might also want to establish maximum THC levels and/or THC:CBD ratios, despite the reality that an adequate scientific basis for such standard-setting does not yet exist. Our Team will assist the WSLCB along all these dimensions.

Step 1. Assist the WSCLB to set appropriate tolerance levels for product contaminants

Before developing testing methodology and other guidelines to minimize contaminants, it is important to develop tolerance levels for Product contaminants, particularly those included in U.S. Pharmacopeia standards:

- Microbiological contaminants: Molds and bacteria such as Aspergillums, Salmonella enteric, Pseudomonas aeruginosa, Staphylococcus aureus, yeasts and Escherichia Coli.
- Pesticides
- Heavy metals and other physical contaminants, like animal dander and glass.

Marijuana can become contaminated with microbiological agents at any point during production through packaging and distribution, which can be a huge deal if not regulated. It is estimated that upwards of 30% of people are allergic to mold and suffer adverse health effects because of it. Certain molds are pathogenic, meaning they are able to infect and cause disease in human beings. There is no current consensus on how many CFU/g of the various molds or bacteria are acceptable; different recommendations are set forth by the American Herbal Products Association, the World Health Organization and the European Pharmacopoeia. The team understands these differences and will help WSLCB determine how best to balance competing objectives in determining how stringent the standards ought to be.

Pesticides used in growing operations can be present in the final Product form, and are known as residual pesticides. Pesticide residues can pose a serious threat to consumer and environmental safety, with varying impacts, but – unlike any other agricultural product intended for ingestion by humans, marijuana is not subject to EPA Pesticide Tolerance Limits Steep Hill Lab has detected the presence of pesticide residue in medical cannabis samples that would be above levels considered to be safe by USDA standards in most agricultural products. USDA standards for tobacco and for hops may help in the development of tolerance guidelines.

Heavy metals can appear in certain cannabis samples depending on soil or nutrient composition; acceptable content should conform to FDA limits. However, cost issues may make heavy metal tests difficult to impose. These tests require their own unique and expensive equipment (acid digestions require additional lab space and exhaust) such that running them in-house may be prohibitively expensive; meanwhile, laboratories currently equipped to perform the task often lack the clearance to handle cannabis samples. The Team would assist the WSLCB weigh these issues of cost and efficiency against health risks.

Step 2. Assist the WSLCB determine statistical error tolerances for measuring active agents, and product labeling processes to convey that information to consumers

The accuracy of testing and labeling is limited by the inherent heterogeneity of an unblended product. Even if the THC and CBD contents of a single plant are known exactly, the psychoactive chemicals within each flower on that plant

might vary substantially. These variations are further exacerbated if sampling is performed on an entire batch of plants at once. These natural variations of psychoactive chemicals should be accounted for as an expected margin of error. Once quantified, this expected margin of error should be prominently displayed on the product's potency label, so that the consumer understands both the quantity likely to produce the desired effect and the risk of accidental overdose. In addition, WSLCB may want to set maximum error margins, so as to remove from the licit market product of unpredictable potency. Our team can calculate the likely costs of various levels of stringency in this regard. One approach would be to require blending or granulation to minimize lot-to-lot variability; focus groups could help determine the extent to which consumers would accept the resulting product rather than seeking whole, unblended flowers on the illicit market.

Once the content of THC and CBD has been determined to the required standard of accuracy, that information needs to be converted into forms readily understandable by consumers. One approach would be a combination letter-and-number and color-code arrangement – in addition to numerical labeling – designed not only to inform consumers but to "nudge" them in the direction of less hazardous forms of marijuana. (Such a possible system is described in more detail in the "methods and approach" section under Category 4.)

Step 3. Determine certification processes for laboratories.

Product testing laboratories must ensure both that all product that reaches consumers meets the standards set by WSLCB and that the label on each lot appropriately reflects the product inside. Thus they perform what is in effect a regulatory function, enforcing the rules set by WSLCB. But unless the state uses its own laboratories, the testing labs will also be commercial enterprises, whose customers are the producers and processors whose activities the labs help regulate. Some industry participants would voluntarily choose labs of high competence and integrity, and some consumers would be able to identify well-tested product and be willing to pay a premium for it. But less scrupulous firms would either try to save money by using the cheapest testing available or seek out labs willing to misreport results to conceal harmful contaminants or misrepresent product quality. Thus WSLCB needs to establish and enforce standards for the laboratories themselves: to "watch the watchmen." There needs to be some process by which a laboratory becomes qualified – and, if necessary, disqualified – for doing this important work.

Standards for certification can include verification of appropriate equipment, training, and practices on the one hand and random verification of results on the other. WSLCB will either create its own certification process or adopt (or adapt) existing processes of public agencies and industry self-regulatory bodies.

The team will advise WSLCB on the range of options, and the likely outcomes (in cost, quality, and integrity) of adopting one rather than another. Preference ought to be given to methodologies and standards that have been scientifically and independently tested.

One element of certification is validation: the repeated verification that the results produced by a laboratory match the facts to within required tolerances. The team will assist the WSLCB to determine optimal validation methods, including processes to verify equipment calibration, personnel credentials, and laboratory methodologies.

Whatever methods are finally determined to be acceptable to the state, validation will need to be conducted initially and on an ongoing basis. Validation entails proving that the accepted methods work presently and continue to work over time. According to the advised method validation, all aspects of methodologies ought to be tested and proven to be valid, including efficiency, optimization, repeatability by personnel, repeatability by different instrumentation, and different laboratories.

Step 4. Assist the WSLCB Determine an Inspections Process

Producers, processors, retailers, and laboratories themselves will all face financial incentives to depart from rules established by WSLCB when doing so reduces costs or increases sales. WSLCB therefore needs to create an inspections process to verify compliance, using the principles of statistical quality assurance while also following up on evidence of potential mis- or mal-feasance derived from consumer, official, or journalistic reports.

Insofar as that inspections process requires laboratory work, WSLCB – as part of its ongoing regulatory responsibilities as opposed to the initial rulemaking phase – may chose to use either a state-owned laboratory or a private laboratory under WSLCB contract for that portion of the inspections process, , since it would be uneconomic for WSLCB to build it own lab, while labs under contract to industry participants cannot be expected to inspect themselves or their clients.

Step 5. Assist the WSLCB Determine a Recall Process for Contaminated or Mislabeled Product

Contaminated or mislabeled product must be removed from the market and destroyed, and the destruction carried out in a way that allows WSLCB to verify that the recalled product has not in fact been either returned to the stream of licit commerce or sold "out the back door."

The team will assist the WSLCB to assess the usefulness of various comparable recall processes, such as the rigorous processes used for controlled substances under the federal Controlled Substances Act, product recall processes for other pharmaceuticals mandated by the Food and Drug Administration, and the simpler processes mandated in the state of Colorado.

CATEGORY 3 – PRODUCT USAGE AND CONSUMPTION VALIDATION

Please answer the questions listed below, attaching additional pages as necessary:

9. **Ability, Capacity and Skills.** In two (2) pages or less, please describe your firm's ability, capacity, and skills and/or expertise to estimate Product Usage and Consumption levels by geographic areas in Washington State.

Introduction

Our Category 3 Product Usage and Consumption Validation team is comprised of a multi-disciplinary and highly-skilled team of researchers, policy makers, economists, statisticians, pricing experts, government advisors and business analysts experienced in the field of criminal and drug policy and with substantial background in marijuana policy. A number of team members have worked on successful marijuana regulation engagements in other jurisdictions.

Our team has the capacity, ability, skills and expertise to estimate Product usage and validate Marijuana consumption amounts and patterns at the state and sub-state levels on an annual basis, all of which is needed to implement a successful Marijuana Program.

Specifically, our team will provide the Washington State Liquor Control Board (WSLCB) with supply and demand data necessary to understand resource allocation, pricing, and projected revenue related to I-502 implementation and to ensure that measures to control supply are adequately developed so that pricing is kept at or below black market levels. Our team is well versed in Product usage paradigms and psychographic-based Product consumption data. Monitoring supply relative to demand is important given its impact on pricing and both producer and consumer willingness to remain within the confines of the program. Program participation and tenure is important to the success of I-502 in terms of consumer safety, for producer participation, quality control, and ultimately revenue and successful revenue prediction. Accurate supply and demand estimates are critical when deciding on the number of production licenses to issue both in the initial allotment and later on.

Team Capacity to Estimate Product Usage and Consumption Levels by Geographic Areas

The team includes the best and brightest in the field of drug policy, demography, economics, accounting, and statistics/data analysis. These experts have been deliberately selected and assembled in a single team to assist the WSLCB in measuring Product usage and consumption levels by State and county levels and along psychographic dimensions.

BOTEC Analysis Corporation is a research and government consulting and advisory firm that has managed, overseen, and worked on similar engagements in the field of criminal and drug policy for the past 30 years. Since its founding, BOTEC has contributed research and government advisory in the fields of criminal and drug policy. Previous areas of work include evaluating community correction programs, estimating the volumes, dangers, and trends of illicit markets, and advising local governments on violence-reduction and incarceration-reform programs. BOTEC is led by CEO Mark Kleiman, Ph.D. Public Policy, Harvard Kennedy School. Dr. Kleiman teaches public policy at UCLA, and is an expert in many aspects of criminal and drug policy, including probation and parole, incarceration, and marijuana policy. Recent author of *Marijuana Legalization: What Everyone Needs To Know* co-authored with Jonathan Caulkins, Angela Hawken, and Beau Kilmer, and *When Brute Force Fails.*

RAND Drug Policy Research Center is a nationally acclaimed drug policy research center comprised of veteran economists, public policy authorities, computer science professionals, finance specialists, and data and operations research experts. RAND Drug Policy Research Center has extensive skills, expertise and experience estimating the size of marijuana markets in the U.S. and abroad; this expertise will be an invaluable base to assist the WSLCB in detailing Marijuana use (total, medical, and recreational) by State and County-levels and projecting volume needed.

RAND Statistics Group is one of the top applied statistics group in the United States. The Group consists of eighteen doctoral-level statisticians, and eight masters-level statisticians. RAND statisticians contribute at all stages of a research project, including collaboration on design, sampling, measurement, analysis, computing, and presentation of the results. In the areas of design, sampling, and measurement, group expertise includes knowledge about clinical

trials, complex survey design and analysis, experimental design, observational study design, computer experiments, survey non-response, imputation and other methods for dealing with missing data, measurement error, psychometrics and scaling, and web-based survey methods. RAND Statistics Group specializes in working with policy issues and dealing with massive datasets, longitudinal data analysis, and causality, among other things.

One of RAND's team members, Dr. Rosalie Pacula is an economist who brings considerable experience understanding the incentives and private/public consequences of different market structures, regulations, and the like. She has published extensively on the supply, demand, and the interacted markets (e.g. alcohol) related to marijuana for over 15 years and wrote one of the first books (*Cannabis Use and Dependence: Public Health and Public Policy*, Cambridge University Press 2003) that described in detail how cannabis might be legalized with a goal of minimizing public health harm. She has examined in detail a variety of marijuana-specific state level policies aimed at reducing harms, including decriminalization policies and medical marijuana policies, looking at the legal and economic aspects of these laws that may or may not make them effective.

Our individual team members contribute expertise in a broad range of social science disciplines and professional skills:

- Luigi Zamarra, CPA, and former Chief Financial Officer of Harborside Health Center, implemented a rigid accounting system at Harborside that helped ameliorate federal concerns regarding product diversion. His accounting expertise will be critical in setting up the program for tracking Product use and consumption over time and within the State.
- Rob MacCoun, a behavioral scientist on the faculty of UC Berkeley Law School who has extensive knowledge and background on the functioning of the Dutch medical marijuana system and will inform the team on lessons learned related to their experience for estimating product usage and consumption.
- Phil Cook, a drug policy researcher and Senior Associate Dean at the Sanford School of Public Policy at Duke University focused on the prevention of alcohol-related problems via restrictions on alcohol availability and expert in collecting and analyzing data related to consumption of alcohol. He has conducted considerable research on the effects of beer taxes on youthful drinking and the consequences thereof, finding that more restrictive policies result in lower rates of abuse, higher college graduation rates, and lower crime rates.
- Tom Schelling, a Nobel prize-winning economist and renowned policy advisor who has studied the impact of illicit drug markets on consumers, bring extensive expertise related to addictive behavior such as smoking, as well as skills and knowledge about how to estimate product usage and consumption to the project.
- Jerome Jaffe, a clinical professor in the Department of Psychiatry at the University of Maryland School of Medicine in Baltimore, works in the Division of Alcohol and Drug Abuse. He served as a top-level government advisor equivalent in rank and stature to the modern day Drug Czar to President Nixon in the 1970s and has vast experience, expertise and knowledge on drug usage and consumption.
- Jonathan Caulkins, one of the foremost leaders in modeling the effectiveness of interventions related to drugs, crime, delinquency and prevention, is the co-director of RAND's Drug Policy Research Center and has published extensively on drug policy.

10. **Experience.** In two (2) pages or less, please describe your firm's experience in statistical research, specifically related to determining demographic and/or psychographic segmentation, preferably related to the use of Cannabis.

Along with estimating the size and geographic characteristics of the market, it will be important for the WSLCB to understand possible demographic and psychographic aspects of the market. Many of the statistical techniques and skills used to estimate Product Usage and Consumption levels by geographic areas in Washington State will also be substantially related to the demographic segmentation of Cannabis use. Therefore, most of the experts presented in Question 9 and the expertise demonstrated there relates to Question 10 as well.

In addition to the experience in the above question, the RAND Drug Policy Research Center team members are engaging in a NIDA-funded study to assess the public health effects of state medical marijuana along demographic and psychographic dimensions. As part of this work, they are examining variation in state-level measures of a range of harms by age group, gender and ethnic group and assessing how they move with changes in medical marijuana policies. Harms examined include recreational use among youth and adults, rates of dependence, emergency room episodes, drugged and drunk driving, and crime. This experience and others bear directly on examining the demographic and psychographic aspects related to I-502 Implementation:

- RAND is currently working with the White House Office of National Drug Control Policy to estimate the number of marijuana users, amount of money spent, and amount of marijuana consumed in the United States for each year, 2000–2010.

- In 2009, RAND was contracted by the European Commission (EC) to estimate the size of the European cannabis market, and recently received another contract from the EC to update the figures using new consumption data. The skills and capabilities utilized in these two projects are invaluable to the WSLCB for detailing Marijuana use (total, medical, and recreational) by State and County-levels and projecting volume needed.

Angela Hawken, PhD is Associate Professor of Economics and Policy Analysis at the School of Public Policy at Pepperdine University where she teaches graduate classes in applied research methods, statistics, crime, and social policy. Hawken led the statewide cost-benefit analysis of California's alternative sentencing initiative, Proposition 36. Hawken's research interests are focused on drugs, crime, and corruption. She was the first to introduce the *Behavioral Triage Model* for identifying, treating, and supervising drug-involved offenders. Most recently she co-authored (with Mark Kleiman and Jonathan Caulkins) *Drugs and Drug Policy: What Everyone Needs to Know*, and a second book in the series (co-authored with Jonathan Caulkins, Beau Kilmer, and Mark Kleiman) *Marijuana Legalization: What Everyone Needs to Know*. Hawken has delivered testimonies to many state legislatures and to the U.S. Congress on issues related to US drug policy. Hawken brings her economics and statistical experience and expertise to the project team.

Dr. Rosalie Liccardo Pacula (PhD in Economics, Duke University) is Senior Economist at the RAND Corporation, Co-Director of the RAND Drug Policy Research Center, Professor at Pardee RAND Graduate School, and Director of RAND Health's Program on Economics, Finance, and Organization. Dr. Pacula has spent her career modeling and publishing studies on illegal markets (illegal to all, or just those that are illegal to youth). She brings considerable experience understanding the incentives and private/public consequences of different market structures, regulations, and the like. She has published extensively on the supply, demand, and the interacted markets (e.g. alcohol) related to marijuana for over 15 years and wrote one of the first books (*Cannabis Use and Dependence: Public Health and Public Policy*, Cambridge University Press 2003) that described in detail how cannabis might be legalized with a goal of minimizing public health harm. She has examined in detail a variety of marijuana-specific State-level policies aimed at reducing harms, including decriminalization policies and medical marijuana policies, looking at the legal and economic aspects of these laws that may or may not make them effective. This experience is coupled with her advanced training in statistical methods focused on identifying causal relationships. *Category 3 Relevant Publications:*

- J. Caulkins, B. Kilmer, R. Pacula, R. MacCoun, & P. Reuter. (2012). Design considerations for legalizing cannabis: Lessons inspired by analysis of California's Proposition 19. *Addiction, 107*, 865–871.
- B. Kilmer, J. Caulkins, R. Pacula, & P. Reuter. (2011). Bringing perspective to illicit markets: Estimating the size of the U.S. marijuana market. *Drug and Alcohol Dependence*, 119, 153–160.

- B. Kilmer & R. Pacula. (2009). *Estimating the size of the global drug market: A demand-side approach.* TR-711. Santa Monica: RAND.

Dr. Beau Kilmer (PhD in Public Policy, Harvard University) is Senior Policy Researcher at the RAND Corporation, Co-Director of the RAND Drug Policy Research Center, and Professor at Pardee RAND Graduate School. *Category 3 Relevant Publications:*

- J. Caulkins, A. Hawken, B. Kilmer, and M, Kleiman, *Marijuana Legalization: What Everyone Needs to Know.* (Oxford University Press, 2012)
- J. Caulkins & B. Kilmer. (In progress). *Estimating the size of the EU cannabis market.* European Commission
- J. Caulkins, B. Kilmer, R. Pacula, R. MacCoun, & P. Reuter. (2012). Design considerations for legalizing cannabis: Lessons inspired by analysis of California's Proposition 19. *Addiction, 107,* 865–871.
- B. Kilmer, J. Caulkins, R. Pacula, & P. Reuter. (2011). Bringing perspective to illicit markets: Estimating the size of the U.S. marijuana market. *Drug and Alcohol Dependence,* 119, 153–160.
- B. Kilmer, S. Everingham J. Caulkins, G. Midgette, P. Reuter, R. Burns, R. L. Pacula, B. Han, & R. Lundberg. (In progress). *What America's users spend on illicit drugs, 2000–2010.* White House Office of National Drug Control Policy.
- B. Kilmer & R. Pacula. (2009). *Estimating the size of the global drug market: A demand-side approach.* TR-711. Santa Monica: RAND.
- In addition, David P. Cavanaugh is a demographer and operations research expert who has previously applied his demographic expertise in the criminal justice arena.

11. **Staff Qualifications and Capabilities.** Please identify staff by name and title, including subcontractors, who would be assigned to the potential contract, indicating their normal responsibilities in your firm. Provide qualifications information on the named staff, including the individuals' particular skills related to this project, education, experience, significant accomplishments and any other pertinent information.

Our team is headed by BOTEC Analysis Corporation, a think-tank specializing in crime and drug policy and acting as the primary contractor on the proposal. BOTEC has thirty years of experience contributing research and government advisory focusing on methods to maximize the effectiveness of crime and drug control policies while minimizing their attendant societal costs. Previous projects include analyses of the volume and danger of illicit cigarette markets, advising the implementation of criminal supervision programs intended to reduce drug abuse among parolees, and Federal research grants aiming to reduce incarceration and to explore the connection between crime and drugs. BOTEC CEO Mark Kleiman hopes to bring to the WSLCB his core staff of analysts, researchers, and evaluators, to be complemented by a highly selective and tight-knit network of experts. The group is assembled to offer a broad range of options and a depth of resources from which the WSLCB may draw according to its particular needs.

BOTEC Analysis' core staff consists of Dr. Mark Kleiman (PhD Public Policy, Harvard Kenned School), senior researchers Dr. Jonathan P. Caulkins (PhD Operations Science, MIT) and Dr. Angela Hawken (PhD Public Policy, RAND), general counsel Lowry Heussler, and managing director Steven Davenport. Dr. Caulkins and Dr. Hawken are both professors of public policy and highly regarded contributors to the study of illicit markets, crime, and drug abuse. While Dr. Kleiman is tasked with overseeing the entire project team, Mr. Davenport's focus is to manage day-to-day project developments and coordinate project activity.

BOTEC offers the WSLCB a wealth of experts in formalized marijuana cultivation and testing, quality standards, statistical modeling, policy analysis, dynamics of illicit markets, law enforcement, drug control, drug dependency, game theory, economics, and rule-making. They've occupied prestige positions ranging from Presidential Advisors to Nobel Laureate. The approach of the Team is to draw top experts in the relevant areas for each aspect where the WSLCB will require consultation. As such, members do not necessarily have titles within the firm but rather each bring their own first rate capabilities and experience to the challenges that will confront WSLCB in estimating product usage and consumption by geography area as well as from a demographic and psychographic perspective. The team will utilize the task-oriented team management system to complete assignments in an efficient and productive manner. This system has already been used by four core members of the team in the composition of a full-length book.

Dr. Mark Kleiman is CEO of BOTEC. He is Ph.D. Public Policy, Harvard Kennedy School. Dr. Kleiman teaches public policy at UCLA, and is an expert in many aspects of criminal and drug policy, including probation and parole, incarceration, and marijuana policy. Recent author of *Marijuana Legalization: What Everyone Needs To Know* co-authored with Jonathan Caulkins, Angela Hawken, and Beau Kilmer, and *When Brute Force Fails.* Other publications include:

- M. Kleiman, *Marijuana: Costs of Abuse, Costs of Control* (Greenwood, 1979)
- M. Kleiman, *Against Excess: Drug Policy for Results* (Basic Books, 1993)

Dr. Jonathan Caulkins (PhD in Electrical Engineering and Computer Science, MIT) is H. Guyford Stever Professorship of Operations Research and Public Policy at Carnegie Mellon University and former Co-Director of the RAND Drug Policy Research Center. *Category 3 Relevant Publications:*

- J. Caulkins & B. Kilmer. (In progress). *Estimating the size of the EU cannabis market.* European Commission
- J. Caulkins, B. Kilmer, R. Pacula, R. MacCoun, & P. Reuter. (2012). Design considerations for legalizing cannabis: Lessons inspired by analysis of California's Proposition 19. *Addiction, 107,* 865–871.
- B. Kilmer, J. Caulkins, R. Pacula, & P. Reuter. (2011). Bringing perspective to illicit markets: Estimating the size of the U.S. marijuana market. *Drug and Alcohol Dependence,* 119, 153–160.
- B. Kilmer, S. Everingham J. Caulkins, G. Midgette, P. Reuter, R. Burns, R. L. Pacula, B. Han, & R. Lundberg. (In progress). *What America's users spend on illicit drugs, 2000–2010.* White House Office of National Drug Control Policy.

Dr. Rob MacCoun (PhD in Psychology, Michigan State University) joined the faculty of UC Berkeley's School of Public Policy in 1993 and the Boalt faculty in 1999. From 1986 to 1993 he was a behavioral scientist at The RAND Corporation, and he has been a Visiting Professor at Princeton's Woodrow Wilson School and Stanford Law School. He has published many studies on illicit drug use and drug dealing, harm reduction, and social influence processes. *Category 3 Relevant Publications:*

- Caulkins, J. P., Kilmer, B., MacCoun, R. J., Pacula, R. L., & Reuter, P. (2012). Design considerations for legalizing cannabis. *Addiction, 107,* 865-871.
- MacCoun, R. J., & Reuter, P. (2011). Assessing drug prohibition and its alternatives: A guide for agnostics. *Annual Review of Law & Social Science, 7,* 61-78.
- MacCoun, R. J. (2011). What can we learn from the Dutch cannabis coffee shop system? *Addiction, 106,* 1899-1910.
- Kilmer, B., Caulkins, J. P., Pacula, R. L., MacCoun, R. J., & Reuter, P. H. (2010). *Altered state? Assessing how marijuana legalization in California could influence marijuana consumption and public budgets.* Santa Monica, RAND.
- MacCoun, R. J. (2010). The implicit rules of evidence-based drug policy, updated. *Addiction, 105,* 1335-1336.
- MacCoun, R., & Reuter, P. (2001). *Drug war heresies: Learning from other vices, times, and places.* Cambridge University Press.

Dr. Phil Cook (PhD in Economics, University of California, Berkeley) is Professor of Public Policy and Professor of Economics and Sociology at Duke University. Over much of his career, one strand of Cook's research concerns the prevention of alcohol-related problems through both regulatory restriction and welfare-improving tax regimes. An early article of his was the first to demonstrate persuasively that alcohol taxes have a direct effect on the death rate of heavy drinkers, and subsequent research demonstrated the moderate efficacy of minimum-purchase-age laws in preventing fatal crashes. Together with Michael J. Moore, he focused on the effects of beer taxes on youthful drinking and the consequences thereof, finding that more restrictive policies result in lower rates of abuse, higher college graduation rates and lower crime rates. His recent book on the subject is *Paying the Tab: The Costs and Benefits of Alcohol Control* (Princeton University Press, 2007).

Dr. Thomas Schelling (PhD in Economics, Harvard University) was awarded the 2005 Nobel Prize in economics, was a professor of economics at Harvard until 1990 and is now a professor emeritus at the University of Maryland. His work on health policy, tobacco and drugs policy, and ethical issues in public policy and in business will bring invaluable and recognized insight to the project team. His article in *Science* "Addictive Drugs: The Cigarette Experience" from 1992 looks at smoking and the social trends around nicotine including the increasing demographic movement of cigarettes concentrating among poorer groups in society and "Assessing Alternative Drug Control Regimes" in 1996 with Peter Reuter and Robert MacCoun as an early look at options between harsh prohibition and sweeping legalization.

Dr. Jerome Jaffe is Clinical Professor of Psychiatry in the Division of Alcohol and Drug Abuse, University of Maryland School of Medicine, and Adjunct Professor, Department of Mental Health, Johns Hopkins Bloomberg School of Public Health. He is internationally recognized as an expert on the addictions. He has worked in this area for more than forty years, in academia and government, as a clinician, laboratory and clinical researcher, teacher, writer, and policymaker. As the first White House "Drug Czar," Dr. Jaffe initiated many of the basic and epidemiological research programs that formed the groundwork for ongoing efforts in drug abuse research, and he introduced programs that radically altered and expanded drug abuse treatment in the United States. His more than 200 publications include peer reviewed articles in scientific journals, chapters in major textbooks of psychiatry, pharmacology, and drug abuse, and books and articles in the popular press. Dr. Jaffe is on the editorial boards of several journals, has served on national and international advisory groups, and is a consultant to private and public agencies concerned with drug abuse treatment and policy. He is a Fellow of the American Psychiatric Association (Distinguished Life), American College of Neuropsychopharmacology (Emeritus), American Academy of Addiction Psychiatry, College on Problems of Drug Dependence, and Honorary Fellow of the Royal College of Psychiatrists and the Society for the Study of Addiction in the UK

A few additional team members and their qualifications have previously been mentioned in answering questions 9 and 10.

12. **Approach and Methodology.** In two (2) pages or less, please provide a complete description of your firm's proposed approach and methodology to be used for Product Usage and Consumption validation as requested in this RFP, to estimate demographic and psychographic segmentation, specifically related to the use of Cannabis.

The Team's proposed approach and methodology are as follows:

Step 1. Estimating the number of marijuana users and amount of marijuana consumed in Washington State

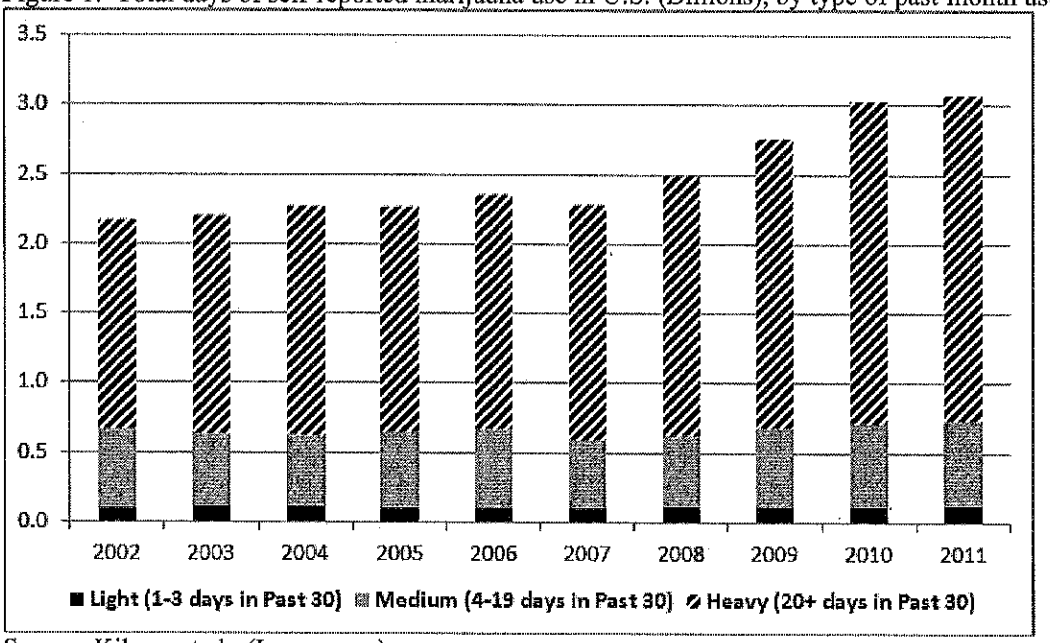
The team currently is under contract with the White House Office of National Drug Control Policy to develop a new approach for generating national estimates of the total number of marijuana users, total amount of marijuana consumed, and total marijuana expenditures at the retail level. The team will use this model to extend national projections through 2012 and then use the most recent data from NSDUH to generate best estimates (with ranges) for Washington State and for each county. That will generate county-level estimates of the current cannabis market; we will then adjust those estimates upward for potential growth due to legal availability and downward for illicit production and import and sales through the medical system, leaving estimates of the potential market to be served by the system WSLCB will design and regulate.

The team will also adjust for *changes in composition.* Current estimates of quantities consumed reflect a mix of higher potency ("sinsemilla") and lower potency products ("commercial grade"), whereas we expect legal sales to be primarily of higher potency materials. In our work on California's Proposition 19, we estimated that grams consumed per hour of intoxication could differ by roughly a factor of 2 between the current market mix and the anticipated post-legalization mix.

In terms of *user volume*, the market is dominated by a relatively small number of very heavy users. (The alcohol market is similar in this regard.) Combining work described above with similar work conducted for the European Commission suggests that the 80/20 Pareto Rule applies fairly literally. The 19% of past-year users who consumed on more than 20 days per month account for about one-third of past-month users, two-thirds of days of use, and 78% of the weight consumed.

Figure 1 displays the total number of marijuana use days reported in NSDUH by type of user for the entire country [Note: Figure 1 is a "raw" estimate not yet adjusted for misreporting or non-response. The proposed team has developed methods for making such adjustments]. At the national level we see that the heavy users (20+ use days in the previous month) account for most of the self-reported use days. Further, the number of use days attributable to this group has increased 40% from 2007-2011. We will generate similar figures for Washington State and its counties using the most recent data available. We can generate similar charts breaking down demand along various psychometric and demographic dimensions (age, educational attainment, duration of use, attitudes toward risk, etc.).

Figure 1. Total days of self-reported marijuana use in U.S. (Billions), by type of past-month user



Source: Kilmer et al. (In progress)

Step 2. Allocate state totals to each of Washington's 39 counties

The team will allocate these state-level figures to the 39 counties using sub-state information from a variety of sources:

- Past month marijuana prevalence for six sub-state regions (2008–2010 NSDUH)
- Percentage of treatment admissions with a marijuana mention for 9 MSAs/PMSAs (2011 TEDS)
- County-level hospital admissions with a primary or secondary diagnosis involving marijuana
- County population and demographic figures (U.S. Census)
- Washington State's Healthy Youth Survey (biennial)—provides a good baseline.

For previous projects, the team has obtained county-level information from Quest Diagnostics about the share of workplace drug tests that detected marijuana. If selected we will seek approval to use these data for this project. The Team could inquire about obtaining county-level aggregated drug testing information for probationers and parolees as an added piece of data corroboration.

Step 3. Estimate the share of marijuana consumed for medical purposes vs. recreational purposes

Under the proposed project, it is more important to know what share of regular users will not purchase from licensed sellers, regardless of reason: whether that is because they grow their own, are under age, prefer products only available from the black market, purchase from a medical dispensary/delivery service, obtain it from a "collective garden," or some combination thereof. Insofar as the medical system enjoys a price advantage compared to the system to be regulated by WSLCB, the financial incentive to obtain a medical card would be greater for consumers who use more, so we might expect that the medical system to draw a larger proportion of heavy users. The same might apply to other untaxed sources.

Creating and fielding a web survey of regular cannabis users in the state would allow us to get a rough idea of this distribution (and learn much more about typical quantities consumed) but this approach raises concerns about whether the respondents are representative of regular users. An alternative approach would be to use respondent-driven sampling (RDS) to, in essence, generate a random sample of regular marijuana users in a jurisdiction (e.g., city,

county, sub-state region). The proposed statistical research subcontractor has experience using both approaches to generate information about marijuana consumption and purchase patterns, and if chosen, will consult with WSLCB about the approach they prefer (RDS is more expensive, but can allow for better inferences).

The team also will assist the WSLCB in understanding changes in consumption patterns as a result of legal supply (e.g., the number of users is likely to rise, but the ratio of heavy users to all users might fall).

Other ways of checking use rates developed from NSDUH and the WA Healthy Youth Survey is to look at data available on heavy use and dependence, which are available from at least two sources: (a) the Treatment Episode Data Set (TEDS) data, and (b) Emergency Department data. The Team has already looked extensively at these data nationally and in specific states to assess the incidence of heavy marijuana use, dependent users, and harms from marijuana use and the associated economic costs. These data sources offer a powerful check to regular household and phone surveys, as they include populations that are not always represented in regular household or phone surveys, including the homeless and incarcerated. Both data sources contain individual patient records on episodes of treatment for medically determined marijuana abuse/dependence. The TEDS data includes patient-level data on all individuals seeking treatment for any substance of abuse from any recognized treatment facilities in the U.S. that receives publicly-funded support (either through state or federal block grants or Medicaid/Medicare payments). This includes hospitals, residential settings, and outpatient clinics. Up to three substances of abuse are listed in TEDS. While geographic information are only available at the CMSA and PMSA level in the public use data file, many states provide access to county level information when asked for the data directly and confidentiality assurances are met. In addition to identifying individuals who meet DSM-IV criteria for abuse and dependence of marijuana, these data can be used to also identify individuals who suffer from relevant mental health comorbidities, including anxiety disorders, depressive disorders, schizophrenia and other psychotic disorders, bipolar disorders and ADHD behavior disorders.

Hospital and ambulatory emergency department data are another excellent source of information on acute problems associated with marijuana abuse and dependence, as individuals treated with problems of abuse/dependence in an emergency department are not always admitted into a hospital (which is the domain caught by the TEDS data). Medical information typically available in these data includes county of admission, and any evidence of mental health co-morbidity by ICD-9 diagnosis. These data, combined with the TEDS data, can provide a comprehensive assessment of the number of heavy users experiencing health problems (including but not limited to abuse/dependence) by county, allowing one to differentiate trends in simple prevalence of any use of marijuana from trends in problematic use.

Step 4. Establish plant yield and growth volume assumptions needed to keep pricing at or below black market levels

The team has extensive experience thinking about cannabis plant yields for different modes of production. For example, to better understand the possible consequences of California's Proposition 19, The Team reviewed the literature, created models, and published cannabis yield and cost estimates for various production choices (i.e., 5x5 plot, grow house, greenhouse, outdoor farms). Building on this work, Team researchers estimated that that it would take less than 10,000 grow houses to meet current U.S. demand for THC. Combining these insights with what we learn about prices (per gram of cannabis as well as per unit of THC) from dispensaries and user surveys will allow us make reasonable projections about the market implications of different production regimes.

The costs of production, processing, testing, and retail sales will put a lower bound on prices. But in a regulated market, with the number of providers at each level limited by WSLCB, sellers might maintain prices above the zero-pure-profit level. Limiting the number of providers has advantages; not only does it ease the task of regulatory inspection, but if license-holders are deriving economic "rent" from higher-than-competitive pricing, their licenses become especially valuable, strengthening the incentive for compliance created by the threat of license suspension and revocation. That advantage, and the public health benefits of reduced consumption – with heavy and problem use, and use by minors, likely to be especially price-sensitive – suggest issuing fewer licenses. Higher prices will also tend to generate greater tax revenues, since the literature suggests that demand responds to price but less than proportionally. On the other hand, having fewer providers will reduce consumer convenience, and higher prices will increase consumers' incentives to seek alternative sources of supply (medical or illicit). Those effects would tend to reduce tax

revenues, and illicit supply would partially defeat the purpose of creating the legal regime. We would attempt to calculate the extent of all these effects, enabling WSLCB to optimize its regulatory decision-making.

Even the most careful set of estimates will be subject to error; behavior in a fully licit cannabis market is outside the range of existing experience and federal policy toward licensed producers and sellers remains unclear. If desired by WSLCB, the Team recommends that a monitoring and course-correction process that would allow the Board to update its policies in light of early experience be designed.

CATEGORY 4 – PRODUCT REGULATION

Please answer the questions listed below, attaching additional pages as necessary:

13. **Ability, Capacity and Skills.** In two (2) pages or less, please describe your firm's ability, capacity, and skills and/or expertise in Product Regulation, including but not limited to, the following:
    a. Experience with State, local or Federal government processes and procedures
    b. Experience in crafting system regulations

WSLCB faces an unprecedented task: creating the world's first system of legal and regulated commerce for marijuana and marijuana products. Doing so involves balancing a variety of goals: public health, public safety, reduction of illicit commerce, public revenue, and administrative feasibility and cost, all within the guidelines set out by I-502, the Open Government Act, other Washington State statutes, and the Board's own procedures.

BOTEC and RAND bring to the task of crafting regulations a wealth of background in government service and research on markets in legal and illegal intoxicants and abusable substances and highly-regulated products. Members of our team have among them more than a century of experience working within regulatory systems and crafting and modifying rules and regulations at federal, state, and local levels, including those relating specifically to marijuana.

Our team is constructed to offer the WSLCB a range of skills to assist with the regulatory process, which our members have practiced at the highest levels:

- **Focus Groups:** The RAND Drug Policy Research Center has done extensive work on the size of the current illicit marijuana markets; the RAND Survey Research Group (SRG) offers the full range of survey-based information-gathering techniques, including focus groups. SRG is staffed with survey methodologists, behavioral scientists, and specialists in the technical aspects of survey research, including fourteen experienced focus group moderators. With over forty years of experience, SRG excels in custom-tailoring survey design to the needs of the client and applying nontraditional survey methods such as interviewing specialized populations, mixing data collection methods, and implementing experimental designs. It offers experience with a variety of outreach methods (mail, telephone, and in-person surveys and focus groups), data abstraction from public and private institutional records, and success in implementing designs in policy areas such as health care cost containment and drug prevention.
- **Market Estimates**: Four of the members of our core team (Jonathan Caulkins, Angela Hawken, Beau Kilmer, and Mark Kleiman) are the authors of *Marijuana Legalization: What Everyone Needs to Know* (Oxford University Press, 2012). That book is based on a survey of the entire scholarly literature, including the publications of the "Altered State" project of the RAND Drug Policy Research Center and Dr. Kleiman's two previous books on drug policy, *Against Excess: Drug Policy for Results* and *Marijuana: Costs of Abuse, Costs of Control*. The Scientific and Legal Advisory Panel includes an array of outstanding experts on drugs and drug policies, Keith Humphreys, Jerome Jaffe, Robert MacCoun, Mark Moore and Thomas Schelling. The team's research background in cannabis policy and markets will allow us to generate independent estimates of the likely consequences of alternative regulatory approaches.
- **Implementing Industry Compliance:** We are prepared to offer WSLCB advice based on practical experience with respect to the impacts its regulations will have on industry functioning. Our team includes the former CFO of Harborside Health Clinic, one of the largest medical marijuana dispensaries in California, and the former CEO and production-operations manager of Bedrocan International, the world's sole fully licit producer of cannabis for sale to end-users.
- **Regulatory management:** Members of our team have held the following positions: Chief Counsel of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Assistant General Counsel (Enforcement) of the U.S. Treasury; Deputy Administrator of the Transportation Security Administration; and Inspector General of the Federal Bureau of Investigation.

14. **Experience.** In two (2) pages or less, please describe your firm's experience in working within the confines of a regulatory system, and experience in creating and/or modifying rule, law, ordinance, and/or guidelines.

Experience with state, local or federal government processes and procedures

Our experts have contributed expertise to all levels of government, including:

- **Federal government:** Jerome Jaffe served as the nation's first "drug czar" as the director of the White House Special Action Office for Drug Abuse Prevention (SAODAP). In that position, he created several of the most important drug data-collection systems still in use. Keith Humphreys served as Senior Policy Adviser to the Office of National Drug Control Policy. Eric Sterling was assistant counsel for the Committee on the Judiciary of U.S. House of Representatives and crafted extensive drug-policy legislation and legislation on illicit tobacco marketing. Michael DeFeo served as Deputy Section Chief for the Organized Crime and Racketeering Section of the Criminal Division of the U.S. Department of Justice and Inspector General of the Federal Bureau of Investigation. Stephen McHale served as Chief Counsel of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Assistant General Counsel (Enforcement) of the U.S. Treasury.
- **State government**: Harris Kenny serves on Colorado Governor John Hickenlooper's Amendment 64 Task Force, Jackie Leigh serves on the Colorado Department of Revenue's and the Colorado Department of Health and Public Environment's medical marijuana advisory committees, and Lowry Heussler has 23 years of experience offering counsel to and practicing agency and administrative law with various Massachusetts regulatory agencies.
- **Local government:** Eric Sterling currently works as a long-term appointee to the Alcohol and Other Drug Abuse Advisory Council of Montgomery County, Maryland, and has held leadership positions within government, including co-vice chair of the Alcohol and other Drug Abuse Advisory Council, and as an advisor to the mayors of Washington, DC and Baltimore, MD.

Experience in crafting system regulations

Stephen McHale has extensive experience in the development of regulatory schemes governing the production, sale and taxation of alcohol, tobacco, firearms and explosives, transportation security, government ethics, and anti-money laundering. Mr. McHale served as Chief Counsel of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Assistant General Counsel (Enforcement) of the U.S. Treasury. As the first Deputy Administrator of the Transportation Security Administration, Mr. McHale was responsible for the development of a scheme for regulating security in all modes of transportation virtually from scratch.

Jerome Jaffe created the national regulatory structure for methadone maintenance and managed the process of moving LAAM through the FDA drug-approval process.

Members of our team have labored to ensure that medical marijuana businesses maintain full compliance with Federal law. Mr. Zamarra, CPA, sounded the alarm to the industry that many if not most marijuana business operators stood in violation of Internal Revenue Service regulations. As CFO of California's Harborside Health Center, he was instrumental in making Harborside the model for transparency in the medical marijuana trade. His rigorous inventory tracking and insistence on full legal compliance arguably kept Harborside a low enforcement priority for federal agents. Despite Harborside's conspicuously large scale of operations, it has never been a target for a federal raid. Jackie Leigh serves as director for a program providing mandatory training to medical marijuana facility operators and employees, and recently presented at the RAND conference on Public Health Regulations for Marijuana. Michael Sautman served as CEO of Bedrocan International, Inc. (BI, California, USA). BI operated as the international affiliate of Bedrocan BV (Netherlands), the only company in the world licensed to produce multiple, diverse cannabis varieties for patients under a national program. Regulated by the Dutch Ministry of Health's Office of Medicinal Cannabis (OMC), Bedrocan's botanical products are manufactured in accordance with Good Agricultural Practices (GAP) and adhere to World Health Organization (WHO) standards for the production of botanical drugs. As CEO, he has consulted lawmakers and regulators in Canada, Israel and several U.S. states regarding how medical marijuana is produced and distributed in The Netherlands. At BI, he initiated Bedrocan's medical marijuana drug approval program with Health Canada, the Canadian Ministry of Health.

Members of our team hold academic positions enabling them to conduct in-depth research into the consequences and intricacies of regulatory schemes. Dr. Moore is the first Herbert A. Simon Professor of Education, Management, and Organizational Behavior and the Hauser Professor of Nonprofit Organizations at the Harvard Kennedy School of Government. Dr. Schelling is a Nobel-Prize winning economist and is former Lucius N. Littauer Professor of Political Economy at Harvard's Kennedy School of Government. Drs. Kleiman, Caulkins, and Hawken all hold professorships at schools of public policy, and co-authored along with Dr. Kilmer "Marijuana Legalization: What Everyone Needs to Know." Dr. MacCoun teaches at UC Berkeley's Boalt Hall and Goldman School of Public Policy, and has extensively studied the Dutch recreational marijuana system. More of our experts' relevant publications are available in the response to question 14.

Members of our team have been active participants in shaping regulations governing medical and recreational marijuana in Colorado. Team member Harris Kenny serves serve on Colorado Governor John Hickenlooper's Amendment 64 Task Force on the Local Authority and Control Working Group, and as a policy analyst at Reason Foundation. He has co-sponsored and contributed to recommendations vital to the Task Force's mission to facilitate successful implementation of marijuana legalization. Jackie Leigh served on multiple Coloradoan medical marijuana advisory committees. She has been influential in the development of the Colorado Medical Marijuana Code and regulations implemented thereafter by multiple regulatory bodies. Ms. Leigh provides regulatory drafting services to numerous Colorado industry trade associations suggesting rule changes to the Colorado Medical Marijuana Enforcement Division. Mr., Zamarra has drafted two pieces of proposed legislation relating to the medical marijuana industry, one in the California Assembly and HR 1840, introduced by Congressman Pete Stark.

Our members have crafted a long list of bills, regulations, and regulatory structures, including: numerous regulatory bills enacted by Congress as counsel responsible for oversight and amendment of Acts, including the Controlled Substances Act, the Gun Control Act of 1968, the Bank Secrecy Act of 1970, Dangerous Drug Diversion Control Act of 1984, Currency and Foreign Transactions Reporting Act Amendments of 1984, Federal Firearms Owners Protection Act, Money Laundering Control, Chemical Diversion and Trafficking Act, Child Pornography and Obscenity Enforcement Act of 1988, and others.

15. **Staff Qualifications and Capabilities.** Please identify staff by name and title, including subcontractors, who would be assigned to the potential contract, indicating their normal responsibilities in your firm. Provide qualifications information on the named staff, including the individuals' particular skills related to this project, education, experience, significant accomplishments and any other pertinent information.

Our team is headed by BOTEC Analysis Corporation, a think-tank specializing in crime and drug policy and acting as the primary contractor on the proposal. BOTEC has thirty years of experience contributing research and government advisory focusing on methods to maximize the effectiveness of crime and drug control policies while minimizing their attendant societal costs. Previous projects include analyses of the volume and danger of illicit cigarette markets, advising the implementation of criminal supervision programs intended to reduce drug abuse among parolees, and Federal research grants aiming to reduce incarceration and to explore the connection between crime and drugs. BOTEC CEO Mark Kleiman hopes to bring to the WSLCB his core staff of analysts, researchers, and evaluators, to be complemented by a highly selective and tight-knit network of experts. The group is assembled to offer a broad range of options and a depth of resources from which the WSLCB may draw according to its particular needs.

BOTEC Analysis' core staff consists of Dr. Mark Kleiman (PhD Public Policy, Harvard Kenned School), senior researchers Dr. Jonathan P. Caulkins (PhD Operations Science, MIT) and Dr. Angela Hawken (PhD Public Policy, RAND), general counsel Lowry Heussler, and managing director Steven Davenport. Dr. Caulkins and Dr. Hawken are both professors of public policy and highly regarded contributors to the study of illicit markets, crime, and drug abuse. While Dr. Kleiman is tasked with overseeing the entire project team, Mr. Davenport's focus is to manage day-to-day project developments and coordinate project activity.

BOTEC offers the WSLCB a wealth of experts in formalized marijuana cultivation and testing, quality standards, statistical modeling, policy analysis, dynamics of illicit markets, law enforcement, drug control, drug dependency, game theory, economics, and rule-making. They've occupied prestige positions ranging from Presidential Advisors to Nobel Laureate.

CEO, Project Leader, and Category 4 Team Leader

Dr. Mark Kleiman is CEO of BOTEC. He has a Ph.D. in Public Policy from the Harvard Kennedy School of Government. Dr. Kleiman teaches public policy at UCLA, and is an expert in many aspects of criminal and drug policy, including probation and parole, incarceration, and marijuana policy. Recent author of *Marijuana Legalization: What Everyone Needs To Know* co-authored with Jonathan Caulkins, Angela Hawken, and Beau Kilmer, and *When Brute Force Fails*. Other publications include:

- M. Kleiman, *Marijuana: Costs of Abuse, Costs of Control* (Greenwood, 1979)
- M. Kleiman, *Against Excess: Drug Policy for Results* (Basic Books, 1993)

Category 4 Key Staff

Dr. Jonathan Caulkins (PhD in Electrical Engineering and Computer Science, MIT) is H. Guyford Stever Professorship of Operations Research and Public Policy at Carnegie Mellon University and former Co-Director of the RAND Drug Policy Research Center. *Category 4 Relevant Publications:*

- J. Caulkins, B. Kilmer, R. Pacula, R. MacCoun, & P. Reuter. (2012). Design considerations for legalizing cannabis: Lessons inspired by analysis of California's Proposition 19. *Addiction, 107*, 865–871.
- B. Kilmer, J. Caulkins, R. Pacula, & P. Reuter. (2011). Bringing perspective to illicit markets: Estimating the size of the U.S. marijuana market. *Drug and Alcohol Dependence*, 119, 153–160.
- B. Kilmer, S. Everingham J. Caulkins, G. Midgette, P. Reuter, R. Burns, R. L. Pacula, B. Han, & R. Lundberg. (In progress). *What America's users spend on illicit drugs, 2000–2010*. White House Office of National Drug Control Policy.
- J. Caulkins & B. Kilmer. (In progress). *Estimating the size of the EU cannabis market*. European Commission

Lowry Heussler, JD, is currently on the Massachusetts Department of Labor and Workforce Development Board of Review and has extensive experience in administrative and agency law. Dr. Heussler has co-authored books with Dr. Kleiman concerning drug policy as well as with BOTEC on crime control; she was a research assistant on BOTEC's Analysis of Cocaine and Heroin Market Structure and for Dr. Kleiman's *Against Excess: Drug Policy for Results*.

Category 4 Key Technical and Regulations Advisors
Eric Sterling, JD
Eric Sterling is president of the Criminal Justice Policy Foundation and was Counsel to the US House of Representatives Committee on the Judiciary from 1979–1989. On the staff of the Subcommittee on Crime he was responsible for drug enforcement and money laundering, among other issues. During the 96th Congress Dr. Sterling worked on rewriting the Federal Criminal Code and has received honors and awards from the US House of Representatives and the Bureau of Alcohol, Tobacco, and Firearms. He provides extensive expertise in Federal government processes, procedures, and regulations.

A member who currently wishes to remain unnamed has served as a business representative on both the Colorado Department of Revenue's and Colorado Department of Health and Public Environment's medical marijuana advisory committees. She has been influential in the development of the Colorado Medical Marijuana Code and regulations implemented thereafter by multiple regulatory bodies. She provides regulatory drafting services to multiple Colorado industry trade associations related to medical marijuana and has provided dozens of presentations and trainings across the nation.

Michael DeFeo, LLB, is a consultant on legislative and regulatory drafting in fields of terrorism, money laundering, asset recovery and corruption for international organizations including the UN Office on Drugs and Crime. As senior legal advisor for the UN Office on Drugs and Crime DeFeo provided instruction to governments through legislative drafting advice and analysis of national legislation.

Stephen J. McHale, JD, has extensive experience in the development of regulatory schemes governing the production, sale and taxation of alcohol, tobacco, firearms and explosives, transportation security, government ethics, and anti-money laundering. Mr. McHale served as Chief Counsel of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Assistant General Counsel (Enforcement) of the U.S. Treasury. In these positions, he was responsible for the developing regulations to implement the Brady Handgun Violence Protection Act and the planning for the regulatory structure to implement the Safe Explosives Act of 2002. He also played a major role in drafting the financial provisions of the USA PATRIOT Act of 2001, and initiating the development of implementing regulations. As the first Deputy Administrator of the Transportation Security Administration, Mr. McHale was responsible for the development of a scheme for regulating security in all modes of transportation virtually from scratch. At ATF and in private practice, Mr. McHale worked on issues arising under the Federal Alcohol Administration Act and the Internal Revenue Code provisions on alcohol, tobacco and firearms excise taxes. In all his regulatory work, he has engaged in extensive stakeholder outreach (including public meetings) with consumers, retailers, wholesalers, manufacturers, trade associations, unions, airlines and other transportation and service providers, and state, local and federal officials.

Luigi Zamarra is a CPA with Henry Levy & Co., CPAs in Oakland, California. He is one of the nation's most experienced business people in understanding challenges particular to the medical marijuana industry. He was previously the Chief Financial Officer of Harborside Health Center, recognized as one of the largest medical cannabis dispensaries in the United States. He has a BS in Commerce and an MS in Accounting from the University of Virginia. He worked with the Big 4 accounting firms for twelve years, rising to the position of Director at PricewaterhouseCoopers, before starting to work with regional businesses as a public accountant in San Francisco. At Harborside Health, the medical marijuana industry leader, he became the point person for the entire industry on income tax issues, including correspondences with the Commissioner of the IRS and lobbying on Capitol Hill. He further assisted with the drafting of legislation HR 1840 proposed by Rep. Pete Stark in the 112th Congress.

Scientific Advisory Panel for Category Four
Dr. Thomas Schelling, PhD in Economics, Harvard University, was awarded the 2005 Nobel Prize in economics, was a professor of economics at Harvard until 1990 and is now a professor emeritus at the University of Maryland. His work on health policy, tobacco and drugs policy, and ethical issues in public policy and in business will bring invaluable and recognized insight to the project team. His 1996 article "Assessing Alternative Drug Control Regimes" written with Peter Reuter and Robert MacCoun was an early look at options between harsh prohibition and sweeping legalization.

Dr. Rob MacCoun, PhD in Psychology, Michigan State University, is a behavioral scientist on the faculty of UC Berkeley Law School who has extensive knowledge and background on the functioning of the Dutch coffee shop marijuana system. *Category 4 Relevant Publications:*

- Caulkins, J. P., Kilmer, B., MacCoun, R. J., Pacula, R. L., & Reuter, P. (2012). Design considerations for legalizing cannabis. *Addiction, 107,* 865-871.
- MacCoun, R. J., & Reuter, P. (2011). Assessing drug prohibition and its alternatives: A guide for agnostics. *Annual Review of Law & Social Science, 7,* 61-78.
- MacCoun, R. J. (2011). What can we learn from the Dutch cannabis coffee shop system? *Addiction, 106,* 1899-1910.
- MacCoun, R., & Reuter, P. (2001). *Drug war heresies: Learning from other vices, times, and places.* Cambridge University Press.

Dr. Mark Moore, PhD in Public Policy, Harvard University, currently holds the positions of the first Herbert A. Simon Professor of Education, Management, and Organizational Behavior and the Hauser Professor of Nonprofit Organizations at the Harvard Kennedy School of Government. He was the Vice Chair on the Committee of Law and Justice for the National Academy of Sciences from 2002–2005, has written extensively on public safety matters especially related to juveniles, and has also chaired committees concerning school violence, urban violence, and alcohol control policies.

Dr. Sally Satel, M.D., is a psychiatrist and lecturer at Yale University's School of Medicine. She is an expert in drug treatment having authored books such as *Drug Treatment: The Case for Coercion.*

Dr. Jerome Jaffe, M.D., is Clinical Professor of Psychiatry in the Division of Alcohol and Drug Abuse, University of Maryland School of Medicine, and Adjunct Professor, Department of Mental Health, Johns Hopkins Bloomberg School of Public Health. He is internationally recognized as an expert on addiction. He has worked in this area for more than forty years, in academia and government, as a clinician, laboratory and clinical researcher, teacher, writer, and policymaker. As the first White House "Drug Czar," Dr. Jaffe initiated many of the basic and epidemiological research programs that formed the groundwork for ongoing efforts in drug abuse research, and he introduced programs that radically altered and expanded drug abuse treatment in the United States.

Dr. Keith Humphreys, M.D., currently is a research professor for the Stanford School of Medicine and a member of the affiliate faculty of the Center for Health Policy at Stanford. From 2009–2010 Dr. Humphreys served as Senior Policy Advisor at the White House Office of National Drug Control Policy where he advised the Director on the prevention, early intervention, and treatment of substance abuse disorders.

Dr. Donald I. Abrams, M.D., is a cancer and integrative medicine specialist at the University of California San Francisco. Dr. Abrams has extensive experience working with medicinal marijuana. Dr. Abrams is a member of the California Medical Association's Legalization and Taxation of Marijuana Technical Advisory Committee.

Dr. Glenn Loury, PhD, is the Merton P. Stolz professor of the Social Sciences, a professor of economics, and professor of public policy at Brown University. He has held the position of professor at Boston University, Harvard's Kennedy School of Government, and the University of Michigan. Loury is an expert on group inequality, economics, and incarceration.

Dr. Angela Hawken, PhD, is Associate Professor of Economics and Policy Analysis at the School of Public Policy at Pepperdine University where she teaches graduate classes in applied research methods, statistics, crime, and social policy. Hawken led the statewide cost-benefit analysis of California's alternative sentencing initiative, Proposition 36. Hawken's research interests are focused on drugs, crime, and corruption. She was the first to introduce the *Behavioral Triage Model* for identifying, treating, and supervising drug-involved offenders. Most recently she co-authored (with Mark Kleiman and Jonathan Caulkins) *Drugs and Drug Policy: What Everyone Needs to Know*, and a second book in the series (co-authored with Jonathan Caulkins, Beau Kilmer, and Mark Kleiman) *Marijuana Legalization: What Everyone Needs to Know.* Hawken has delivered testimonies to many state legislatures and to the U.S. Congress on issues related to US drug policy.

Dr. Jonathan Kulick, PhD, is a senior project director at the School of Public Policy at Pepperdine University. He has co-authored a chapter on federal drug policy in reference book on addiction and drug abuse and co-authored white paper on counternarcotics policy.

Bob Jesse is currently a research strategist for John Hopkins University and has worked extensively on different practical approaches to drug policy. He has extensive experience with legal and policy writing.

16. **Approach and Methodology.** In two (2) pages or less, please provide a complete description of your firms' proposed approach and methodology to be used in assisting the WSLCB with developing rules and a regulation strategy for the state of Washington's new Marijuana System.

Policy choices are to be judged by their results. In advising the Board on developing a regulatory system for the newly legal marijuana market, we would propose to project the likely results of alternative choices and identify the trade-offs among the outcomes of interest so that the Board can make fully-informed choices.[1] Having identified the Board's preferred system, we would then work with the Board to embody that system in regulatory language.

The first step in developing a regulatory strategy is to list the evaluative dimensions of the problem: the aspects of the world that could become better or worse as a result of alternative choices. The preamble to the statute identifies several of these: economizing on law enforcement resources to allow them to be focused on violent and property crime, taking the cannabis business out of the hands of criminals, and producing revenue for the state. Other sections of the law point to public health and safety concerns: use by minors, maladaptive use, health care utilization, and auto accidents. The product-labeling provisions suggest a concern for consumer protection and satisfaction. The Board should also be concerned with controlling its administrative costs and avoiding challenges to appropriate use of authority.

This long list of objectives confronts the Board with a complex decision problem, because a given policy choice might improve one outcome dimension while worsening another.[2] For example, tighter regulations leading to higher prices might have the unwanted side-effect of moving some consumers away from regulated sales and toward the illicit market. Our goal would be to clarify the choices confronting the Board.

Having identified the outcome dimensions of interest, we would then identify the regulatory choices to be made, including the number of licenses to be issued at each level, the rules for testing and labeling products, restrictions on products and marketing, and the systems for monitoring compliance and sanctioning violations.

The next step would be to project, based on existing data and freshly-gathered information (e.g., from focus groups and user surveys—described in Category 2), the likely results of different combinations of regulatory choices in terms of the identified outcome dimensions, taking into account the incentives created for suppliers and consumers, including the incentives for violating the rules.

The result would be a menu of regulatory choices, with a projection of the outcomes of each choice and thus the identification of the tradeoffs among the valued outcome dimensions.
After the Board chooses its preferred set of options, we would then work with the staff to embody that choice in regulatory language and assist in the process of formally adopting the resulting regulations, as modified by public and industry feedback.

In creating the first draft of regulations, BOTEC proposes to review Title 16 of the Washington Administrative Code, especially WA ADC 16-695-005 (rules relating to ginseng) with an eye to fitting a marijuana section into the existing regulatory scheme for certification, inspections and quality control. This part of the regulations will create the licensed marijuana grows as anticipated in Part III, Section 4 of I-502: the producers that regulation and inspections will be needed to ensure food-grade safety measures in the use of fertilizers and pesticides, for example. We anticipate that the retailer's license referenced in the same section will be codified in Title 314 of the Washington Administrative Code, implementing and empowering the Washington state liquor control board.

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[1] Arguably, the proposed research team has more experience thinking about these tradeoffs for cannabis than anyone else the world (e.g., Kleiman, 1989; Kleiman, 1992; MacCoun, Reuter, & Schelling, 1996; MacCoun & Reuter, 2001; Kilmer, Caulkins, Pacula, MacCoun, & Reuter, 2010; Caulkins, Hawken, Kilmer, & Kleiman, 2012—bold indicates proposed team member).

[2] Many of these tradeoffs are highlighted in the seminal article on assessing alternative drug control regime which by two of our team members (Berkeley Law Professor Robert MacCoun and Nobel Laureate Tom Schelling).

Example: Product labeling. The issues surrounding product labeling can serve as an example of the analytic process we propose. Cannabis is a much more complex commodity than alcohol, with at least two important active agents (THC and CBD). (Other chemicals may also turn out to have significant impacts on the user experience.) THC is anxiety-inducing (and, in high doses, can even cause transient psychotic episodes); CBD may counteract both anxiety and psychosis.

Most of the high-potency (as measured by THC) marijuana that now dominates the market has only traces of CBD; ratios of 25:1 THC:CBD are not uncommon. But some strains run as low as 1:2. Under conditions of legal production, with extraction and re-blending, it wouldn't be technically hard to produce almost any desired ratio. Some users reportedly prefer lower-ratio, "mellower" product. Why the current high-price market is dominated by high-ratio material is obscure; it may be that users in the illicit market equate intoxicating power with quality, and biologically it appears that CBD production comes at the expense of THC production. It might also be that high-ratio cannabis is prized by the minority of heavy users who have become THC-tolerant, and that the new users brought in (or back in) to the cannabis market by legalization might prefer lower-ratio product, resulting (perhaps) in fewer emergency-department visits and a lower rate of problem use. If so, that could prove a substantial advantage of a legal marijuana market over the existing illegal market.

Accurate labeling alone might be expected to reduce the risk of adverse effects. In addition, the Board's powers to require testing and labeling might allow it to "nudge" the market toward the use of less hazardous forms of marijuana. (Or that goal might prove chimerical.)

Designing labels that convey the relevant information in a form the users can grasp will require careful analysis, informed by focus groups or other means of gathering consumer opinion. Presumably the labels should have the percentages of each relevant chemical (THC and CBD to start with, with the possibility of expanding the list as scientific knowledge of the effects of different chemicals grows.) But there are at least two ways of making that information more accessible to consumers unfamiliar with cannabinoid chemistry: which is to say, most users.

One option would be a letter-and-number system. For example, the THC content of the product (roughly speaking, its intoxicating power) might be represented by letters from A through F, with A representing the smallest concentration of THC and F the highest (to counteract the current market perception that high potency equals high quality). The ratio of THC to CBD could be represented by numbers from 1-6, with lower numbers reflecting higher ratios. Thus "A-1" material might, for example, reflect a THC content below 5% and a THC :CBD ratio of no more than 2:1, while "F-6" would mean more than 15% THC and a ratio of 15:1 or more.

In addition or instead, those two dimensions could be represented graphically by color-codes and cross-hatching, with bluer shades representing lower ratios and redder shades higher ratios and no cross-hatching representing low THC content and heavy cross-hatching reflecting high THC content. (A separate question would be whether to put an absolute cap on either THC content or THC:CBD ratio, at some risk of creating an illicit market for material with higher concentrations or ratios.)

Labeling edible or potable products poses additional complexity due to the presence in unheated cannabis of THC-acid – reportedly not intoxicating - rather than THC itself, and the difficulty of comparing the THC concentration of a food to be swallowed to that of the herbal product to be smoked or otherwise inhaled. While thinking through these complexities we will not lose sight of the fact that a simple statement on edible packaging stating:

1) The effect of this edible may take up to X minutes to arrive, and
2) Adults should not consume more than one edible every Y hours

could help reduce the number of overdoses and emergency room visits, especially among naïve consumers.

Similar analyses would inform our analysis of the number of producers, processors, and retailers to be licensed. Limiting the number of producers will tend to create "market power" and thus increase prices to consumers. Higher prices could help protect public health by reducing the prevalence of very heavy and chronic use and of use by juveniles (some of whom will be supplied by adults buying on the licit market). If producers have market power and

can therefore extract what economists call "oligopoly rents," they will tend to be more obedient to the Board's regulations because the threat of license suspension and revocation would represent more potential financial loss than would be the case if market competition drove prices down to where sellers were barely covering their costs. But on the other hand higher prices would also increase the incentives for tax evasion and illicit production, requiring greater enforcement effort to maintain any given level of compliance. If the Board decides to award fewer licenses than there are applicants, it will be necessary to devise a fair and transparent process for choosing among potential licensees.

Since there has never, anywhere in the modern world, been a fully licit commercial market in cannabis, the shape that market will take and the consequences in terms of health, safety, and illicit activity cannot be precisely known in advance. Whatever set of initial regulations the Board enacts can only reflect the best knowledge available, based on the current illicit market. Those policies might require revision in light of experience. In addition, even if the initial regulations were perfectly designed for the initial phase of a licit market, changes in the composition of the consumer population and in consumer knowledge and preferences might call for different regulations in the not-very-distant future. We would propose to help the Board design, not only the initial regulatory regime (including both the rules themselves and the monitoring and enforcement processes needed to ensure compliance with them) but also a monitoring system that would inform subsequent "course corrections."

COST PROPOSAL

The evaluation process is designed to award this procurement not necessarily to the Proposer of least cost, but rather to the Proposer whose proposal best meets the requirements of this RFP. However, Proposers are encouraged to submit proposals which are consistent with State government efforts to conserve state and federal resources.

Instructions to Proposer: Proposer shall complete either Table 1 **or** Table 2 below by entering their Not-to-Exceed (NTE) Hourly Rate **or** Not-to-Exceed Daily rate for Initiative 502 Consulting Services. For the purposes of this RFP, one day shall consist of a total of eight (8) hours.

Proposer is instructed to be familiar with the Initiative 502 language when preparing their response. A link to the I-502 document is located in Appendix B of the RFP for Proposer's convenience.

Table 1: Hourly Rate

Description	NTE Hourly Rate
Not-to-Exceed (NTE) **Hourly** Rate for I-502 Consulting Services as stated in this RFP	$ 292 p/hour *

Table 2: Daily Rate

Description	NTE Daily Rate
Not-to-Exceed (NTE) **Daily** Rate for I-502 Consulting Services as stated in this RFP	$ ____ p/day

* As currently calculated, these costs are for professional services only and do not include travel expenses, which will be billed without markup. Alternatively, if awarded the contract, we will work with the WSLCB to determine the best method for projecting expense costs.