NEIGHBORHOOD COALITION
NeighborhoodCoalitionSonomaCounty.com

January 10, 2026

By email

Administrator Lee Zeldin (Zeldin.Lee@epa.gov)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Petition to List Commercial Cannabis and Hemp Cultivation Operations under § 111(B)(1)(A) of the Clean Air Act (CAA); to Promulgate Standards of Performance under §§ 111(B)(1)(B) and 111(D) of the CAA; and Petition to List β-Myrcene as a Hazardous Air Pollutant under § 112 of the CAA

Dear Administrator Zeldin:

With the enclosed petitions, the Neighborhood Coalition hereby asks the U.S. Environmental Protection Agency to List Commercial Cannabis and Hemp Cultivation Operations under § 111(B)(1)(A) of the Clean Air Act (CAA); to Promulgate Standards of Performance under §§ 111(B)(1)(B) and 111(D) of the CAA; and Petition to List β-Myrcene as a Hazardous Air Pollutant under § 112 of the CAA.

We look forward to your attention and response to these petitions.

Sincerely yours,

Craig S. Harrison

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cc: Aaron Szabo, Assistant Administrator for Air and Radiation (Szabo.Aaron@epa.gov)
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BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

THE NEIGHBORHOOD COALITION,

***Petitioner*.**

v.

LEE ZELDIN, ADMINISTRATOR, U. S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

PETITION TO LIST COMMERCIAL CANNABIS AND HEMP CULTIVATION OPERATIONS UNDER § 111(B)(1)(A) OF THE CLEAN AIR ACT; TO PROMULGATE STANDARDS OF PERFORMANCE UNDER § 111(B)(1)(B) AND § 111(D) OF THE CLEAN AIR ACT; AND PETITION TO LIST β-MYRCENE AS A HAZARDOUS AIR POLLUTANT UNDER § 112 OF THE CLEAN AIR ACT

I. INTRODUCTION.

The Neighborhood Coalition hereby petitions the U.S. Environmental Protection Agency (EPA) to use its authority under Clean Air Act (CAA or the Act), § 111, 42 U.S.C. § 7411, (1) to list commercial cannabis and hemp cultivation operations (CCOs) as a category of sources under CAA § 111(b)(1)(A); (2) to promulgate standards of performance for new CCOs under CAA § 111(b)(1)(B); and (3) to prescribe regulations for State performance standards for existing CCOs under CAA § 111(d). The Neighborhood Coalition hereby simultaneously petitions EPA to use its authority under CAA § 112, 42 U.S.C. § 7412, to add β-Myrcene, a primary terpene in cannabis and hemp emissions, to the Hazardous Air Pollutant list. Both petitions are supported by the identical factual basis.

During recent decades, cannabis (also called marijuana) has become legal in 40 states for medical use and 24 states for recreational use.[1] The 2018 Farm bill legalized the cultivation of industrial hemp under federal law.[2] Industrial hemp is the identical plant as marijuana (genus *Cannibis*), except hemp by federal law is limited to 0.3% THC (Delta-9-Tetrahydrocannabinol) content. As a result of these developments, increasing numbers of commercial CCOs are being operated throughout this nation because of opportunities for the sale of cannabis, cannabis products, hemp, and hemp products. Cannabis and hemp products include those containing cannabinoids and/or terpenes. Some describe this phenomenon as a "Green Rush."

CCOs contribute significantly to anthropogenic emissions of terpenes, especially β-Myrcene,

[1] https://en.wikipedia.org/wiki/Legality_of_cannabis_by_U.S._jurisdiction (viewed Dec. 17, 2025).

[2] Establishment of a Domestic Hemp Production Program, 7 CFR Part 990.

which is toxic and carcinogenic to humans and animals.[3] The California Office of Environmental Health Hazard Assessment deemed β-Myrcene to be a carcinogen in 2015.[4] In addition to toxicity and carcinogenicity, inhalation of noxious cannabis emissions from cannabis cultivation can nausea, headaches, cough, eye irritation, and respiratory distress including asthma.[5] Despite these public health risks, EPA does not require CCOs to meet any testing, performance, or emission standards under the CAA. Given available evidence, much of it summarized in this petition, the EPA Administrator has reasonable cause to find, and should find immediately, that air emissions from CCOs cause and contribute significantly to air pollution that is reasonably anticipated to endanger public health and welfare. Because CCOs emit significant amounts of air pollutants which have been shown to have negative effects on human health and on welfare, the Administrator must promulgate nationwide standards of performance to minimize the impacts from new and existing CCOs and add β-Myrcene to the list of Hazardous Air Pollutants.

The Neighborhood Coalition has a vital interest in reducing unhealthy emissions of the pollutants from CCOs to improve human health. Listing CCOs under CAA §§ 111 and 112, and promulgating strong national air emissions performance standards for new and existing CCOs, will have an immediate positive impact on the Neighborhood Coalition's members and public health in many states. Promulgating new source performance standards and listing β-Myrcene as

[3] Neighborhood Coalition, Toxicities of Cannabis Volatile Emissions from Cultivation (Jan. 7, 2025) ("Cannabis Toxicities"), Exhibit 1.

[4] Office of Environmental Health Hazard Assessment. Mar. 24, 2015. Chemical Listed Effective March 27, 2015 as Known to the State of California to Cause Cancer: β-Myrcene.

[5] Cannabis Toxicities, Exhibit 1.

a Hazardous Air Pollutant will create a strong incentive for new CCOs to use methods that protect public health and welfare. It will enable government agencies and private citizens to enforce the applicable standards when owners or operators of CCOs violate those emissions limits. In addition, EPA must act immediately to prescribe regulations for states to set performance standards for existing CCOs.

The threat to public health and welfare caused by the air pollutants emitted by CCOs necessitates an immediate determination that CCOs cause or contribute significantly to the air pollution that endangers public health and welfare, the listing of CCOs, their regulation by EPA under CAA § 111, and the addition of β-Myrcene to the list of Hazardous Air Pollutants. The Administrator should list CCOs under § 111(b)(1)(A) as an industry requiring regulations under CAA §§ 111(b)(1)(B) and (d), that reflect the "degree of emission limitation achievable through the best system of emissions reduction that has been adequately demonstrated." 42 U.S.C. §§ 7411(a)(1), (b), (d).

Accordingly, for the reasons discussed below, as further detailed in the exhibits, the Neighborhood Coalition respectfully requests that EPA undertake rulemakings that:

- find that the emissions of terpenes from CCOs, including the toxin/carcinogen β-Myrcene, constitute air pollution that endangers U.S. public health or welfare;
- announce the Administrator's judgment that emissions of terpenes, including the toxin/carcinogen β-Myrcene, from CCOs contribute significantly to air pollution that is reasonably anticipated to endanger public health and welfare;
- list CCOs as a category of stationary sources pursuant to CAA § 111(b);
- promulgate for CCOs performance standards for air emissions of terpenes, including the toxin/carcinogen β-Myrcene, from new and existing CCOs pursuant to the authority of CAA §§ 111(b) and 111(d); and
- add β-Myrcene to the list of Hazardous Air Pollutants pursuant to CAA § 112(b)(3)(B).

II. INTERESTS OF THE PETITIONER.

The Neighborhood Coalition is a non-profit charitable organization based in Sonoma County, California. It advocates for sustainable, environmentally sound, and neighborhood-compatible cannabis policies in conjunction with education of the public on the health and safety impacts of cannabis use. Many of the Neighborhood Coalition's members have personal experience living near CCOs with the attendant health and welfare problems caused by unhealthy cannabis emissions. Its members are affected by the air pollution caused by CCOs. They have a strong personal interest in protecting their own health as well as the health of their families and neighbors. Dr. Deborah Eppstein, who holds a PhD in biochemistry,[6] is the primary scientific advisor to the Neighborhood Coalition. The Neighborhood Coalition files this petition both on its own behalf and on behalf of its members.

III. LEGAL BACKGROUND.

A. The Clean Air Act.

The CAA is the primary federal statute regulating air quality and air pollution. The CAA was enacted "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b)(1). EPA is the agency charged with implementing the Act's mission and is the national leader for the federal air programs and the delegating authority to state programs.

1. CAA Section 111: New Source Performance Standards.

In 1970, Congress amended the Act to include nationwide uniform emission standards for categories of stationary sources to complement national ambient air quality standards and prevent new pollution problems. 42 U.S.C. § 7411. Section 111 addresses air pollution problems

[6] CVs of Experts, Exhibit 2.

that endanger public health and welfare, and are common to an industry. Section 111 performance standards apply regardless of a region's ambient air quality and are triggered when a new source is constructed or an existing source undergoes a major modification. The Act requires the EPA Administrator to set and revise "a list of categories of stationary sources" that cause, or contribute significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare. 42 U.S.C. § 7411(b)(1)(A). Section 111 further requires the Administrator to set standards of performance for new sources in a listed category within one year of listing, 42 U.S.C. § 7411(b)(1)(B), and to prescribe regulations for existing sources in a listed category, 42 U.S.C. § 7411(d). Performance standards under § 111 are to "reflect … the degree of emission limitation achievable through the application of the best system of emissions reductions which (taking into account the cost of achieving such reduction and any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated." *Lignite Energy Council v. U.S. E.P.A.*, 198 F.3d 930, 932 (C.A.D.C., 1999); 42 U.S.C. § 7411(a)(1). This technology requirement is called "best demonstrated technology."

A stationary source is defined as "any building, structure, facility, or installation which emits or may emit an air pollutant." 42 U.S.C. § 7411(a)(3). In determining what meets the standard for listing for a category of sources in § 111, the Act defines several terms to guide decision making. An "air pollutant" is broadly defined as "any air pollution agent or combination of such agents, including any physical, chemical, biological…substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant…" 42 U.S.C. § 7602(g). To determine whether a particular air pollutant meets the endangerment standard required by § 111, the Administrator considers its effect on public health

and welfare. While the CAA does not define "public health," the legislative history defines the term broadly. *See American Lung Ass'n v. E.P.A.*, 134 F.3d 388, 388 (D.C. Cir. 1998). The Act states that all "language referring to effects on welfare includes, but is not limited to, effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants." 42 U.S.C. § 7602(h). This sweeping definition guides and supports the Administrator's ability to list and regulate new and existing CCOs under CAA § 111 as shown below.

2. CAA Section 112: Hazardous Air Pollutants.

In 1990, Congress amended the Act to require technology-based National Emission Standards for Hazardous Air Pollutants. 42 U.S.C. § 7412. The amended Act includes an initial list of 189 specific hazardous air pollutants to be regulated. 42 U.S.C. § 7412(b)(1). It provides that "any person may petition the Administrator to modify the list of hazardous air pollutants," and "such petition shall include a showing by the petitioner that there is adequate data on the health or environmental defects of the pollutant or other evidence adequate to support the petition." 42 U.S.C. § 7412(b)(3). "Within 18 months after receipt of a petition, the Administrator shall either grant or deny the petition by publishing a written explanation of the reasons for the Administrator's decision." *Id.* After a substance is added to the list of Hazardous Air Pollutants, the Administrator must promulgate applicable national emission standards for hazardous air pollutants pursuant to 42 U.S.C. § 7412(d).

IV. FACTUAL BACKGROUND.

There is no dispute that CCOs produce and emit gases into the ambient air from cannabis plants, both marijuana and hemp. Many of the gases emitted from CCOs have been incontrovertibly

linked to health and environmental harms. Notable among the effects of these gases are risks to human respiratory health.

Cannabis plants emit many volatile organic compounds (VOCs), including 140 different terpenes.[7] A terpene is a volatile, unsaturated hydrocarbon, and includes β-Myrcene and α-Linolenic acid; terpenes comprise a significant component of cannabis emissions. The characteristic "skunk" odor from cannabis plants is primarily due to volatile thiols, which tend to be created when α-Linolenic acid breaks down under ultraviolet rays of sunlight into methyl and butyl thiols.[8] In recent years terpene content in cannabis has been increasing. Cannabis plants have been selectively bred for high-terpene content because consumers prefer terpene-rich products, and commercial producers prefer them because of their consequent command of higher wholesale prices.[9] Commercial producers employing a combination of high-terpene-cultivars with various optimization and enhancement techniques can quintuple terpene content.[10] The strong smell emitted from cannabis cultivation is noxious to most people. All people have "sensitive receptors" to cannabis terpenes, whether babies, children, adults, or the elderly. Children are generally at greater risk of respiratory harm; their lungs are still developing and they are more susceptive to air pollutants.[11] People with conditions such as asthma or other respiratory diseases, or any illness whether acute or chronic, can be even more adversely affected. Residents living adjacent to cannabis cultivation sites who are exposed to noxious terpenes experience

[7] Yolo County 2019. Cannabis Land Use Ordinance EIR.

[8] *Id.*

[9] Terpene Belt Farms. 2025. How to Boost Cannabis Terpene Content for Production.

[10] *Id.*

[11] California Air Resources Board : Children and air pollution (viewed Dec. 17, 2025).

symptoms such as nausea, headaches, difficulty breathing, cough, eye irritation, and sore throat.[12] Some people develop asthma exacerbations or even new-onset asthma.[13] In Sonoma County, neighbors living adjacent to outdoor cultivation sites often cannot open windows or use their yards during the summer and fall due to the overpowering odor from CCOs.[14] Some residents require gas masks to be able to use their yards, as depicted in the New York Times.[15]

Exposure to the stench of cannabis increases electric consumption and raises utility bills because natural air conditioning by opening windows at night, common in California during summer and autumn, is impossible. In Santa Barbara County wine tourism has been negatively impacted when cannabis emissions have encroached on vineyards and tasting rooms.[16]

The marijuana industry claims that cannabis emissions are just another agricultural odor like ammonia and hydrogen sulfide that waft from manure. Some say that rural residents should

[12] *See* Cannabis Toxicities, p. 1, and accompanying citations, Exhibit 1.

[13] Weaver *et al.*, Fatal Occupational Asthma in Cannabis Production - Massachusetts, 2022. MMWR Morb Mortal Wkly Rep 2023 Nov 17;72(46):1257-1261 (2023); Pacheco *et al.*, Work-related asthma in the cannabis industry; findings from California, Massachusetts, Michigan and Washington. J. Occup Environ Med. June 3; 67 (10: 862-868 (2025)

[14] Northbay Biz. 2020. What's it Like to Live 100 feet from 15,000 Cannabis Plants?

[15] Fuller. 2018. 'Dead skunk' stench from marijuana farms outrages Californians. New York Times.

[16] Romano. 2020. In Santa Barbara Battle Between Cannabis and Wine, Grand Jury Reprimands County Supervisors. Wine Spectator.

either accept breathing cannabis emissions in their homes or move elsewhere. Cannabis emissions are not a mere nuisance; they are dangerous to human health. In 2015, California's Environmental Protection Agency's Office of Environmental Health Hazard Assessment listed β-Myrcene as a chemical known to cause cancer.[17] β-Myrcene can account for 50-70% of the volatile organic compounds in cannabis emissions. β-Myrcene is highly volatile and can travel 2 miles or more if downwind.[18] In contrast, emissions from poultry and cow manure consist of hydrogen sulfide, methane, and carbon dioxide. None are deemed to be carcinogens.

A. CCOs.

Most CCOs are not "agriculture" in the conventional sense of the word. Former U.S. Attorney McGregor Scott in Sacramento described commercial CCOs as "industrial agriculture."[19] Various chemicals and additives are used, often lacking local soils. The activity intensely uses water and fertilizers. Plants are manipulated and processed. Female plants are not exposed to pollen because this would inhibit the production of THC, cannabidiol (CBD), and terpenes, as well as result in seeds in the buds, lowering the commercial value. California excludes marijuana from State "right to farm" protections against being sued for nuisances. It defines marijuana cannabis as an "agricultural product," not an agricultural crop. Cal. Bus. and Prof. Code § 26067.

Outdoor cannabis plants in California are typically grown in "grow bags" or "geo pots" as depicted below, with highly amended soils, including chemical additives and soils that are often brought in from offsite. High humidity and dampness in many parts of coastal California

[17] Office of Environmental Health Hazard Assessment. 2015. Chemical Listed Effective March 27, 2015 as Known to the State of California to Cause Cancer: β-Myrcene.

[18] Cannabis Toxicities, p. 2, Exhibit 1.

[19] Thompson. 2018. Agents seize Northern California pot houses tied to Chinese.

facilitate molds that destroy cannabis plants. Accordingly, most “outdoor” grows are in hoop houses for much or all the growing season, as depicted below. Hoop houses are open to the ambient air. Even a one-acre outdoor CCO has a high level of activity that requires fifteen or more employees working daily, and larger operations have correspondingly more workers.

Indoor CCOs are common in many regions of this nation such as Colorado because weather precludes outdoor cultivation much of the year. Even in benign climates in Southern California, indoor CCOs are common in locations such as Carpentaria. They typically employ HVAC systems and dehumidifiers to maintain consistent temperatures, air circulation, and proper moisture levels to avoid mold and rot, and consequent cannabis loss. A filtration system can

control particles and odors in the growing area. Filters can prevent VOCs from encroaching nearby properties and subjecting neighbors to unhealthy cannabis emissions. Indoor commercial grow rooms rely on adjustable overhead grow lights. Notably, confirming the toxicity of the emissions from the plants, workers at indoor grows typically wear protective gear tantamount to

"moon suits" to protect them from the plants' toxic emissions. Marijuana grown under controlled indoor conditions is typically several times more valuable than cannabis grown outdoors.[20]

Because of health and other problems associated with outdoor CCOs, few people voluntarily live near one. A private survey of Sonoma County residents in 2018 found that 75% want to live at least 1/4 mile away; 62% want to be at least ½ mile away; and 52% at least one mile away. Only 19% were comfortable living adjacent to a CCO. These findings parallel the results of a poll taken by the Sonoma County Press Democrat.[21]

B. CCOs Emit Unhealthy and Hazardous Volatile Organic Compounds.

EPS defines VOCs as "any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in

[20] HdL. 2022. Fiscal Analysis of the Commercial Cannabis Cultivation Industry, pp. 17-18.

[21] Kovner. 2018. Press Democrat Poll finds sharp division in Sonoma County over cannabis cultivation.

atmospheric photochemical reactions. . . .” 40 C.F.R. § 51.100(s). Outdoor CCOs produce large amounts of unhealthy and hazardous VOC emissions,[22] especially terpenes such as β-Myrcene, that cause negative effects on people who work in a CCO.[23] As noted above, in recent decades cannabis plants have been bred and manipulated to maximize terpene content.[24] Neighbors living near outdoor CCOs are involuntarily exposed to unhealthy emissions containing β-Myrcene and other toxic substances. Large outdoor cannabis grows can blanket large areas with hazardous emissions and noxious odors that harm residents, food products, wine grapes, and tourism. Such problems occur in Santa Barbara County, California, where a certified class action nuisance suit against an outdoor CCO is scheduled for trial in 2026.[25]

Cannabis plants emit unhealthy and hazardous compounds especially during flowering and harvest.[26] Exposures are amplified when winds blow cannabis emissions toward residences, especially in locations such as valleys where thermal inversions can trap them. Cannabis emissions can travel far even without wind. As depicted in the map below, marijuana emissions from a one-acre outdoor CCO in autumn 2023 in Bennett Valley, Sonoma County, was detected

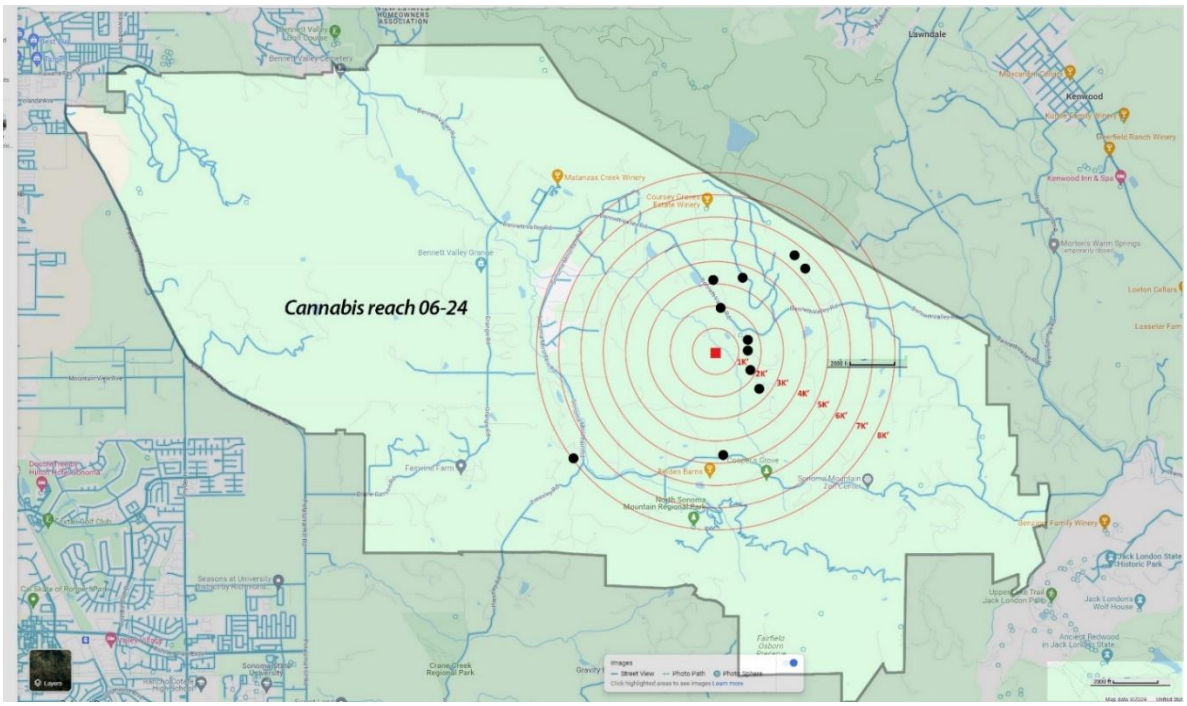
[22] Zheng *et al*. 2021. A narrative review on environmental impacts of cannabis cultivation. J. Cannabis Res (3), Article 35.

[23] Beckman *et al.* 2021 California cannabis cultivation and processing workers: A qualitative analysis of physiological exposures and health effects. Am J Ind Med Jan 66(1):75-84.

[24] Terpene Belt Farms. 2025. How to Boost Cannabis Terpene Content for Production; Get Canna Card. 2025. Terpene Rich Strains for Mood Balance: How Aromatic Compounds Shape Emotional Wellness.

[25] Burns. 2025. ‘Landmark’ Ruling Certifies a Class Action Against Valley Crest for ‘Nuisance Odor’ in Carpinteria Valley.

[26] Monticelli *et al.* 2025. Following the smell: terpene emission profiles through the cannabis life-cycle. Environ Sci Process Impacts. Jul 16;27(7):1823-1838.



up to 8,000 feet from a CCO (red square; each concentric circle is 1,000 feet). Residents of a home 2,500 feet from the CCO could not open their windows or use their yards for several weeks. Neighbors can be exposed to the hazardous odors for months at a time, 24 hours a day, seven days per week. Depending on the proximity to neighboring properties, wind direction, topography, climatic conditions, meteorology, and stage of plant growth, appropriate separation distances from outdoor grows can require thousands of feet or even two miles from a CCO.[27]

C. Hazardous Emissions from Cannabis Plants.

β-Myrcene, a dominant terpene in most varietals of cannabis,[28] is carcinogenic.[29] The cumulative

[27] Kern County. 2017. Cannabis Land Use Ordinance Project Draft Environmental Impact Report.

[28] Zheng *et al*. 2021. A narrative review on environmental impacts of cannabis cultivation. J. Cannabis Res (3), Article 35; FDA. 2018. FDA Removes 7 Synthetic Flavoring Substances from Food Additives List; Samburova *et al*. 2019. Dominant volatile organic compounds (VOCs) measured at four Cannabis growing facilities: Pilot study results. J Air Waste Manag Assoc. Nov; 69(11):1267-1276.

[29] Office of Environmental Health Hazard Assessment. 2015. Chemical Listed Effective March 27, 2015 as Known to the State of California to Cause Cancer: β-Myrcene.

levels of β-Myrcene and other terpenes inhaled by people living near outdoor CCOs, as discussed below, can be at levels that are projected to be toxic if not carcinogenic.[30] The risks are greater for children, the elderly, the infirm, and likely fetuses in utero. Cannabis emissions can cause immediate deleterious health effects such as nausea, headaches, cough, eye irritation, respiratory distress, and asthma.[31] β-Myrcene was the sensitizing agent in a hops-caused respiratory hypersensitivity and impaired driving-related skills.[32] β-Myrcene contributes to the formation of secondary pollutants, including formaldehyde and formic acid,[33] both of which cause eye irritation and nausea.[34] Formaldehyde, a carcinogen listed under California's Proposition 65, reacts with air to form ground-level ozone,[35] another known irritant.

1. Toxicity and Carcinogenicity Testing in Animals.

Toxicity testing in animals such as rodents is a normal first step before testing any new drug

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[30] Cannabis Toxicities, Exhibit 1.

[31] Beckman *et al*. 2021. California cannabis cultivation and processing workers: A qualitative analysis of physiological exposures and health effects. Am J Ind Med Jan 66(1):75-84; Natl Toxicol Program Tech Rep Ser 2010: Dec (557): 1-163 (2010); Beckman *et al.* 2023. A pilot study of respiratory and dermal symptoms in California cannabis cultivation workers. J Agromedicine Jan 28(1):28-35; Weaver *et al*. 2023. Fatal Occupational Asthma in Cannabis Production - Massachusetts, 2022. MMWR Morb Mortal Wkly Rep 2023 Nov 17;72(46):1257-1261; Sack *et al*. 2023. The Emerging Spectrum of Respiratory Diseases in the US Cannabis Industry. Semin Respir Crit Care Med. 2023 Jun; 44(3): 405–414; Strunk. 2020. Yes to cannabis! Just not in my backyard. An analysis of odor-based claims in the cannabis industry. American Bar Assn Brief 49:32-37.

[32] Cannabis Toxicities, Exhibit 1.

[33] Atkinson and Arey. 2003. Gas-phase tropospheric chemistry of biogenic volatile organic compounds: A review. Atmos. Environ.3, 37: 197-219.

[34] Delikhoon *et al*. 2018. Characteristics and health effects of formaldehyde and acetaldehyde in an urban area in Iran. Environ. Pollut. 242: 938-951.

[35] *Id*.; California Code of Regulations, Quantitative risk assessment, Title 27, § 25703.

candidate in humans. The National Toxicology Program (NTP) tested β-Myrcene for carcinogenicity due to its use as a flavoring food additive (albeit in very small amounts) and its similarity to D-Limonene, another terpene that NTP had previously tested.[36] The pharmaceutical industry and the Food and Drug Administration (FDA) understand that even a non-toxic dose in mice or rats may be toxic in humans, and clinical trials typically start at one-tenth of the non-toxic dose in animals. Compounds that are carcinogens in animal testing are often terminated from entering clinical trials for human pharmaceutical drug development. The NTP studies showed β-Myrcene caused kidney and liver toxicity in rodents after 70 days, and at two years caused cancer in mice and rats at the lowest dose tested by oral gavage.[37] Toxicity increased with duration of dosing from three weeks to two years, including liver and kidney toxicities, chronic inflammation, bone marrow and lymph node atrophy, and tissue necrosis. At the highest dose tested, all rodents died within a week. At the two-year point, liver and kidney cancers developed at the lowest dose. These results prompted California in 2015 to list β-Myrcene under Proposition 65 as a compound known to cause cancer.[38]

A sub-chronic (90-day) toxicity study was done with a different strain of rats with much lower doses in feed to assess safety for the food additive industry.[39] Because this study did not entail two years of dosing nor two animal species, it was not a carcinogenicity study. Nonetheless, the

[36] Natl Toxicol Program Tech Rep Ser, NTP Toxicology and Carcinogenesis Studies of D-Limonene (CAS No. 5989-27-5) in F344/N Rats and B6C3F1 Mice (Gavage Studies) Natl Toxicol Program Tech Rep Ser Jan:347:1-165 (1990).

[37] Natl Toxicol Program Tech Rep Ser 2010: Dec (557): 1-163.

[38] Office of Environmental Health Hazard Assessment. 2015. Chemical Listed Effective March 27, 2015 as Known to the State of California to Cause Cancer: β-Myrcene .

[39] Bastaki *et al.* 2018. Absence of renal adverse effects from B-myrcene dietary administration in OECD guideline-compliant subchronic toxicity study. Food and Chemical Toxicology 120: 222-229.

results "were indicative of the target organ toxicity pattern that at higher intake levels, such as those tested in the NTP studies, produces more severe toxicity and leads to associated neoplastic lesions."[40] The cannabis industry sometimes claims that β-Myrcene is harmless because it occurs naturally in certain foods such as carrots and hops. This claim is specious. Very small amounts of naturally-occurring compounds can be lethal, including castor beans (ricin), mushrooms such as *Amanita phalloides* (α-amanitin), and sprouted potatoes (glycoalkaloids). Some compounds that are vital for health or useful as medicines in small amounts are lethal at high concentrations. Examples include vitamin D, vitamin A, iron, warfarin, and sodium chloride. The concentrations of β-Myrcene in carrots and in beer made with hops are many orders of magnitude lower than what humans can be exposed to from cannabis plant emissions. A human would need to consume each day 300 pounds of carrots or drink 1,400 beers to equal the amount of β-Myrcene inhaled in one day at 100 parts per billion (ppb) β-Myrcene.[41] "The dose makes the toxin."

Inhalation of terpenes is potentially more threatening to human health than ingestion because inhaling increases bioavailability.[42] "Brain exposure of a molecule via the blood can be significantly lower than exposure resulting from direct brain exposure of the molecule by inhalation because of metabolism, distribution into other body organs/tissues, and difficulty in crossing the blood brain barrier."[43] Moreover, "exposure by inhalation may cause brain toxicities not seen in the rodent toxicity studies" because there are no toxicity studies on inhalation.[44]

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[40] *Id.*

[41] *See* Cannabis Toxicities p. 3, n.3, Exhibit 1.

[42] Letter from Dr. Srinivasan Venkatehwwara to Board of Supervisors (June 27, 2025), Exhibit 3.

[43] *Id.*, p. 2.

[44] *Id.*

2. Calculating Toxic Levels and Carcinogenicity of β-Myrcene.

Toxic levels in humans can be calculated using conversion from toxic levels in animal studies to equivalent human dosing levels, using well-accepted conversion factors employed by the pharmaceutical industry, toxicologists, and the FDA.[45] The calculations must account for the higher bioavailability of inhalation versus oral ingestion and predicted accumulation in humans.[46] **The calculated human-equivalent toxic doses of β-Myrcene reflect body weight and are 3.5 mg/day for a 15 kg person (*e.g.*, a 33 pound 3-year-old) and 14 mg/day for a 60 kg person (*e.g.*, a 132 pound adult)**.[47] These doses are the human-equivalent to the lowest dose tested in mice, which was highly carcinogenic after two years of exposure. Toxic effects on kidney and liver in rodents were observed within three months.[48]

Because β-Myrcene was carcinogenic at the lowest dose tested in rodents, no lower, non-toxic dose could be determined.[49] Thus, further dose reductions are needed to estimate toxic and safe exposure levels for chronic exposure. As noted above, it is standard to use a one-tenth reduction to estimate a lower "toxic" level. Using this and a 50% absorption of β-Myrcene from air **yields a calculated "safe" exposure level of 0.5 ppb for the child and 2 ppb for an adult.[50] "**Safe" exposure levels for

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[45] Cannabis Toxicities, p. 2, Exhibit 1; Nair and Jacob. 2016. A simple practice guide for dose conversion between animals and human. J basic Clin Pharm. Mar-May 2016; 7(2): 27-31.

[46] Cannabis Toxicities, Exhibit 1; Chayasirisobhon. 2020. Mechanisms of action and pharmacokinetics of cannabis. Perm J 2020; 25: 19.200; Ravula *et al.* 2019. Pharmacokinetic and Pharmacodynamic Characterization of Tetrahydrocannabinol-Induced Cannabinoid Dependence After Chronic Passive Cannabis Smoke Exposure in Rats. Cannabis Cannabinoid Res Dec 6;4(4):240–254.

[47] Cannabis Toxicities, Appendix, Part B, Table 2, Exhibit.

[48] Natl Toxicol Program Tech Rep Ser 2010: Dec (557): 1-163 (2010).

[49] *Id.*; Cannabis Toxicities, p. 5, Exhibit 1.

[50] *Id.*, pp. 4-5.

infants and developing fetuses logically might be much lower.[51] These illustrative calculations show that β-Myrcene can pose a serious health threat.

3. Estimating Safe Human Exposure Levels of β-Myrcene.

Another accepted approach for determining safe human exposure levels or Occupational Exposure Limit (OEL) of β-Myrcene in the air uses the formula OEL = POD/ (AF_c x a x S x MF x V).[52] Using the rat data, **this estimates a "safe" exposure level of 2.7 ppb for a child and 10.7 ppb for an adult.[53]**

4. Level of Exposures to Cannabis Emissions.

The threshold of human odor detection of cannabis emissions provides good information about the levels of cannabis emissions, including β-Myrcene, to which neighbors of CCOs are exposed. A study of human odor detection in Santa Barbara County found that when "terpene concentrations range between 20 and 50 ppb, greater than half of the participants report odors."[54] Thus, when residents of Kern County and Nevada County, California, reported detecting cannabis odors 1 and 2 miles away from cultivation sites the strong implication is that the levels of β-Myrcene were at least in the 20-50 ppb range.[55] Moreover, cannabis emissions can be

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[51] Letter from Dr. H. Alan Cohen (June 25, 2025), Exhibit 4. During pregnancy, inhaled cannabis emissions can cross the placenta. Zoorob *et al.* 2024 Exhibit. Cannabis use during pregnancy. Fam Pract Manag 31(4): 19-21; Feghali *et al.* 2015. Pharmacokinetics of drugs in pregnancy. Semin Perinatol 2015: Nov 39(7):512-519.

[52] Cannabis Toxicities, Exhibit 1; Sargent and Kirk. 1988. Establishing airborne exposure control limits in the pharmaceutical industry. Am Ind Hyg Assoc J. 1988 Jun; 49(6):309-13.

[53] Cannabis Toxicities, p. 13, Table 3, Exhibit 1.

[54] Letter from Dr. Mark L. Kram to Sonoma County Board of Supervisors (July 9, 2025), p. 2, Exhibit 5.

[55] *Id.*

analyzed with quantitative scientific methods in real time in the field using gas chromatography, which avoid human subjective determinations. Emissions measured 2,600 feet from a 4-acre grow were 440 ppb.[56] There is a critical need for additional site-specific empirical assessment with confirmation testing to allow regulatory agencies to set standards for unhealthy and hazardous cannabis emissions.[57] Concentrations of β-Myrcene are generally correlated to distances from a CCO and are generally higher when the affected site is downwind.

When humans detect cannabis odors, they are probably inhaling levels of β-Myrcene that exceed 20-50 ppb. When the odor is strong, β-Myrcene can be orders of magnitude higher than 20-50 ppb. Unregulated and unhealthy emissions from outdoor CCOs (or from indoor CCOs if emissions are not properly filtered) can reach several thousand ppb of β-Myrcene.[58]

5. Harm From Exposure to Toxic and Carcinogenic Cannabis Emissions.

Residents near outdoor CCOs can be involuntarily exposed to toxins and carcinogens in their homes when cannabis emissions enter through windows and doors. They can breathe toxins essentially continuously for months at a time, year after year. Anyone who smells cannabis emissions is inhaling at least 20 ppb of β-Myrcene, which would rapidly enter the bloodstream. The longer the exposure and the higher the concentrations, the greater the risk of toxicity and cancer. The amount of β-Myrcene inhaled during a single growing season may be toxic to the liver and kidneys and over several years can exceed the carcinogenic dose determined through controlled tests with animals**.**

[56] *Id.*, p. 8.

[57] *Id.*, p. 4.

[58] Dr. Kram measured over 2,000 ppb at a distance of 520 feet from a roof vent. *Id.*, p. 8.

Chronic exposure to a compound generally causes toxicity at much lower doses than observed for acute exposure.[59] At 100 ppb, children are exposed to toxic doses of β-Myrcene that can cause liver and kidney damage after only three months, and adults after 12 months.[60] Even at ambient levels of only 10 ppb, which is generally below the level of human odor detection, children are exposed to toxic doses after five years if the exposure to β-Myrcene is six months per year; it approaches the projected toxic levels for adults after 10 years.[61] Exposures can vary depending on the number of harvests per year, whether a particularly high-emitting cannabis varietal is cultivated, and site-specific geographic and weather conditions that may expose humans to even higher levels if they are located downwind of a CCO when plants flower.[62]

The cumulative levels of β-Myrcene that neighbors can be involuntarily exposed to is significant, may cause toxic effects, and ultimately may be carcinogenic.

Dr. George Rutherford, a distinguished Professor Emeritus at UC San Francisco, concluded that regulators should "seriously consider the toxic and carcinogenic effects of β-Myrcene to which residents are exposed involuntarily and act in a way to protect the public health."[63] Dr. Rutherford is a former State Epidemiologist and State Health Officer for California as well as professor emeritus of Epidemiology, Preventive Medicine, Pediatrics and History at UC San

[59] Hulla *et al.* 2014. Toxicity, Subchronic and Chronic, Encyclopedia of Toxicilogy, 3rd ed., pp. 626-633.

[60] Cannabis Toxicities, p. 5 and Table 4B, Exhibit 1. When the Safety Ratio of projected toxic dose to inhaled dose is less than 1, the inhaled dose is greater than the projected toxic dose; exposures even at a Safety Ratio of 10:1 (*i.e.*, absorbed inhaled dose is one-tenth of the toxic dose) can pose health risks.

[61] *Id.*, p. 5 and Table 4A.

[62] Letter from Dr. Mark L. Kram to Sonoma County Board of Supervisors (July 9, 2025), p. 2, Exhibit 5.

[63] Letter from Dr. George Rutherford to Sonoma County Board of Supervisors (Exhibit 6).

Francisco and adjunct professor in the School of Public Health at UC Berkeley, with over 300 peer-reviewed publications.[64] EPA should heed his advice and regulate emissions from CCOs.

V. DISCUSSION.

A. EPA Should Regulate CCOs Pursuant to CAA § 111.

Section 111 of the CAA requires the EPA Administrator to list a category of stationary sources if it "causes, or contributes significantly to air pollution which may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7411(b)(1)(A). This petition seeks the addition of CCOs to the list of sources subject to regulation under § 111 because they meet the endangerment standard. In listing CCOs, the Administrator must use his judgment to determine that the CCO source category satisfies a two-part test. First, the Administrator must determine that air pollution of the kind emitted by CCOs "may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7411(b)(1)(A). Second, the Administrator must determine that CCOs cause or contribute significantly to this air pollution. *Id.* It is clear from the facts presented above and the discussion below that CCOs are a stationary source category within the meaning of § 111, and that the air pollutants emitted by CCOs contribute significantly to air pollution problems that endanger public health and welfare.

The CAA does not require absolute scientific certainty or proof of actual harm when making an endangerment finding. *Massachusetts v. EPA*, 549 U.S. at 506 n.7. To the contrary, the Administrator must list CCOs and promulgate standards of performance if they "***may reasonably be anticipated***" to endanger public health or welfare. 42 U.S.C. § 7411(b)(1)(A) (emphasis added). The plain meaning of that phrase authorizes, if not requires, the Administrator to act to

[64] Expert CVs, Exhibit 2.

prevent harm and to act in conditions of uncertainty. The legislative history confirms that Congress wanted to "assure that regulatory action can effectively prevent harm before it occurs." *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1152, (D.C. Cir. 1980), citing H.R. Rep. No. 95-294 at 49 (1977).

1. **CCOs are "Stationary Sources" Within the Meaning of CAA § 111 and EPA Regulations.**

CAA § 111 defines a "stationary source" as "any building, structure, ***facility***, or installation which emits or may emit an air pollutant." 42 U.S.C § 7411(a)(3) (emphasis added). EPA's regulations under this provision use the term of art "facility" in the regulatory definition of concentrated animal feeding operations. 40 C.F.R. § 122.23 App. B ("an animal feeding operation where more than 1,000 'animal units' … are confined at the *facility…"* (emphasis added)). In this regard, CCOs are analogous to concentrated animal feeding operations. CCOs can have thousands if not tens of thousands of plants that emit harmful VOCs,[65] while concentrated animal feeding operations typically have more than a thousand animals that emit harmful air pollutants. CCOs clearly meet the definition of a stationary source because they are "facilities" that emit air pollution.

2. **CCOs Emit Harmful Air Pollutants Under the Clean Air Act.**

As set forth above, the emissions from CCOs constitute air pollution that endangers health and welfare. CAA § 111 is not limited to regulating criteria pollutants and their precursors; EPA has the authority to promulgate performance standards for pollutants "for which air quality standards have not been issued or which are not included on a list" under § 108(a) or § 112(b)(1)(A). 42 U.S.C. § 7411(d). The air pollutants emitted by CCOs meet the statutory definition of "air

[65] The number of plants per acre can vary widely. For example, Oregon State University's Extension Service recommends that hemp be spaced to grow about 1,500 plants per acre. Roseberg. 2020. What is the optimum spacing for hemp plants? EM 9618.

pollutant" under the Act. Specifically, CCOs emit certain VOCs (terpenes, including the toxin/carcinogen β-Myrcene) that endanger human health.

The CCO air emissions described above are air pollutants under the plain language of the CAA and the "ordinary, contemporary, common meaning" of the term because they are emitted into the ambient air. *Perrin v. U.S.*, 444 U.S. 37, 42 (1979), citing *Burns v. Alcala*, 420 U.S. 575, 580-581, (1975); *See Consumer Product Safety Commission v. GTE Sylvania*, *Inc*. 447 U.S. 102, 108 (1980) ("the starting point for interpreting a statute is the language of the statute itself"). The Act defines an "air pollutant" as an

> air pollution agent or combination of such agents, including any physical, chemical, biological…substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant…" 42 U.S.C. § 7602(g).

Courts have generally interpreted the definition of "air pollutant" broadly. *See Alabama Power Co. v. Costle*, 636 F.2d 323, 352 n. 60 (D.C. Cir. 1979); *Massachusetts v. EPA,* 549 U.S. 497, 528 (2007) (the definition of an "air pollutant" is "sweeping"). When Congress used expansive language in the CAA's definition of "air pollutant," it intended a broad grant of authority to EPA. *Massachusetts v. EPA*, 549 U.S. at 528. The Court also stated that "[o]n its face, the definition [of 'air pollutant'] embraces all airborne compounds of whatever stripe, and underscores that intent through the repeated use of the word 'any.'" *Id*. at 529.

The terpenes emitted by CCOs plainly meet the sweeping statutory definition of "air pollutant" under 42 U.S. Code § 7602(g). While neither EPA nor the courts have established a standard for determining a "significant contributor" to air pollution, the growing number of CCOs, the startling quantity of dangerous VOCs that CCOs can produce and inflict upon neighbors, and the severity of the air pollution problems associated with those emissions is strong evidence that

CCOs are "significant contributors" to air pollution. *National Asphalt Pavement Association v. Train*, 539 F.2d 775, 784 (D.C. Cir. 1976).

Odors and associated physical manifestations (*e.g.*, respiratory irritation, asthma, nausea, headache) constitute some of the major public complaints about outdoor CCOs and have been linked to the presence of significant levels of VOCs. VOCs are present with all types of cannabis production methods. Pursuant to the requirements of CAA § 111, CCOs must be listed as a category of sources because these air pollution problems endanger public health and welfare. 42 U.S.C. § 7411(b)(1)(A). Even if additional research linking negative health and environmental impacts with CCOs should be undertaken, the CAA does not require absolute scientific certainty or proof of actual harm when making an endangerment finding. *Massachusetts v. EPA*, 549 U.S. at 506 n.7. The Administrator must list CCOs and promulgate standards of performance if they "*may reasonably be anticipated*" to endanger public health or welfare (emphasis added). 42 U.S.C. § 7411(b)(1)(A). The plain meaning of that phrase authorizes, if not requires, the Administrator to act to prevent harm and to act in conditions of certainty. The legislative history behind that language supports the notion that Congress wanted to "assure that regulatory action can effectively prevent harm before it occurs." *See Lead Indus. Ass'n v. EPA*, 647 F.2d 1130, 1152, (D.C. Cir. 1980), citing H.R. Rep. No.95-294 at 49 (1977).

The Supreme Court found that EPA cannot refuse to regulate "by noting the uncertainty surrounding various features" of air pollution. *Massachusetts v. EPA*, 549 U.S. at 534. There is more than enough scientific evidence to meet the endangerment standard for unhealthy emissions from CCOs. Studies document instances of respiratory illness, lung inflammation, and increased vulnerability to respiratory diseases, such as asthma" among the effects CCO emissions can have

on human health.[66] The cannabis industry is aware that these problems can harm workers. As depicted elsewhere, it is common for workers within CCO facilities to wear full body protective gear and masks to avoid serious respiratory problems. Unfortunately, two cannabis workers have died from occupational asthma from exposure to unhealthy emissions from cannabis.[67]

Children and teenagers who attend school or have homes near CCOs may be at higher risk for asthma. Many jurisdictions require minimum setbacks from schools to protect children while ironically imposing lesser setbacks to their homes where they spend much more time.[68] In rural areas, children of economically-challenged farm workers are often the most affected population.

Evidence shows that CCOs, especially outdoor operations, pose a risk to human health and welfare. The VOC emissions from CCOs meets the endangerment standard as well. Regulating unhealthy VOC emissions will reduce risks to human health caused by CCOs.

3. The Administrator Must Exercise His Authority under CAA § 111 to List and Promulgate Performance Standards for CCOs.

Outdoor CCOs (and indoor CCOs that fail to employ adequate exhaust air cleansing systems) are

[66] Beckman *et al*. 2021. California cannabis cultivation and processing workers: A qualitative analysis of physiological exposures and health effects. Am J Ind Med Jan 66(1):75-84; Natl Toxicol Program Tech Rep Ser 2010: Dec (557): 1-163 (2010); Beckman *et al.* 2023. A pilot study of respiratory and dermal symptoms in California cannabis cultivation workers. J Agromedicine; Jan 28(1):28-35; Weaver *et al*. 2023. Fatal Occupational Asthma in Cannabis Production - Massachusetts, 2022. MMWR Morb Mortal Wkly Rep 2023 Nov 17;72(46):1257-1261; Sack *et al.* 2023. The Emerging Spectrum of Respiratory Diseases in the US Cannabis Industry. Semin Respir Crit Care Med. Jun; 44(3): 405–414 (2023); Strunk. Yes to cannabis! Just not in my backyard. An analysis of odor-based claims in the cannabis industry. American Bar Assn Brief 2020 49:32-37. California Dept of Public Health May 2024 Occupational Health Watch.

[67] Weaver *et al*. 2023. Fatal Occupational Asthma in Cannabis Production - Massachusetts, 2022. MMWR Morb Mortal Wkly Rep 2023 Nov 17;72(46):1257-1261; California Dept of Public Health May 2024 Occupational Health Watch.

[68] For example, the current Sonoma County Ordinance No. 6245 § 26-88-254(f)(6).

a public health threat to neighbors and others who involuntarily breathe toxins and carcinogens. CCOs contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare. 42 U.S.C. § 7411(b)(1)(A). CCOs meet the definition of a stationary source under the Act, and therefore are eligible for listing. *See* 42 U.S.C §§ 7411(a)(3), (b)(1)(A). The CAA is a precautionary statute and "demand[s] regulatory action to prevent harm, even if the regulator is less than certain that harm, is otherwise inevitable." *Ethyl Corp. v. EPA*, 541 F.2d 1, 25, (D.C. Cir. 1976). Section 111 was designed to "emphasize the precautionary or preventative purpose of the act (and, therefore, the Administrator's duty to assess risks rather than wait for proof of harm)."[69] Because of the serious consequences caused by unhealthy emissions from CCOs, the Administrator should take immediate action to regulate CCO emissions under § 111.

Once the Administrator finds that CCOs contribute significantly to air pollution that endangers public health or welfare, no discretion exists as to whether he must regulate such emissions from this industry under CAA § 111. *Nat'l Res. Def. Council, Inc. v. Train*, 411 F.Supp. 864, 868 (S.D.N.Y. 1976). Because of the large amounts of dangerous pollutants from CCOs, like other categories of stationary sources regulated under § 111, EPA must list them as a category of sources under § 111. "A long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently." *Transactive Corp. v. U.S.*, 91 F.3d 232, 237 (D.C. Cir. 1996); *see also Indep. Petroleum Ass'n of Amer. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) ("An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.").

[69] H.R. Rep. 294, 50-51 (1977) (amendments "emphasize the precautionary or preventive purpose of the act (and, therefore, the Administrator's duty to assess risks rather than wait for proof of actual harm)").

The Neighborhood Coalition requests that the Administrator list this industry under CAA §111, based on currently available scientific data demonstrating that unhealthy CCO emissions contribute significantly to air pollution. The Administrator also must issue new and existing CCO performance standards and consider issuing secondary standards to protect public welfare.

4. A National Approach Using CAA § 111 to Regulate Air Pollutant Emissions from CCOs Is Necessary and Feasible.

Under the existing regulatory approach, state and local authorities are doing little, if anything, to protect the public from CCO emissions. The CAA was enacted in part to address the concern that states can compete for economic development by having low environmental standards to attract mobile capital and businesses seeking lower compliance costs.[70] This phenomenon is sometimes called the "race to the bottom."

This may be occurring in California, which has an economic interest in fostering outdoor CCOs to produce affordable marijuana that can eventually be sold nationwide. California's Department of Cannabis Control has been aware of the problems with toxic cannabis emissions for years, but has done nothing to address this problem. For example, the Department of Cannabis Control in December 2025 awarded $30 million in cannabis research grants, none of which even study toxic cannabis emissions.[71] Currently California residents must invoke nuisance laws to try to protect themselves from CCOs. A class action nuisance case in Santa Barbara County is scheduled for trial in 2026.[72] Neighbors filed suit in Petaluma to enjoin a CCO that caused significant breathing

[70] Schmalensee and Stavins. 2019. Policy Evolution under the Clean Air Act, p. 28. J. Economic Perspectives 33:27-50.

[71] Department of Cannabis Control, Cannabis Academic Research Grants. California has awarded $80 million for public health, environmental, criminal justice, and research initiatives since 2020; none address this issue.

[72] Burns. 2025. 'Landmark' Ruling Certifies a Class Action Against Valley Crest for 'Nuisance Odor' in Carpinteria Valley.

problems for neighbors, including a young paraplegic who needed a breathing tube to avoid suffocation.[73] The purpose of the CAA is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare . . . ." 42 U.S.C. § 7401(b). EPA should set nationwide minimum emissions standards under CAA § 111 to protect individuals and communities. Neighbors should not have to pay for expensive nuisance suits to protect themselves from commercial operations that spew toxic and carcinogenic emissions. The vast majority cannot afford the legal fees.

A national approach is especially needed now because marijuana has recently become legal in most states.[74] Hemp has been widely cultivated to produce CBD since Congress legalized industrial hemp in 2018. The Drug Enforcement Administration will soon reschedule marijuana under the Controlled Substances Act,[75] encouraging even more CCOs. Setting national performance standards will address risks to public health and welfare by setting minimum emissions limits at levels that ensure safety and promote the public health and welfare. County, city, and state authorities cannot be trusted to protect public health and welfare. They often stymy such protections to foster economic development or to enrich the families of public officials or their donors.

Setting CAA § 111 performance standards can reduce emissions from CCOs. Relevant technologies include design, equipment, work practice, and operational standards. 42 U.S.C. §

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[73] Johnson. 2018. Neighbors file federal lawsuit to shut down Sonoma County cannabis grower.

[74] https://en.wikipedia.org/wiki/Legality_of_cannabis_by_U.S._jurisdiction (viewed Dec. 17, 2025).

[75] 89 Fed. Reg. 44597 (May 21, 2024). President Trump's Executive Order Increasing Medical Marijuana and Cannabidiol Research (Dec. 18, 2025) will expedite rescheduling which may be completed during 2026.

7411(h)(1). Pollution reduction can be achieved through a variety of means and is not limited to end-of-pipe controls. Simple work practice changes might significantly reduce unhealthy emissions from CCOs. For example, requiring minimum distances of CCOs from residences and businesses and requiring site-specific air quality studies to establish setbacks would reduce exposures.

If work practices fail to prevent exposures to unhealthy emissions, EPA could ban outdoor CCOs altogether. Marijuana could be required to be grown indoors or in greenhouses where facilities could be required to install and operate well-maintained filtration systems. Demonstrated technology can capture and reduce unhealthy emissions by 95% or more to prevent terpenes from exiting a structure. Such systems can include spraying fog or mists with chemicals into the air to destroy terpenes, along with charcoal or high efficiency particulate and VOC filtration devices. Continuous emission monitors to measure terpenes are available, analogous to what EPA has required for electric steam generating units for 40 years. Indoor CCOs must have mandatory maintenance criteria and enforceable shutdowns if they fail to achieve the performance standards.

Best demonstrated technology is continually being updated, and current technology and work practices are sufficient to set standards. Courts have routinely agreed that "adequately demonstrated" does not mean that the facilities must already be capable of achieving standards. CAA § 111 "looks toward what may fairly be projected for the regulated future, rather than the state of the art at present…" *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 391 (D.C. Cir. 1973). The technologies and work practices discussed above can provide significant reductions in unhealthy CCO emissions while new technologies are being developed.

B. **EPA Should List β-Myrcene as a Hazardous Pollutant Under CAA § 112.**

For similar reasons as those for regulating CCOs under CAA § 111, the Administrator should add β-Myrcene to the Hazardous Air Pollutant list under CAA § 112. The Neighborhood Coalition is confident that the information contained in this petition demonstrates that that there are ample data showing "adverse effects to human health," CAA § 112(b)(3)(B), resulting from exposure to β-Myrcene. Animal data have shown liver and kidney toxicity and clear evidence of carcinogenicity. The potential exposure of the general public and sensitive subpopulations to unregulated emissions from CCOs is adequate to support the listing of β-Myrcene as a Hazardous Air Pollutant under CAA § 112(b)(3)(B).

VI. CONCLUSION.

Mitigating the cannabis industry's significant yet underappreciated role in air pollution problems is vital for the health and sustainability of the communities where they operate. The negative impacts from unhealthy outdoor CCO emissions are already occurring and will only worsen as more marijuana and hemp are grown. Scientific consensus supports immediate listing of CCOs, the issuance of new source performance standards for the industry, and the listing of β-Myrcene as a Hazardous Air Pollutant. Based on the information contained in these petitions, the Administrator should determine that CCOs and β-Myrcene contribute significantly to air pollution that endangers public health and welfare.

For all these reasons, EPA should (1) list CCOs under CAA § 111; (2) promulgate standards for new, modified, and existing CCOs under CAA § 111; and (3) list β-Myrcene as a hazardous air pollutant under CAA § 112.

Respectfully Submitted,

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January 10, 2026

Exhibit 1. Neighborhood Coalition, Toxicities of Cannabis Volatile Emissions from Cultivation (Jan. 7, 2025).

Exhibit 2. CVs of Experts.

Exhibit 3. Letter from Dr. Srinivasan Venkatehwwara to Sonoma County Board of Supervisors (June 27, 2025).

Exhibit 4. Letter from Dr. H. Alan Cohen to Sonoma County Board of Supervisors (June 25, 2025).

Exhibit 5. Letter from Dr. Mark L. Kram to Sonoma County Board of Supervisors (July 9, 2025).

Exhibit 6. Letter from Dr. George W. Rutherford to Sonoma County Board of Supervisors (November 6, 2024).

Exhibit 1

NEIGHBORHOOD COALITION

NeighborhoodCoalitionSonomaCounty.com

January 8, 2026

Toxicities of Cannabis Volatile Emissions from Cultivation

Respiratory Irritation

Toxic and Carcinogenic Levels of ß-Myrcene

(Updated from October 18, 2024 Report)

SUMMARY

Volatile emissions released from cannabis plants during cultivation are known to cause respiratory harm, including irritation of the lower and upper respiratory track. Up to 70% of workers at indoor facilities without proper protection reported respiratory irritation, half with asthma, which can be serious, even fatal. Residents, customers and workers near outdoor cultivation fields breathe these same volatile cannabis emissions and have also experienced respiratory illness. Workers, often performing strenuous activities, on or near outdoor cultivation fields have increased exposure due to increased respiratory rates. Although workers are exposed 40-60 hr/week, residents are exposed to high emission levels continuously during flowering and harvest, often 6 months/year with two growth cycles.

Furthermore, one of the dominant volatile compounds released during cultivation, the terpene ß-Myrcene, is a potent carcinogen listed on California's Proposition 65, in addition to its irritant properties. Scientific analyses confirm that people living or working near cannabis fields are exposed to high levels of ß-Myrcene, in the range that caused toxicities and ultimately cancer in laboratory animals. Children are particularly vulnerable, as they are more susceptible to all air pollutants.

Analyzing odors can be achieved with quantitative scientific methods in real time in the field (e.g., gas chromatography), thus avoiding subjective and varying determinations by human nasal receptors. Multiple studies have defined that necessary mitigation is to attenuate odors by long separation distances. Thus, **policy makers have the tools necessary to require mitigations to protect public health: either sufficiently long setbacks to prevent terpenes from leaving the cultivation parcel or only allowing indoor/greenhouse cultivation with appropriate filters, both in conjunction with quantitative terpene monitoring.**

I. TOXICITIES OF CANNABIS EMISSIONS DURING CULTIVATION

The Neighborhood Coalition[1] has confirmed that published literature shows that inhalation of cannabis emissions causes respiratory harm [1-8,41] including asthma which can lead to deaths. Children are at greater risk of respiratory harm as they are more susceptive to air pollutants [45].

People often find odors from cannabis cultivation objectionable. These emissions are not mere annoyances. They have resulted in immediate deleterious effects (including in cannabis workers) encompassing nausea, headaches, cough, eye irritation, respiratory distress and asthma, including two deaths from asthma [2-7, 17, 41]. Up to 70% of cannabis workers reported respiratory irritation with half of those reporting asthma [4]. Neighbors are exposed to these same cannabis emissions but are exposed 24/7 (168 hr/wk), thus 4 times the exposure time as workers who are only exposed 40 hr/wk. In addition, workers on adjacent agricultural lands are exposed for 40-60 hr/wk.

ß-Myrcene is also contained in Hops used in beer manufacture; it was found to be the sensitizing agent in a brewery inspector employee with respiratory hypersensitivity [8].

Real-life experience confirms that exposure to even low levels of cannabis cultivation odor causes physical illness (nausea, respiratory irritation, headache, aggravation of asthma) and prevents residents from using their yards or opening their windows. In addition to the confirmed toxicities of cannabis cultivation emissions, a dominant component in cannabis emissions, ß-Myrcene, inhaled by people living near outdoor cannabis cultivation sites can reach amounts that may be toxic and carcinogenic [3]. The risks are likely even greater for children and fetuses in utero.

ß-Myrcene is listed under Proposition 65 as a cancer-causing compound [9][2] and also showed toxic effects in rodents on liver and kidney after only 3 months [3]. Neighbors living and working near an outdoor cannabis cultivation operation are involuntarily exposed to cannabis emissions that contain this toxin and carcinogen. ß-Myrcene also contributes to formation of secondary toxic pollutants in the air including formaldehyde [10], also a carcinogen listed on Proposition 65, and formic acid, both of which cause eye irritation and nausea [11]. It also leads to formation of ground-level ozone [12, 37], also a known irritant.

Volatile cannabis emissions are greatest during flowering and harvest [13, 37]. Often cannabis harvest occurs at the same time as harvest on adjacent parcels, increasing exposure; inhalation of these emissions by farm workers also increases their health risks. Exposures are amplified when winds are

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[1] The Neighborhood Coalition advocates for sustainable, environmentally sound, and neighborhood-compatible cannabis policies in conjunction with education of the public on the health and safety impacts of cannabis use. Our lead researcher, Dr. Deborah Eppstein, consulted with experts in the pharmaceutical, cannabis analytical chemistry, drug delivery, pulmonary and public health fields, including two former Public Health Officers for California.

[2] As OEHHA wrote in its response to comments concerning listing of ß-Myrcene under Proposition 65 [36] and as per CCR Title 27, § 25703 [38] "Human cancer potency shall be derived from data on human or animal cancer potency."

blowing toward workers or residences. Anyone who smells cannabis is being exposed to ß-Myrcene by inhalation, which is a direct and rapid route for small lipophilic compounds to enter the bloodstream [14] as well as to cross the blood-brain barrier entering the brain [50, 51].

The longer the exposure and the higher the concentrations, the greater the toxicity and cancer risk to individuals. The amount of ß-Myrcene inhaled in a single season may cause liver or kidney toxicity and over several years can exceed the carcinogenic dose determined through controlled tests with animals [3]. Children are subject to greater risk due to higher exposure per body weight, increased respiratory rate, and their developing lungs and more rapidly dividing cells as they grow. During pregnancy, terpenes inhaled in cannabis emissions can cross the placenta [15, 53] and the developing fetus may be exposed to significantly greater amounts of ß-Myrcene than the mother on a relative body-weight basis.

Cannabis emission and terpenes have been shown to travel over 3000 ft in the absence of wind [16] and up to 2 miles ([42] including data from Kern County Cannabis EIR and Kram report]). Air dispersion models show very high odor levels from a 1-acre grow [Figure 3-1 in ref 42, including data from Yolo County Cannabis EIR]: at 100 ft, 30 Odor Units (~600-1500 parts per billion (ppb) ß-Myrcene [21]); at 1000 ft, 5 Odor Units (~100-250 ppb ß-Myrcene), and even at 2500 ft, 2.5 Odor Units (~50-125 ppb ß-Myrcene). This projection is for flat topography with no wind or air inversions. Depending on the proximity to the neighboring properties, size of the cultivation field, wind direction, local topography, and prevailing climatic conditions, appropriate separation distances for neighbors, farmworkers and businesses (e.g., winery tasting rooms) from outdoor cannabis fields can require thousands of feet from the cannabis operation. This problem is compounded when multiple grows are in close proximity.

Analyzing odors can be achieved with quantitative scientific methods in real time in the field (e.g., gas chromatography) [21], thus avoiding subjective and often varying determinations by human nasal receptors. Toxic/safe limits can be set using conversion from toxic levels in animal studies to equivalent human dosing levels, using methodology employed by pharmaceutical industry, toxicologists, and FDA (Appendix; [33], [Appendix C in ref 42]).

II. TOXICITY OF ß-MYRCENE

A. Animal Toxicity Testing

Toxicity testing in rodents is a normal first step before testing a new drug candidate in people. The National Toxicology Program (NTP) decided to test ß-Myrcene in animal carcinogenicity models due to its use as a flavoring food additive (albeit in very small amounts) and its structural similarity to D-limonene, another terpene that NTP had previously tested [35].

The NTP studies of ß-Myrcene showed toxicity and clear evidence of carcinogenicity in animal testing: it caused toxicity (kidney and liver) in rodents by oral gavage after 3 months and at 2 years caused liver and kidney cancers in mice and rats, respectively, at the lowest dose tested [3]. Toxicity increased in the animal studies with duration of dosing from 3 weeks to 2 years, including liver and

kidney toxicities, chronic inflammation, bone marrow and lymph node atrophy, and tissue necrosis. At the highest dose tested, all animals died within a week. At the 2-year point, liver and kidney cancers were present at the lowest dose.

A subchronic (90 day) toxicity study was done in a different strain of rats with much lower doses (in feed) to assess safety for the food additive industry [48]. Although this study was not a carcinogenicity study as that requires 2-years of dosing in two species, it is relevant that the authors also concluded the results "were indicative of target organ toxicity pattern that at higher intake levels, such as those tested in the NTP studies, produces more severe toxicity and leads to associated neoplastic lesions." The amounts of ß-Myrcene used in food additives are orders-of-magnitude lower than those neighbors are exposed to from breathing cannabis emissions (Appendix). Other effects of ß-Myrcene in animal testing include developmental [46] and reproductive toxicities [47] in rats at slightly higher doses, and sedative-hypnotic activity in mice [54].

All the animal toxicity studies were done with ß-Myrcene dosed orally. As detailed in the Appendix (p11), oral dosing results in ~3-5 times lower uptake than by inhalation [34]. Thus, due to this greater update by inhalation, equivalent toxic levels by inhalation are reached at 3-5 times lower calculated levels as compared to oral dosing (i.e., to expose the body to the same toxic amount).

Toxicity/safety studies in humans with isolated ß-Myrcene have not occurred. Thus, one must rely on animal safety/toxicity data to project safety for humans. Separate from carcinogenicity, liver and kidney toxicity concerns based on animal testing, we found two publications on effects of ß-Mrycene in people, one on cognitive impairment and one on sensitization, both of which are relevant to human safety concerns:

1) As high ß-Myrcene levels in cannabis have been associated with sedation [22], a pilot study was conducted in human volunteers tested with a driving simulator [55]. Ingestion of isolated ß-Myrcene in people showed significant impairment of driving-related skills (double-blind, placebo-controlled crossover study).

2) ß-Myrcene was determined to be the sensitizing agent in respiratory hypersensitivity in a brewery inspector [8].

Furthermore, inhalation provides a direct route to the brain via the olfactory pathway [50, 51], resulting in much higher drug levels in the brain than from oral delivery. No animal toxicity/safety studies have been conducted using the inhalation delivery route for ß-Myrcene; unknown brain toxicities may exist.

In 2015,California listed ß-Myrcene under Proposition 65 as a compound known to cause cancer, concluding that the cancers formed were relevant to human toxicity [9]. Additionally, the Food and Drug Administration (FDA) removed ß-Myrcene from its list of approved food additives in 2018 [19].[3] More recently, we and others have raised additional safety concerns from ß-Myrcene from

[3] FDA wrote that as the dose of ß-Myrcene typically used as a food additive is very low, it did not think it posed a public health risk as a food additive under those conditions of intended use. Nevertheless, because it is a proven carcinogen the agency delisted it. Some cannabis and ß-Myrcene proponents argue that because ß-Myrcene occurs naturally in certain foods, it is non-toxic. This is an incorrect assumption; natural occurrence

cannabis cultivation as ß-Myrcene is a terpene present in cultivation emissions from all varietals of cannabis, often as the dominant terpene [1, 18, 40]. ß-Myrcene is also known to be a skin and eye irritant [49].

Our research team employed two accepted methods to project "toxic" and "safe" exposure levels of ß-Myrcene for people living or working near outdoor cannabis cultivation sites, based on animal toxicity and carcinogenicity data. These are detailed in the Appendix and summarized below.

B. Calculating Projected Toxic and Safe Levels of ß-Myrcene

Method 1 (Appendix Part B):

Using well-accepted factors employed by the pharmaceutical industry to convert rodent dosing to human dosing [33], plus accounting for higher bioavailability of inhalation versus oral ingestion of cannabis compounds [34] and predicted accumulation in humans [34, 43], the calculated human-equivalent toxic dose of ß-Myrcene is reached at only 3.5 mg/day for a 15 kg person (e.g., a 33 pound 3-year-old) and at 14 mg/day for a 60 kg person (e.g., a 132 pound adult) (Appendix, Table 2). These doses were calculated as the human-equivalent to the lowest dose tested in mice, which was deemed highly carcinogenic after 2 years of exposure. Toxic effects on kidney and liver were also observed in the 3-month rodent study [3].

ß-Myrcene was carcinogenic at the lowest dose tested in the animal carcinogenicity study; no lower, non-toxic dose was determined [3; footnote 4]. Thus, one must factor in further dose reduction to estimate toxic and safe exposure levels for chronic exposure. The pharmaceutic industry and the FDA understand that even a non-toxic dose in mice or rats may be toxic in humans, and clinical trials typically start at 1/10th or less of the equivalent non-toxic dose in animals. Since no non-toxic dose was determined in the carcinogenicity study, we used 1/10 reduction to estimate a lower "toxic" level of 0.35 mg/day for a small child and 1.4 mg/day for an adult, which at 50% absorption of ß-Myrcene from air gives a projected **toxic chronic exposure** at **~5 ppb for a small child**, and **~20 ppb for an adult**. If another 1/10 factor is then used as an estimate of a "safe" level (thus 1/100 of lowest toxic dose tested), this predicts a **"safe"** exposure level of **0.5 ppb for the child and 2 ppb for the adult**.

Method 2 (Appendix Part B)

Another accepted approach for determining safe chronic human exposure levels calculates

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does not equate with safety. Many toxic compounds occur naturally, including in tobacco, sprouted potatoes, many mushroom species, kidney beans, castor beans, and some fish as well as cannabis. Many compounds with significant cellular toxicity occur naturally in plants, hence their use to treat cancer. Likewise, many foods and beverages people choose to consume are known to cause health issues including cardiovascular disease and cancer (e.g., animal fats, red meat, bacon, excess sugar, alcohol), but people consume these by choice. ß-Myrcene also is present in low levels in some foods (e.g., carrots) and beverages (e.g., beer made from hops) [22, supplement Table 2 for levels], but the levels ingested by humans are orders-of-magnitude lower than the grams inhaled from chronic exposure to cannabis odors. For example, even ignoring the much lower absorption by ingestion vs inhalation, one would need to consume 135,000 g carrots (297 pounds) or drink 1400 beers each day to equal the amount of ß-Myrcene inhaled in one day at 100 ppb ß-Myrcene [Appendix, A, p 10-11]. As the human exposure is chronic, that same 297 pounds of carrots or 1400 beers would need to be consumed each day, chronically.

Occupational Exposure Limit (OEL) of ß-Myrcene in the air using the formula OEL = POD/ (AF_c x a x S x MF x V) [42, 44]. Using the rat data, this projects a "**safe"** exposure level of **ß-Myrcene** in the air of **2.7 ppb for the child** and **10.7 ppb for the adult** (Appendix, Table 3).

III. DISCUSSION

Harm to Residents, Workers and Vulnerability of Children

People living or working near outdoor cannabis cultivation operations are involuntarily exposed to cannabis emissions including ß-Myrcene on agricultural parcels, in their yards as well as in their homes when vapors enter through windows and doors. They breathe it in 24/7, often for 3-6 months a year. Exposures can continue year after year. Chronic exposure [20] to a compound generally causes toxicity at much lower doses than observed for acute exposure. The quantity of ß-Myrcene inhaled by neighbors (which is similar for children and adults) can be calculated (Appendix Part A, Table 1) and compared to the projected toxic levels (Appendix Part B, Tables 2 and 4). As shown in Table 4B, at **100 ppb, projected toxic doses are reached for children after only 3 months exposure**, and for adults after 12 months exposure. Even at ambient levels of only 10 ppb, which is below the level of odor detection for most people [21], the amount of ß-Myrcene absorbed in 6 months per year over a 5-year period is at the projected toxic dose for children (Appendix, Table 4A) and approaches the projected toxic levels for adults by 10 years. **For outdoor cultivation sites with two harvests per year, cumulative exposure of 60 grams ß-Myrcene occurs after 10 years at 1000 ppb, which is 50 times the projected toxic dose for adults (Safety Margin 0.02), and 200 times the projected toxic dose for children (Safety Margin 0.005), respectively (Table 4C).**

Safety Margin is Toxic Dose divided by Inhaled Dose. When the Safety Margin of projected toxic dose to inhaled dose is less than 1, this means that the inhaled dose is greater than projected toxic dose; exposures even at a Safety Margin of 10:1 (i.e., inhaled dose is one-tenth of the toxic dose) can pose health risks.[4] Note that this risk is in addition to the known respiratory toxicities that occur from breathing cannabis emissions (ß-Myrcene, which is a known irritant, may be one of the compounds causing this irritation.) If exposures are even higher (e.g., due to proximity, meteorological conditions, grow area and/or several large nearby cultivation areas), the amount inhaled can reach hundreds of grams after several years.

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[4] Safety Margin and Therapeutic Index. Therapeutic Index (TI), the ratio of the toxic dose to the effective dose [23], is often well over 100 for pharmaceutical drugs, indicative of a good risk/benefit profile. It is lower for some drugs, such as morphine with a TI of 70. Drugs with lower TI often require extensive monitoring of drug levels. Risk-benefit is taken into account for drugs with lower TI. For ß-Myrcene, there is no therapeutic benefit, only risk, and we thus calculated a "**Safety Margin**" (the ratio of calculated toxic dose of ß-Myrcene over the inhaled amount absorbed); this Safety Margin is extremely low (thus toxic) by pharmaceutical safety standards, and exposure even at 100 ppb shows that the inhaled dose approaches or exceeds the calculated toxic dose after 3 or 12 months exposure (child and adult; Appendix Table 4B). As the lowest level of toxic dose was not determined in animal studies, we also performed the analysis at 1/10 the lowest dose tested. Results at that level showed likely toxicity even over 3 months of inhalation by a child at ambient levels of only 10 ppb (Tabler 4A).

These calculations show that based on ambient levels of ß-Myrcene near outdoor cannabis cultivation sites [21; 42 Fig 3-1, 1 Odor Unit = 20-50 ppb; thus for a 1 acre grow, ave is ~1050 ppb at 100 ft, ~175 ppb at 1000 ft, and ~82 ppb at 2500 ft, with higher ppb levels for larger grows], the total amount of ß-Myrcene that neighbors are involuntarily exposed to is significant (Table 1), may cause toxic effects and ultimately be carcinogenic, with even greater risk for children (Table 4) as well as infants and fetuses in utero.

Furthermore, unlike pharmaceutical drugs that take into account risk-benefit, there is **absolutely no therapeutic benefit** for neighbors or workers **from inhaling ß-Myrcene, only risk**. To put this in context, the lower limit of terpene concentration where more than 50 percent of volunteers reported odor detection is between ~20-50 ppb [21, 42 Kram report]. Levels when the odor is strong or close to cultivation fields can be orders of magnitude higher. Uncontrolled emissions from an outdoor cannabis cultivation site (or from an indoor facility if the odors are not properly filtered) can reach hundreds to thousands ppb ß-Myrcene. Exposure levels can be even higher at locations downwind of a cannabis site when flowering plants are mature. Odor masking or neutralizing agents are not effective for outdoor cannabis fields.[5]

Risk is higher for infants and children due to multiple factors including their lower weight, higher respiratory rates, immature and developing lungs, and greater physical activity as well as the fact that their cells are more rapidly dividing as they are growing. Since children are smaller than adults, the dose of ß-Myrcene in mg/kg body weight is much higher. As such, a lower total dose may be toxic (Appendix, Table 2). This is consistent with the fact that air pollution affects children [25] much more than adults. On average, a 20 kg (44 pound) 5 yr old child inhales 11,664 L/day, [25] similar to but slightly higher than adult inhalation. Yet for the 5 yr-old, pollutants are concentrated over a 3-4 times smaller body mass. Risk is further magnified for infants or with in-utero exposure of developing fetuses. Most low molecular weight and lipophilic compounds cross the placenta [15], and ß-Myrcene is both low molecular weight and very lipophilic [28]. Cannabis can cross the placenta [26, 53] and can cause low birth weight and neurocognitive deficits [27]. As the projected toxic dose level of ß-Myrcene in cannabis is calculated in mg/kg body weight, the dose experienced by the mother is magnified manyfold in the tiny fetus. Toxicity and carcinogenicity are increased by exposure over a multi-year period. As the rodent studies confirmed, longer exposure times to ß-Myrcene increased toxicity in various organs, long before full-blown cancers appeared.

This paper is not intended to address safety or health effects from ingesting or smoking cannabis. Interested readers are referred to a recent review [52] concerning therapeutic use of cannabis and cannabinoids as well as a review of health risks. The authors concluded "Evidence is insufficient for

[5] Odor "neutralizer" approaches have employed chemicals that "trap" the cannabis odor-causing molecules (but do not destroy the carcinogen) [24] and approaches using chemical oxidizing agents [24]. Although odor-neutralization may have utility when sprayed near exhaust fans along the perimeter of indoor grow facilities, it is very different for outdoor grows. For outdoor sites, the physics associated with odor emissions from a large area converging with neutralizer releases at the perimeter render contact incomplete over the larger area of the outdoor cultivation site.

the use of cannabis or cannabinoids for most medical indications." They also referenced many studies showing health harms from ingesting or inhaling cannabis including cardiovascular, pulmonary, neurocognitive and psychiatric risks and fetal risks from use in pregnancy [52, and Table 4 in 52].

IV. CONCLUSIONS AND POLICY RECOMMENDATION

This report summarizes known respiratory harms caused to workers, customers as well as residents near outdoor cannabis cultivation fields. It also addresses that ß-Myrcene, a carcinogen listed on California's Proposition 65, may reach levels in people from breathing cannabis emissions that are equivalent to those confirmed carcinogenic in animals. Children are known to be particularly vulnerable to respiratory and lung damage from air pollutants and may be exposed to toxic levels of ß-Myrcene from outdoor cannabis cultivation in as little as 3 months. Although the calculations in this report are illustrative and actual levels will vary, they show that neighboring properties are exposed to substantial levels including ß-Myrcene. Due to the known respiratory harm and carcinogenicity risk, these cannabis emissions should be regulated as a serious health threat to humans.

There is no effective way to prevent cannabis emissions from leaving cultivation site premises when grown outdoors; the only mitigation for outdoor cultivation to protect the public from exposure to these toxins is long separation distance that takes into consideration size of the cultivation area, topographic and meteorological conditions. Enclosed cannabis operations including indoor and greenhouse cultivation, drying, and processing facilities must be equipped with sufficient filtration (carbon scrubbers) to remove and prevent all emissions from leaving the structure. As topography and climate conditions affect the distance terpenes travel, quantitative monitoring (e.g., gas chromatography) should be required at parcel line to confirm no terpenes leave the cannabis operation's parcel.

Cannabis cultivation represents a public health threat to residents, customers and workers[6] on neighboring properties when it involuntarily exposes them to breathing unhealthy emissions containing toxins and carcinogens, including ß-Myrcene. Property owners must be able to safely and peacefully enjoy their businesses, yards and homes as is codified in the California Code's nuisance provisions (CCC § 3479 and HSC 41700).

[6]Cannabis workers are exposed to ß-Myrcene [34] as well as other toxins and should use protective respirators and dermal protection. Due to the recent adoption of legal commercial of cannabis in California and elsewhere, studies on health of cannabis workers have only recently been appearing in scientific publications. Publications reported dermal irritation and respiratory problems including asthma [2-7, 17], and two asthma fatalities [5, 41]. Terpenes in hops, which contains ß-Myrcene, have been reported to cause dermatitis and asthma in workers [8]. See also review of air quality impacts from cannabis cultivation facilities [18]. Farm workers on adjacent parcels are also exposed to these same toxins.

APPENDIX

Calculation of Amount of ß-Myrcene Inhaled by Humans From Outdoor Cannabis Cultivation Sites

A. Amount of ß-Myrcene Inhaled by Humans Exposed to Cannabis Odor

Facts: Avogadro's number is 6.022×10^{23} molecules/mole of compound and a mole is defined as the molecular weight in grams [29]. ß-Myrcene (abbreviated as ß-Myr in calculations) has a molecular weight of 136.23 g/mole [30]. The volume of a mole of a gas (e.g., air) at Standard Temperature and Pressure (STP) is 22.4 L [31].

Thus: the number of molecules in one Liter of air is calculated as:

$(6.022 \times 10^{23}$molecules/mole of air) x (1 mole of air/22.4 Liters) = 0.27×10^{23}moleules air per 1 Liter air

The definition of 1ppb (part per billion) of ß-Myr is 1 molecule ß-Myr per billion (10^9) molecules of air.

Thus: the **number of molecules of ß-Myr, at 1 ppb, per L of air, is:**
(1 molecule ß-Myr/10^9 molecules air) x (0.27×10^{23} molecules air/1L of air) = 0.27×10^{14} molecules ß-Myr/L air at 1 ppb.

Thus: converting to **g of ß-Myr at 1 ppb** of air:
(0.27×10^{14} molecules ß-Myr/L air) x (136.23 g ß-Myr/6.022×10^{23} molecules/mole ß-Myr) =
6.1×10^{-9} g ß-Myr/L air at 1 ppb of ß-Myr.

An average human adult breathes 11,000 L air/day. [32]. A 5-yr old child weighing 20 kg (44 pounds) breathes 11,664 L air/day [25], which is concentrated over a 3-4 fold lower body mass than in an adult.

Thus: average amount ß-Myr inhaled per day by a human adult at 1 ppb of ß-Myr if 100% absorption[7] from the lungs is [30, 32]:

(11,000 L air/day) x (6.1×10^{-9} g ß-Myr/L air) = $67{,}188 \times 10^{-9}$ g ß-Myr/day.
Multiplying by 10^3 mg/g gives $67{,}188 \times 10^{-6}$ mg ß-Myr/day,
which is **0.067 mg ß-Myr/day at 1 ppb ß-Myr (or 0.071mg for child [25]; for simplicity, we used the lower value of 0.067 mg ß-Myr/day for both adult and child calculations)**.

Over one outdoor growing per year, neighbors typically are exposed to high levels of cannabis odors for 3 months. The exposure time is doubled to 6 months per year with two growing cycles.

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[7] The actual amount of ß-Myrcene absorbed by neighbors (and workers) exposed to cannabis odors will vary depending on factors including concentration of ß-Myrcene in the odor plume, wind and weather conditions, level of exertion by the person and hence daily volume of air inhaled, and amount absorbed by the lungs. The amount absorbed by inhalation depends on relative efficiency of inhaled absorption, which at generally is 3-5X greater by inhalation vs oral ingestion for cannabinoids [34]. The calculations in Appendix Parts A and B used the more conservative estimate of 3X great bioavailability of inhaled vs oral, which show that ß-Myrcene inhaled from cannabis emissions by neighbors (and workers) can be significant and in the realm of toxic and carcinogenic levels.

Projected ß-Myrcene inhaled per day by a human (adult or child); summarized in Table 1 below:

At 10 ppb

if 100% absorption from air:

0.67 mg ß-Myr/day x 90 days = 60 mg in 3 mo, or 120 mg in 6 mo; or 1200 mg = 1.2 gm in 10 yr (at 6 mo/yr)

if 50% absorption from air:

0.336 mg ß-Myr/day x 90 days = 30.2 mg in 3 mo; or 60.4 mg in 6 mo; or 604 mg = 0.60 g in 10 yr (at 6 mo/yr)

At **100 ppb**

if 100% absorption from air:

= 6.7 mg ß-Myr/day x 90 days = 600 mg in 3 mo; or 1200 mg in 6 mo; or 12,000 mg = 12 g in 10 yr (at 6 mo/yr)

if 50% absorption from air:

= 3.36 mg ß-Myr/day x 90 days = 302 mg in 3 mo, or 604 mg in 6 mo; or 6040 mg = 6 g in 10 yrs yr (at 6 mo /yr)

At **1000 ppb**

if 100% absorption from air:

= 67 mg ß-Myr/day x 90 days = 6000 mg in 3 mo, or 12,000 mg in 6 mo; or 120,000 mg = 120 g in 10 yr (at 6 mo/yr)

if 50% absorption from air:

= 33.6 mg ß-Myr/day x 90 days= 3020 mg in 3 mo; or 6040 mg in 6 mo; or 60,400 mg =60 g in 10 yr (at 6 mo /yr)

Table 1. ß-Myrcene Dose in People Breathing Air at 10-1000 ppb ß-Myrcene

Exposure Concentration (ppb) (% absorption from air)	Daily Dose (mg)	Dose in 3 - 6 mo (g)	Cumulative Exposure in 5-10 yr (at 6 mo/yr)
10 ppb (100% uptake)	0.67 mg	0.060 - 0.120 g	0.6 - 1.2 g
10 ppb (50% uptake)	0.336 mg	0.030 - 0.060 g	0.3 - 0.6 g
100 ppb (100% uptake)	6.7 mg	0.60 - 1.200 g	6 - 12 g
100 ppb (50% uptake)	3.36 mg	0.30 - 0.60 g	3.0 – 6.0 g
1000 ppb (100% uptake)	67 mg	6.0 - 12 g	60 - 120 g
1000 ppb (50% uptake)	33.6 mg	3.0 - 6.0 g	30 - 60 g

The exposure ranges of 10-1000 ppb are based on real-time field measurements [21]. As children and adults have similar inhalation volumes, amount absorbed is comparable for children and adults.

ß-Myrcene occurs naturally in some food and beverage substances, such as hops, carrots, lemongrass, and bay leaves as well as cannabis [22], yet the levels consumed by people are orders of magnitude lower than when exposed to cannabis emissions. For example, to get the same amount of ß-Myrcene absorbed by a person in one day at 100 ppb ß-Myrcene (assuming 100% absorption; 6.7 mg/day), using the levels measured in ref [22], Suppl Table 2, and also assuming 100% absorption of ß-Myrcene from oral ingestion of food and beverages (which is a large over estimate, as it likely is in the 5-10% range as is THC oral absorption [34]), one would need to **consume 135,000 grams = 297 pounds of carrots each day** *[Calculation: 6.7 x 10^{-3} g ß-Myr inhaled / 150 x 10^{-9} g ß-Myr per g carrots, x 3 to account for higher bioavailability of inhalation vs oral = 135,000 g carrots*

each day] **or 1406 beers each day** [*Calculation: average 40 µg ß-Myr/L beer x 3.8 L/128 oz = 1.19 µg/oz beer = 14.3 µg B-Myr/12 oz beer. Comparing to the 6.7 mg/day inhaled by people exposed to 100 ppb, this is [6.7 x x 10^{-3} g ß-Myr inhaled/ 14.3 x10^{-6}g ß-Myr/beer] x 3 to account for higher bioavailability of inhalation vs oral) = 1406 beers/day].* In summary, the amount of ß-Myrcene people ingest by choice in foods and beverages in miniscule compared to the amount absorbed by inhalation of cannabis volatile emissions.

B. Calculation of Mouse and Rat Toxicity and Carcinogenicity Dose-Equivalent in Humans

Assumptions. Since human absorption and pharmacokinetic data do not exist for ß-Myrcene, we used assumptions of inhalation bioavailability, inhalation vs oral bioavailability and half-life/accumulation based on other similar molecules with like lipophilicity, as detailed below.

ß-Myrcene Is Predicted to Accumulate in People

Although it is known that ß-Myrcene does not accumulate in rats due to its short half-life and thus rapid clearance, the chemical properties of ß-Myrcene, being highly lipophilic (fat-soluble), would predict **accumulation in humans but not rats**. Although ß-Myrcene is very lipophilic, it has a short 4.5 hr half-life in rodents which lack much body fat and thus ß-Myrcene does not accumulate in rodents. (It takes 4-5 half-lives to clear a compound from the body; thus 4.5 hr/half-life x 4-5 half-lives/clearance is 18- 22.5 hr, meaning no ß-Myrcene remains in rodents from each daily dose before the next dose is given and thus there is no accumulation). However, very lipophilic compounds such as ß-Myrcene are predicted to accumulate in humans as do other lipophilic cannabis compounds (humans have more body fat). One can look at the similarly very lipophilic cannabis compound THC to extrapolate to predict levels of accumulation of ß-Myrcene that will likely occur in people. THC accumulates for 1-3 weeks in occasional users [34], and for 4-8 weeks in chronic users (vs short half-life and no accumulation in rats who have little body fat [43]). We used a conservative value of assuming only 2 weeks accumulation for ß-Myrcene in humans when calculating the equivalent human toxic dose.

METHOD 1- Calculation of Human Equivalent "Toxic" and "Safe" Dose of ß-Myrcene

The lowest dose tested in the NPR toxicity and carcinogenicity study [3] was 250 mg/kg/day, 5 days/wk in rats and mice by oral gavage; this equates to 179 mg/kg/day ß-Myrcene as the animals were dosed 5 days a week. There was dose-dependent toxicity at all doses with increasing toxicity associated with duration of dosing. Toxicities were documented for all doses and included kidney and liver degeneration, chronic inflammation, and weight loss and lethargy. Toxicity increased with duration of dosing from 23 to 70 days (over a 3-month period), culminating with kidney and liver carcinogenicity after 2 years, the longest duration evaluated (2 years is the standard carcinogenicity test). Regarding acute toxicity, all animals died early on at the highest dose tested (4g/kg), with many deaths at the intermediate doses as well. Applying well accepted factor employed by the pharmaceutical industry of 0.081 to convert from mouse dose (or 0.135 from rat) to human dose [33] (to account for the slower metabolic rate of humans and the difference in surface area to blood volume) results in a projected toxic daily dose in humans if ingested orally of 14 mg ß-Myrcene/kg/day. However, since humans will be exposed by inhalation from breathing the air containing cannabis emissions, one must account for the higher bioavailability of cannabis compounds by inhalation vs oral uptake. Compounds have much higher bioavailability when inhaled, as this provides a direct route into the blood stream, avoiding first-pass metabolism by the liver and low absorption from the gut as occurs for many compounds, including cannabinoids [34]. Literature on cannabinoids shows 3-5 fold lower bioavailability from

oral administration vs inhalation in humans [34]. The animal toxicity studies were all done by oral administration. When this much lower uptake by the oral route vs inhalation is factored in, the equivalent toxic dose calculated for humans from inhalation is then 3-5X lower than shown from oral dosing to account for the 3-5 higher uptake by inhalation. We used the more conservative figure of 3X lower; then projected toxic daily dose of ß-Myrcene in humans when inhaled is 14 divided by 3 = 4.7 mg/kg/day[8], before adjustment for accumulation. To adjust for accumulation, we conservatively assumed a 2-week accumulation in humans as compared to no accumulation in rodents as discussed on page 11. This would result in ~20-fold higher levels in humans than if it had the same 4.5 hr half-life as in rodents. Accounting for this accumulation in humans, the daily toxic dose would be projected to be ~20-fold lower, which is **0.23 mg/kg/day[8].** Finally, it should be noted that the toxic daily dose may likely be further lower as discussed above and in footnote 4, as a maximum non-toxic level (toxic threshold) was not determined in the animal tests since the lowest exposure dose was carcinogenic.

Multiplying 0.23 mg/kg/day by the weight of a human in kg gives the projected toxic inhalation dose based on the lowest dose tested and 1/10 lowest dose, on a daily basis and after 3 months (when significant toxicity was seen in animal studies) as shown in Table 2.

Table 2. "Toxic" Dose of ß-Myrcene by Inhalation in People (Method 1)*

A. Weight in kg (pounds)	**Toxic Dose**	
	lowest dose tested	1/10 lowest dose
15 kg (33 pound) child		
mg/d (ppb)	3.5 mg/d (= 52 ppb)	0.35 mg/d (= 5.2 ppb)
g in 3 months	0.31 g	0.031g
60 kg (132 pound) adult		
mg/d (ppb)	14 mg/d (= 209 ppb)	1.4 mg/d (= 21 ppb)
g in 3 months	1.24 g	0.124 g

B. Projected accumulated toxic dose after 3 months	
Adult (0.23 mg/kg/day)	1.24 g
Using 1/10 low dose	0.124g
Child (0.23 mg/kg/day)	0.31 g
Using 1/10 low dose	0.031 g

*To convert ß-Myrcene from mg/day to ppb (Appendix Part A, p8):
Air inhaled per day is 11 x 10^3L/day; 1 ppb is 6.1 x 10^{-6} mg/L air.
Thus [6.1 x 10^{-6} mg/L air/1 ppb] x [11 x 10^3L air/day] = 67.1 x 10^{-3} mg/ day = **0.0671 mg/day = 1 ppb**

[8] If the rat data are used instead of the mouse data, the conversion factor is 0.162 and calculated daily toxic human dose is 0.38 mg/kg/d, which is 8.7 ppb for the child. If the ratio of 5X inhaled/oral bioavailability is used, the human projected toxic dose is 60% (i.e., 3/5) lower than that shown.

METHOD 2. Calculation of Human Equivalent "Safe" Dose of ß-Myrcene

This method calculates an Occupational Exposure Level (OEL) using the formula [42]

$$\mathbf{OEL = POD/ (AF_c \times a \times S \times MF \times V)}$$

POD is Point of Departure, the highest non-toxic dose tested - or in this case as all doses tested were toxic, the lowest dose tested. POD is in mg/kg body weight/day, x the body weight of the affected individual. We used 15 and 60 kg, to account for a 33-pound small child and a 132-pound adult. We used a figure of 179 mg/kg/day from the rat carcinogenicity study as we did also in Method 1.

AF_c is a composite adjustment factor, accounting for interspecies difference (5), intraspecies differences (5), subchronic to chronic (1), conversion from lowest toxic dose tested to extrapolate to a non-toxic dose (10). Thus total AFc was 5 x 5 x 1 x 10 = 250.

"**a**" is a factor to account for differences in bioavailability from the dosing route used in the animal to the exposure in humans. As the rat studies were done with oral dosing (oral gavage) but humans will be inhaling myrcene from the air, the increased bioavailability for inhalation vs oral is 3-5 fold [34]. We used "a" of 3 to be on the conservative side.

S is the accumulation factor. We used a conservative estimate of accumulation over 2 weeks (detailed above on page 11) [34]), which gives ~20-fold higher levels at steady state than if no accumulation.

MF is to account for residual uncertainties; we used 1 (no residual uncertainties).

V is the volume of air inhaled during the assessed period. We assumed 24 hr exposure a day as neighbors are exposed to the contaminated air chronically, thus 11,000 L/day or 11 m^3/day for a 24 hr day [30, 32].

Using the above factors, OEL = 179 mg/kg/day x (15 or 60 kg)/ (250 x 3 x 20 x 1 x 11m^3/day) is calculated for people weighing 15 kg or 60 kg (33 or121 pounds) and shown in Table 3.

Table 3. Safe Exposure Levels (OEL) of ß-Myrcene in the Air for Humans (Method 2)[9]

Weight in kg (pounds)	mg/m^3	ppb
15 kg (33 pound) child	0.016 mg/m^3	2.7 ppb
60 kg (132 pound) adult	0.065 mg/m^3	10.7 ppb

Although the two methods use different assumptions, their results are similar. Method 2 shows safe level of ß-Myrcene in the air as 2.7 ppb for the child, whereas Method 1 shows 5 ppb or 8.7 ppb as toxic as calculated from the lowest toxic dose from the mouse or rat studies, respectively. Given that the adjustment factor in

[9] See Appendix Part A, p8. To convert ß-Myrcene from 1 mg/m^3 (= 1 mg/10^3L) to ppb myrcene:
1 mg /103 L x (L/6.1 x 10-6 mg)/1 ppb = 0.164 x 103 ppb = 164 ppb myrcene. Thus 1 mg/m^3 = 164 ppb.
(When SafeBridge used the above formula to calculate OEL [42], they failed to account for the higher bioavailability by inhalation, the increased accumulation in humans, the 24 hr daily exposure, and the smaller weight of children.)

Method 2 to extrapolate to non-toxic dose was just an estimate, and Method 1 only gave the toxic dose, this difference is not unreasonable. If the same adjustment factor of 3 is applied to Method 1, then a 'safe' level 1.7 or 2.9 ppb is obtained, thus very similar to Method 2. These numbers are consistent with the further analysis in Table 4, which suggests that 10 ppb would show toxicity. These methods all use different assumptions, but the results all suggest that chronic exposure should be limited to less than 2-3 ppb ß-Myrcene.

C. Calculation of Safety Margin (Toxic Level divided by Amount ß-Myr Inhaled)

A Safety Margin[4] (Toxic Dose divided by the Inhaled dose) of 1 means that the Toxic Dose equals the Inhaled Dose. **The higher the Safety Margin, the better the safety.** To put this in context: Pharmaceutical drugs typically have a Safety Margin (called Therapeutic Index for pharmaceuticals) of 100 or more (i.e., the toxic dose is 100 time higher than the therapeutic dose) and even a recreational drug such as cocaine has a Safety Ratio of 15:1 [23], yet cocaine use still results in overdoses and death.

As shown in Table 4, the projected Toxic Dose of ß-Myrcene over Inhaled Dose (i.e., Safety Margin) is quite low (thus very dangerous) at 100 ppb exposure after only 3 to 6 months and even at 10 ppb, it is at toxic amounts after 5 years and will be progressively worse (i.e., it decreases) for every additional year of exposure. **Sonoma County has approved granting permits with no term limits; neighbors will be exposed to ß-Myrcene for as long as they live near an outdoor cannabis operation.** Even if only at 10 ppb ß-Myrcene, often undetectable by the human nose, the Safety Margin for a child after 30 months is 1, thus at toxic levels. People are being forced to breathe a known toxin and carcinogen with no therapeutic benefit, with a projected lower Safety Margin than cocaine, that causes liver and kidney toxicity with short term exposures, can cause developmental/reproductive toxicities and can cause cancer with longer-term exposures. No pharmaceutical drug, perhaps other than a cancer therapeutic, would be approved with such a high toxicity.

Note that the above Safety Margins assume that a lower non-toxic ß-Myrcene level is known. However, since no lower non-toxic dose was determined[10], we also included a calculation using 1/10 of the lowest dose tested, projecting that this lower dose may also be toxic. When the 1/10 lower dose levels are used, the Safety Margin even at the low exposure level of 10 ppb shows that a toxic exposure is obtained after just 3 months (one growing season) for a child (Table 4A). Furthermore, as chronic exposure causes toxicity at lower dose levels than does shorter-term exposure [20], over a multi-year period, humans could suffer permanent damage to liver and kidneys long before any cancer appeared.

IN SUMMARY, the daily and cumulative amount of ß-Myrcene inhaled by people living or working near outdoor cannabis cultivation sites can be substantial and in the range of or greater than the comparable dose that was unequivocally determined to be toxic and carcinogenic in animals. Furthermore, as a non-toxic and non-carcinogenic dose was not determined in animals, the lowest toxic dose calculated for humans is projected to be lower than that shown. Taken together, one can project that chronic safe exposure levels should be no greater than 1 ppb ß-Myrcene to protect children.

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[10] The NTP toxicology and carcinogenicity study of ß-Myrcene was conducted due its structural relationship to d-limonene, its high production volume, and high level of human exposure (eg, use in food flavorings) [3]. Dr. R. S. Chhabra of NTP stated that "this was one of the very few studies in the history of the NTP where doses were missed so dramatically" [ref 3, comment by Dr. Chhabra, p14].

Table 4. Safety Margin for ß-Myrcene (Method 1)[4]

Toxic Dose of ß-Myrcene[11] Vs. Cumulative Dose Inhaled by Humans[12]

A. 10 ppb: Inhaled human dose of ß-Myrcene in g

	3 - 6 mo		5 yr (6 mo/yr)		10 yr (6 mo/yr)	
	Adult	Child	Adult	Child	Adult	Child
Cumulative inhaled dose	0.03- 0.06	0.03-0.06	0.3	0.3	0.6	0.6
Safety Margin	**41 - 21**	**10- 5**	**4.0**	**1.0**	**2.1**	**0.5**
at 0.1 low dose	**4.1 - 2.1**	**1 - 0.5**	**0.4**	**0.1**	**0.2**	**0.05**

B. 100 ppb: Inhaled human dose of ß-Myrcene in g

	3 - 6 mo		5 yr (6 mo/yr)		10 yr (6 mo/yr)	
	Adult	Child	Adult	Child	Adult	Child
Cumulative inhaled dose	0.3 – 0.6	0.3 – 0.6	3.0	3.0	6.0	6.0
Safety Margin	**4.1 – 2.1**	**1.0 – 0.5**	**0.4**	**0.1**	**0.2**	**0.05**
at 0.1 low dose	**0.4 – 0.2**	**0.1 – 0.05**	**0.04**	**0.01**	**0.02**	**0.005**

C. 1000 ppb: Inhaled human dose of ß-Myrcene in g

	3 - 6 mo		5 yr (30 mo)		10 yr (60 mo)	
	Adult	Child	Adult	Child	Adult	Child
Cumulative inhaled dose	3 – 6	3 – 6	30	30	60	60
Safety Margin	**0.4 – 0.2**	**0.1 – 0.05**	**0.04**	**0.01**	**0.02**	**0.005**
at 0.1 low dose	**0.04–0.02**	**0.01–0.005**	**0.004**	**0.001**	**0.002**	**0.0005**

[11]Calculated from mouse toxicity studies as described in Appendix, Part B, Method 1, Table 2B, using projected 3-month toxic dose (based on human equivalent to lowest dose tested in mice). As noted, oral bioavailability of cannabis compounds is 3-5 times less than by inhalation [34]; we used the more conservative figure of 3 times lower in calculating the projected human toxic dose. If the oral bioavailability is 5 times lower, then the projected toxic dose and Safety Margin would be 60% less than is shown.

[12]Dose of ß-Myrcene projected as inhaled in either 1 growing season (3 months) or 2 growing seasons (6 months) each year, at 10, 100 and 1000 ppb (See Table 1). These estimates assume 50% absorption of inhaled ß-Myrcene; the projected dose will vary depending on amount of ß-Myrcene absorbed by the lungs.

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Exhibit 2

NEIGHBORHOOD COALITION

NeighborhoodCoalitionSonomaCounty.com

CVs of Experts

Attachment 1. Dr. Alan Cohen

Attachment 2. Dr. Deborah A. Eppstein

Attachment 3. Dr. Mark L. Kram

Attachment 4. Dr. George W. Rutherford

Attachment 5. Dr. Srinivasan Venkatehwwaran

Attachment 1

ALAN H. COHEN, MD, FAAP, FCCP, FAAAAI, FACAAI

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EXECUTIVE TEAM MEMBER / SENIOR VICE PRESIDENT GLOBAL / CHIEF MEDICAL OFFICER

Highly experienced medical executive with deep expertise in clinical medicine, medical affairs, drug development, safety and pharmacovigilance, business development/asset acquisition/due diligence as well as post-approval commercial launch, publication planning and commercial/sales team support in both small & large global pharmaceutical/biotech companies. Successful at building and leading diverse, high-performance teams that strive to be collaborative, inclusive and goal oriented. Highly effective at establishing and maintaining stakeholder relationships, working with both academic and private sector healthcare professional opinion leaders, as well as payers and providers to promote scientific advancements, public health, drug development and safety. Experience and successful execution with a broad variety of orphan and more common healthcare products, drugs and disease conditions, including a wide range of cardio-respiratory drugs and drug/ device combinations for both adults and children, Schedule 3 controlled substances, infectious disease therapies, vaccines and biologics, cardiopulmonary, psychiatric drugs, poison/toxin antidotes as well as oncology therapies and supporting products for GI and nutritional disorders. Many therapies for orphan/rare diseases, pediatrics & first in class.

- Medical Leadership - Patient Focus
- Team Building, Highly Collaborative
- Leveraging Stakeholder Partnerships
- Medical Regulatory Compliance
- Medical Affairs & Commercial Support
- Strategic Planning & Tactical Execution
- Medical & Clinical Research
- Pharmacovigilance & Safety Oversight

PROFESSIONAL EXPERIENCE

Senior Vice President – Clinical Development, Therapeutic Area Head – Pulm, CV & Rare Diseases
4D Molecular Therapeutics (10/2023 - on)

4DMT is a clinical stage biopharma company inventing and developing innovative products to unlock the full potential of genetic medicine to treat large market diseases. We use our transformative vector discovery platform, termed Therapeutic Vector Evolution, to create customized and proprietary gene delivery vehicles to deliver therapeutic payloads to specific tissue types associated with the underlying disease via the optimal route of administration. Our product design, development and manufacturing engine empower us to efficiently create our valuable and diverse product pipeline. This combination of bold innovation and relentless execution gives 4DMT the capacity to revolutionize genetic medicines and strive for potential curative therapies.

Clinical & Translational Development Program Responsibilities:

- **4D-710** – Cystic Fibrosis – Inhalation Gene Therapy Phase 1 / 2 Development Program – NCT05248230
  I am the medical lead on this Phase 1/2 multicenter, open-label, single dose trial of 4D-710 investigational gene therapy in adults with CF who are ineligible for or unable to tolerate CFTR modulator therapy.
- **4D-301** – Fabry Disease - Phase 1/2 Trial of Gene Therapy in Adults with Fabry Disease – NCT04519749
  I am the medical lead on this Phase 1-2 prospective multicenter, open-label, dose-escalation trial to assess the safety, tolerability, and pharmacodynamics of 4D-310 following a single IV administration. The study population is comprised of adult males and females with Fabry Disease. This is an IV administered AAV targeting cardiomyocytes.
- **4D-725** – Alpha1-Antitrypsin Deficiency Lung Disease – Translational gene therapy disease target for this genetically-driven orphan form of COPD/emphysema. I am leading the translational efforts, engaged with regulatory agencies, global KOLs and clinician scientists in advance of initiating this early-stage clinical program.

Executive Level – Biotech & Pharma Medical Consulting (5/2023 - on)
C-Suite: Clinical Development, Medical Affairs, Safety & Pharmacovigilance

I am consulting and advising a variety of early stage, pre-clinical and clinical stage public and privately held biotech and pharma companies regarding their biomedical platforms, translational animal and biomarker identification, as well as helping with “proof in principle’ clinical target selection. I have most recently been recruited as “acting-CMO” and serving as a senior level medical and clinical expert for a variety of small, pre-clinical biotechnology start-ups as well as established publicly traded clinical stage pharma companies. My work includes disease target identification and clinical development strategic planning on a wide range of rare diseases, including cardio-pulmonary and metabolic conditions, as well as respiratory pathogens.

Chief Medical Officer & Senior Vice President – Clinical Development & Medical Affairs
In Vivo/Monogenomic Diseases

Metagenomi, Inc. (3/2022 – 4/2023)

Metagenomi is a pre-clinical, gene editing company committed to developing potentially curative therapeutics by leveraging a proprietary toolbox of next-generation gene editing systems to accurately edit DNA where current technologies cannot. Our metagenomics-powered discovery platform and analytical expertise reveal novel cellular machinery sourced from otherwise unknown organisms. We adapt and forge these naturally evolved systems into powerful gene editing systems that are ultra-small, extremely efficient, highly specific and have a decreased risk of immune response. These systems fuel our pipeline of novel medicines and can be leveraged by partners. Our goal is to revolutionize gene editing for the benefit of patients around the world. I was hired as the first and only full time medical leader, to help advance our pipeline of novel, proprietary gene editing tools from the bench to successful clinical trials and ultimately approval, potentially offering actual cures for rare, life limiting/altering monogenetically-driven diseases. I served on the executive committee and lead all translational and clinically relevant work streams. I worked closely with our basic scientists, business development and partnered clinical teams in a matrix process to help bridge and unify all aspects of pre-clinical, translational, and first-in-human efforts. I also worked closely on all partnering activities for both in vivo and ex vivo applications of our genomics "toolbox". Metagenomi, Inc. went public in Q1 2024, and is now listed on the NASDAQ (MGX).

<u>In Vivo Development Programs and Partnerships Currently include:</u>

- **Metagenomi** – solely controlled programs publicly announced include Hemophilia A, Cystic Fibrosis.
- **Moderna** (2021-on) working with executive and scientific leadership on our collaborative gene editing disease targets. These include unnamed orphan diseases, including renal, CV and metabolic disease targets
- **Ionis** (2022-on)– working with executive leadership re. our established collaborative partnering programs. These include ATTR-CM, amyloid heart failure – in the orphan disease, CV and metabolic space as well as additional unnamed rare and more common genetic disease targets in the CV, metabolic and renal arena.

Vice President, Global Medical Affairs – Eidos Therapeutics, Inc (BridgeBio) (3/2020 – 3/2022)

Eidos Therapeutics started as a public (Nasdaq: EIDX) clinical stage biopharmaceutical company focused on addressing the large and growing unmet need in diseases caused by transthyretin, or TTR, amyloidosis (ATTR). In Q1 2021 Eidos was acquired by BridgeBio (Nasdaq: BBio) and Eidos was de-listed. Our scientist/clinicians were seeking to treat a well-defined family of diseases at their collective source by stabilizing TTR. Our product candidate, acoramidis (AG10), is an orally administered small molecule designed to potently stabilize TTR, a potentially best-in-class treatment aiming to hasten the progression of ATTR diseases. Founded in 2013, Eidos was led by a team of industry veterans responsible for developing over 30 molecules through IND applications and more than 10 approved drugs. Together with patients and physicians, we aimed to bring a safe, effective and disease-modifying treatment for ATTR to market in the coming years. We performed a global Phase 3 study (AR-301) targeting adults with confirmed ATTR-CM with NYHA functional Class I-III severity of cardiomyopathy-related heart failure. The two registrational endpoints include change in six-minute walk test distance at 12 months and all-cause mortality, as well as cardiovascular-related hospitalizations at 30 months. We also had a Phase 3 development program in ATTRPN (polyneuropathy) in 2022. As VP of Global Medical Affairs, I was responsible for creating and overseeing a fully integrated Global Medical Affairs team supporting all services, in support of our global development activities. I built out all Medical Affairs functions, including all recruitment and oversight in prep of pre-launch/launch activities for pivotal studies in the US & EU (Zug, SZ). Team of 12+. Included creation and highly successful launch (with Medscape/WebMD) of the first *International Congress of ATTR Amyloidosis* (ICAA) Global Academic Meeting, hosted website and content page (www.ICAAMeeting.com) and published Proceedings (*Am J Cardiology*). Acoramidis (*Attruby*™) is now an approved therapy indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular death and CV-related hosp.

<u>Medical Affairs Activities Include:</u>

- US/EU Field-base Medical Directors – responsible for HCP & KOL engagement & support of Clinical trial conduct
- Medical Information Services – including frequently asked questions (FAQs) & standard response letters (SRL's)
- Publication Planning – for Eidos Clinical studies, Pivotal trials, Open label extension study trial conduct
- Investigator Initiated Research support – review, approval and facilitation of support of independent research
- Medical Education – review & support of CME / non-CME accredited medical efforts, including creation of ICAA.
- Advisory Boards – Academic and Community Physician educational and round table discussions / meetings
- Medical Regulatory Review Committee member – for review of scientific / medical content
- Medical Library Support – catalogue and maintenance of medical references / documents company-wide

- Patient Advocacy & Support Group – support of Amyloid/ATTR patient and specialty support groups
- Disease & Specialty Organization Support – engagement and support of HCP/Disease relevant groups
- Clinical Operations / Clinical Trial – support engagement of Primary Investigators (PIs) and co-PIs
- Health Economics Outcomes Research – working w academics, HEOR/health authorities & sales/marketing
- EU Head of Medical Affairs - Hired and overseeing Medical Affairs roles & growth, Zug, Switzerland

Global Clinical Leader, Drug Development (Pediatric/Orphan) – Bayer US Pharma (3/2018 – 5/2020)
Bayer employs over 13,000 workers in over 50 facilities throughout the US, in addition to corporate offices in Germany and globally. As a member of the then newly created (late 2017-early 2018) Pediatric Clinical Development team (n=5, 3 in Germany & 2 in US) at Bayer, I served as a medical expert/lead, consultant and director of pediatric and adult focused development programs in a variety of areas, including cardiovascular (PPHN), pulmonary (refractory cough), ophthalmology (ROP), hematology/oncology, sleep disordered breathing (OSA) and a variety of orphan diseases. I worked closely with the global Bayer R&D, Clinical & Medical teams cross functionally, as well as Regulatory functions in the US and internationally, in support of current products and new development programs. I represented Bayer in international, academic, regulatory and healthcare related committees and organizations including the ATS, INC etc. My work included translational M&A/due diligences, Phase 1-3 clinical development programs and post approval efforts in my areas of expertise including cardiorespiratory disorders involving children and adults, novel and orphan therapeutic areas as well as the development of companion diagnostics, novel clinical trial endpoints and new clinical/medical targets. In mid-2018 Bayer acquired Monsanto to expand their agricultural business. Since this announcement they made significant changes in their business priorities, R&D and Clinical ops and all clinical and medical functions worldwide. At the early stages of the COVID-19 pandemic, under strict statewide sheltering in place rules I was recruited and transitioned (in 3/2020) to a leadership role at Eidos Therapeutics, Inc.

Clinical Development Programs:

- **Pediatric Ophthalmology Development Program in Retinopathy of Prematurity (ROP)** Phase 3 – Aflibercept (VEG-F inhibitor) – Global clinical development program started in 2019 for EU, Japan & US (Regeneron partnership development program(s). I am serving as Global Clinical Leader – focus on pediatric medical issues.
- **Sleep Disorders/Obstructive Sleep Apnea** (NCT03603678) – Phase 2 SANDMAN Study assessing the utility of a Potassium Channel Inhibitor in the management of patients with confirmed OSA.
- **Refractory Chronic Cough** (NCT03310645/NCT03535168) – **BAY1817080** in Healthy Volunteers and patients with RCC – Proof in Concept Phase 1/2 Development Program(s). Supporting activities and disease targets in Children and Adults in Phase 1/2 and Phase 2/3 programs.
- **Soluble Guanylate Cyclase (sGC) Stimulator** (Riociguat) – undisclosed targets – translational work ongoing
- **Additional programs and new drug entities** are also being assessed and considered – with my clinical development and medical input – all ongoing.

Committees & Additional Job Roles:

- **Global Protocol Review Committee** member (2018 – ongoing) – reviewer of global trial programs
- **Clinical Development Global Meeting Planning Committee** (2019)

Awards:

- **Innovative Clinical Development Award & "Spot" Bonus** – Oct 2019 – for innovative approach to two specific Orphan & Pediatric Development Program Concepts – in Cardiovascular (PH/PPHN) and Respiratory (Cough).

Senior Vice President – Global Clinical & Medical Affairs - Aridis Pharma, Inc. (7/17-3/18);
Clinical & Medical Advisory Board Member – Aridis Pharma, Inc. (1/2007-6/2017; 3/2018 – 12/2023)
Aridis was a privately held, now public (Nasdaq: ARDS since 8/2018), clinical stage biopharmaceutical company, developing breakthrough therapies for antibiotic resistant infections and addressing the growing problem of antibiotic resistance. Aridis' suite of anti-infective monoclonal antibodies (mAbs) offers opportunities to profoundly alter the current trajectory of increasing antibiotic resistance and improve the health outcome of many of the most serious life-threatening infections particularly in hospital settings. Aridis products have been funded by the NIH, US Dept. of Defense, US Dept. of Health & Human Services' BARDA, USAID, Regional Centers of Excellence, as well as the non-profit PATH/Gates Foundation. Human mAbs are being developed as anti-infective drugs targeting key pathogens, including *S. aureus* (including MRSA & MSSA) and *P. aeruginosa*. Complementing these mAbs is a broad-spectrum anti-infective candidate based on gallium (Panaecin™). Current clinical development programs include: AR105-002 mAb (Aerucin®) – targeting *P. aeruginosa* pneumonia Phase 2/3; AR 301 mAb (Salvecin™) – targeting *S. aureus*

pneumonia Phase 3; Panaecin™ - targeting both Gram negative & positive bacterial pathogens via their iron acquisition pathways in Phase 1/2A HVs then 2B CF subjects. I have served as a Clinical Advisory Board member since 2007, with a brief time as SVP of Global Clinical & Medical Affairs from 7/2017 thru 3/2018, when leadership needed my full-time support for multiple programs, including:

- **AR301-003 (Salvecin™)** – Global Phase 3 Program: Human mAb (IgG1) targeting *Staphylococcus aureus* alphatoxin for passive immunotherapy against *S. aureus* infections resulting in pneumonia with respiratory failure. Salvecin™ is being studied as adjunct therapy to standard of care antibiotics. The mode of action is independent of the antibiotic resistance profile of *S. aureus* targets.
    - Wrote, researched & submitted the Pediatric Study Plan to FDA post EOP2 meeting 2017
- **AR105-002 (Aerucin®)** – Global Phase 2 Program: Human mAb targeting *Pseudomonas aeruginosa* pneumonia for use as an adjunct to standard of care antibiotic therapies for pneumonia with respiratory failure. Aerucin® binds to alginate, a surface polysaccharide which plays a critical role in colonization, biofilm formation, virulence and invasive disease. Aerucin® was found to bind to 90% of all *P. aeruginosa* strains tested.
    - Supporting activities including: CRO engagement, Scientific Advisory Board Meetings, Global Clinical PI/Site support, partnering activities with investment community, BARDA etc.; Safety Reviews, data review and analysis, Medical Monitor/oversight and safety reviews, site selection and geographical reach/epidemiology, partnering activities, diagnostic device partnering efforts etc. Program unblinded & discontinued in Q3 2019.
- **AR501-002 (Panaecin™)** – Phase 1/2A (2018-on): Gallium citrate administered via inhalation to healthy adults and those with CF lung disease (chronic infection / colonization with *P. aeruginosa*) to assess safety and PK. Indication for management of CF lung disease due to chronic bronchitis, bronchiectasis and respiratory infections. Collaboration and funding support with the CF Foundation. I am overseeing this entire clinical program.
    - Protocol writing, CRO RFPs and selection process, engagement with KOL and CF Foundation, DSMB engagement, Regulatory (FDA/EMA) engagement, medical oversight, statistical assessment, translational work with basic scientists and researchers, manufacturing issues etc. Orphan Designation FDA approved 2019 - with my medical input re. submission/supporting documents. Working with Regulatory team – co-authored documents in support of QIDP designation (2018) and Fast Track Designation (2018). Additionally - First healthy volunteer (HV) patients enrolled and dosed in Q4 2018. Ongoing Medical advisor and safety oversight for MAD portion of study – ongoing through 2019-2020 before advancement into CF adults via CFF Therapeutic Development Network (TDN) in H2 2020

Chief Medical Officer & Senior Vice President - Therabron Therapeutics, Inc. (2/16 – 5/17) Therabron was a privately held, clinical-stage, biopharmaceutical company, developing a new class of drugs based on the naturally occurring Club Cell secretoglobin family of proteins, including the CC10 protein and physiologic analogues -- having both anti-inflammatory and immunomodulatory modes of action. We completed enrollment on a global Phase 2 clinical trial in premature infants Q2 2016 and had plans to advance additional programs in the respiratory disease space. Prior to being shut down in Q2 2017, due to financial constraints, I was responsible for redirecting the company focus to our next development area, Bronchiolitis Obliterans (BO), which remains the most common life limiting condition post lung transplantation, with no known treatments. Under my leadership, we successfully completed enrollment of our Phase 2 study and in Q1&Q2 2017 we achieved orphan drug designation for the next generation molecule issued by both the FDA and EMA. I have overseen all clinical development activities, as well as regulatory and safety – engaging CROs and interfacing with both the scientific and clinical / medical HCP communities. I reported directly into our CEO, and I was directly involved with all partnering, collaborative and funding efforts supporting our scientific and clinical programs. Anticipating the planned un-blinding of our Phase 2 program in Q3 2017, the Board of Directors and the lead (solo) VC firm funding our research and trial activities opted to cease operations and we underwent a shutdown in Q2 2017, including myself, our former CFO and CEO and all R&D/research staff.

- **CLA-CC1010-02 –** Efficacy of recombinant human Club (Clara) cell 10KDA protein (CC10) administered to premature neonates with respiratory distress syndrome – Enrolling upwards to 88 premature infants at 6 clinical development sites in the USA and EU to assess the safety and efficacy of CC10 and to determine the optimal dose for future (Phase3) clinical studies. Co-PIs include Dr. John M Davis – Chief of Newborn Medicine at Tufts Medical Center and Dr. Richard B Parad at Harvard Medical School.

CLA-CC10-XX-01 - Safety and tolerability of recombinant human Club (Clara) cell 10 KDA protein (CC10) administered intravenously to adults post bilateral lung transplantation with bronchiolitis obliterans syndrome (BOS). – I conceptualized the program, convened an international Advisory Board of world-class transplant experts, drafted the protocol and investigator brochure, successful completed the Pre-IND meeting with the Transplantation & Ophthalmology Division FDA in Q1 2017 and following an RFP screened CROs for deployment of the program in H2 2017 – before we were put on hold due to financial limits.

- **FDA Fast Track Designation** – Oversaw regulatory writing and submission for CG100 – resulting in FDA Fast Track designation for rhCC10 for the prevention of chronic lung disease of premature birth – Q2 2016
- **Corporate Scientific Advisory Board** – selection and creation of Therabron's Advisory Board with KOLs from both pediatric & adult pulmonary disciplines, including experts in COPD, Lung Transplant, asthma, pulmonary fibrosis & lung physiology. Q2 2016
- **Clinical Trial Oversight and Enrollment Completion** – for global Phase 2 study in premature infants. Finalized Statistical Analysis Plan & FDA end-of-Phase 2 meeting plans.
- **Lung Transplant / BOS Advisory Board** – oversaw selection & creation of Therabron's Global Lung Transplantation Advisory Board with internationally recognized experts – to advise on future development of next generation IV formulation of rhCC10.
- **FDA Rare Pediatric Disease Designation** – Oversaw regulatory writing and submission for CG100 – Successfully Granted Rare Pediatric Disease Designation Q2 2016
- **Invited Speaker** – Thomas L Petty Aspen Lung Meeting 2016 – Presented scientific rationale and development plans for rhCC10 Lung Transplantation/BO/BOS clinical program – academic conference University of Colorado Annual Meeting Q2 2016
- **Bronchiolitis Obliterans – Orphan Designation - both FDA & EMA Granted Orphan Designation – Q1 & Q2 2017** – Responsible for writing & submission of ODD requests to both FDA & EMA regulatory agencies as well as OOPD BOS filing; Draft protocol for Phase 1B study completed / shared with Lung Transplantation Scientific Advisory Board at European Respiratory Society & in early Q4 2016 with US KOLs. (FDA Designation #16-5502)
- **DSUR Submission to USA & EU 2016 –** Submitted US and EU – Q4 2016

Chief Medical Officer – Eddingpharm (California & China) (3/14 – 2/16)

Served as the first CMO for this growing Chinese specialty pharma/biotech company est. in China in 2001. Focused on novel drugs serving key therapeutic areas: Clinical Nutrition, Oncology, Antibiotics, Respiratory / Allergy and Cardiovascular. Hired to bring novel drug development and manufacturing to China by expanding their product portfolio as well as supporting and growing current products (n=15) and global partnerships/alliances. We partner with globally recognized companies, including GSK, BRAUN, Pharmacosmos, Chiesi, Syndax, Immutep, Ablynx, ALK, Cardiome, Prosonix/Circassia and Amarin - for drug development. Overseeing Clinical Development programs, Medical Affairs, Safety and Pharmacovigilance and Medical Advisor for Sales/Marketing and BD teams in support of commercial products and programs in China. The founder and Board decided to transition all USA-based clinical development/medical affairs activities and programs from the USA to Mainland China in Q4 2015. I increasingly needed to be in China for all drug development, medical / clinical trial activities with the Chinese FDA in 2015-2016, and as such I opted not to permanently relocate and attain full-time residency in China as an employee of EDP. I transitioned from EDP to my role as CMO at Therabron in Q1 2016.

- **EDP 103 – Phase I Study** – Assess PK/PD, MTD, DLT & safety of Entinostat, in Locally Recurrent or Metastatic Breast Cancer. Syndax global/China partner
- **EDP317 - Phase I Study** – Assess Safety, MTD, PK/PD, Tumor Response and future Dose/Schedule of EDP317 (formerly ACTB-1003 or BAY82-9307) in Advanced Malignancies. Transitioned 2015 from USA to only China dev.
- **EDP301 -** Phase III Ready Study - Telatinib in Combination w SOC - fluoropyrimidine & platinum (eg. Capecitabine or 5-FU & Cisplatin) as First-line Therapy for Metastatic Stomach/GEJ Cancer. Transitioned 2015 from USA to China only development.
- **Advancing Development & Manufacturing Programs** for China / Asia include partnerships with a variety of global partners including: Syndax, Prosonix / Circassia, Amarin, Cardiome etc. Oncology, Cardiopulmonary & Metabolic Dis.
- **Medical Affairs** – China-centric team of > 750 salespeople including Medical Affairs team. I helped to establish a formal Medical Affairs function in China, along with many of our partners (aka GSK, Chiesi, Ablynx etc) formalizing training, SOPs and conduct in China and outlying areas.

Executive Director - Clinical Development & Medical Affairs - Boehringer Ingelheim (12/12 – 2/14)
I lead a team responsible for both medical affairs and clinical development in respiratory and new development areas. Engagement with global KOL/HCP's, patient advocacy/orphan disease groups and leadership of specialty societies, globally. I oversaw and led the USA based Medical Affairs team in support of their asthma, COPD and IPF/ILD programs

- **Phase III / IIIb and IV** development programs, selection of new, earlier stage molecules and targets of interest for currently approved & development programs
- **Phase 3B Study in IPF – 1199.187:** Evaluating nintedanib on HRCT quantitative lung fibrosis score, lung function, 6MWT and SGRQ after 12 mo. of treatment in patients with IPF (upwards to 18 mo. follow up).
- **IPF Patient Registry** – in collaboration with the DCRI (Duke University Clinical Research Institute) – launched the first and largest multicenter IPF patient registry ever initiated.
- **Clinical Trial Deliverables** – Including: IPF (nintedanib – 2 Phase III trials), TINA/Asthma program – including > 18 Phase II/III trials conducted globally.
- **Field-based Medical Affairs Team** – Helped oversee the writing, editing and creation of all the training materials used for the education of our MSL team, as well as the sales/commercial team - in preparation of nintedanib IPF drug launch and in support of all asthma and COPD therapies for USA, Canada & in partnership with EU team(s).
- **Investigator Initiated Studies (IIS)** – Responsible for USA-based review and sign off all respiratory proposals – including COPD, Asthma, IPF and involving Corp team.
- **Educational Grants** – Responsible for USA educational grant proposals/programs
- **Publication Planning** – Central medical role in publication planning for all USA respiratory pubs with corporate colleagues and international partners.
- **Advisory Boards / Investigator Meetings** – supported, organized, and played a central role in all Ad Bds involving TINA (asthma) and IPF (nintedanib) development programs.
- **SSc-ILD & Pediatric (ChILD)** – worked in support of product line extension, including systemic sclerosis – ILD and pediatric ILD indications – which are now approved/expanded indications for nintedinib, globally.

Senior Vice President – **Med Affairs** - **InterMune (Roche/Genentech - acquired) – SF, CA** (11/09 –11/12)
Created, oversaw, and directed many critical activities to support the successful approval and launch for IPF, first in EU and later in the USA. I worked to create the USA-based and ultimately Global Medical Affairs team, overseeing all medically related activities to support the post-approval and launch of pirfenidone (Esbriet): EU, USA, Canada & ROW.

- **Field-Based Medical Affairs Team** – Including PhD's, PharmD's, RNs – supporting all professional communications and interactions with KOL's
- **Medical Education efforts** – including CME and non-CME programs at major academic institutions, professional societies and specialty meetings of all kinds.
- **Publications** – High quality peer-reviewed publications, including writing, editing and support of all manuscripts. In 2011 alone, we published and supported the completion of 12 peer-reviewed original research papers, as well as 5 platform presentations and abstracts at 3 international conferences.
- **Advocacy Support** – worked closely with support groups, their families and HCPs. This included compassionate use / indigent care programs globally
- **Advisory Meetings with KOL's** – included presentations at Advisory Committee meetings with globally leadership, Scientific Ad Bds, academic and 1:1 meeting.
- **Medical Information Services** – Included the successful creation of 60+ standard response letters following spontaneous requests for info by HCPs
- **Sales & Marketing Support** – Medical reviewer and advisor re lung abnormalities and inborn errors of metabolism, supporting marketing and sales with launch/support of products for IPF & Actimmune (for CGD - divested 7/12)
- **Patient Registry, International Congress Meeting(s), Fellowship Grant Program(s), Medical Education Newsletter (internal)** – leadership role in initiating, organizing, coordinating and planning activities post approval and launch of Esbriet (pirfenidone).
- **Life Cycle Management** – working closely with R&D, Drug Discovery, BD etc. to help define new clinical applications of pirfenidone (Esbriet) for other conditions, including connective tissue disorders like systemic sclerosis (SSc-ILD), NASH, nephrotic fibrosis, bronchiolitis obliterans syndrome (BOS) post lung transplantation/stem cell transplantation/bone marrow transplantation etc.
- **Investigator Sponsored Trial (IST) support** – including review, approval and support of basic science, genomics, biomarkers, animal research and human trials by KOLs world-wide: 40+ ISTs supported, incl. NIH & Dept Chairs.

- **Co-Author Patent for use of pirfenidone in BO/BOS Lung Transplantation -** "Methods of Improving Microvascular Integrity" International Patent Application No. 14/771, 241 (GNE REF NO. P32771-US-1) **-** Provisional Patent Application No. 61/793,035 (filed 2014). EU Patent Application No./Patent No. 14767657.1 – 1453 PCT/US2014025895 (EU Patent Office 10/26/15 – filed 3/13/14).

- **Positions Held**:
  Executive Committee Member, Promotional Review Committee Member – EU & USA, Medical Review Committee Member – Chair – EU & USA, Compliance Committee – Member, Pirfenidone Steering Committee Member Commercialization Team – Member, Product Safety Committee – Member, Grants Review Committee Team Member – Chair, Named Patient Program Team Member, Canadian Communication Team Member, Post Authorization Safety Study Team Member, Core Labeling Committee Team Member, Pirfenidone Core Project Team Member, Core Labeling Committee (CLC) Core Labeling Working Group (CLWG), Canadian Labeling Negotiation Team Member

Vice President - Clin Dev & Med Affairs - MAP Pharma, Inc. (Allergan - acquired) (9/08 – 11/09)
I oversaw all Phase I to IV clinical trials associated with UDB & Device platform to successful NDA submission(s), medical oversight, safety & pharmacovigilance. Assisted with ALL partnering work (Astra Zeneca) re the UDB program – for the entirety of the partnership (12/08-7/09). Responsible for protocols, vendor selection/oversight, PI and site screening/selection, investigator meetings etc. Decision to shut down UDB program in 9/09 post failed Phase III results. MAP BoD/Exec Team opted to advance a Phase III Migraine Program instead, and I chose to leave post decision.

Unit Dose Budesonide (UDB) – proprietary submicron formulation of budesonide for pediatric asthma including
- Study 301 – Phase III – Randomized, double-blind, placebo-controlled efficacy study (12-week, n=360) helped to complete, un-blinded and presented at American Thoracic Society 2009 International conference
- Study 301X – Phase III - Randomized, double-blind, placebo controlled – active controlled extension – long-term safety extension study (40 wk) closed out 7-09. I served as medical monitor US and Ex-US and helped to complete and close out this program, including study reports, safety overview, FDA meetings etc.

Next Generation – MAP20 – Aeroneb® GO – underway in 9/09-10/09.
- Study 201 - Phase II **–** A Randomized, Open-Label, 3-Dose, 3-Period, Crossover Phase II Study Investigating the Tolerability, and Pharmacokinetics of Submicron Budesonide in Children ages 4 to 11 years old with a History of Mild-To-Moderate Stable Asthma. Start to finish Q3-4 2009 as planned. CDER IND/IDE # 72,242; Clinicaltrials.gov ID# NCT00995904

- **New Inhalation Devices Development - for Children & those with COPD:**
  - **MAP0000-CL-P001 PHASE I / II** - An Observational and Comparative Study Evaluating the Inhalation Profiles of Children Aged 3 through 11 years with Mild-to-Moderate Asthma Using A Proprietary Breath Actuated Pressurized Metered-Dose Inhaler (pMDI) and Proprietary Mouthpiece Design Compared to the In- Check Dial™ to Simulate the Flow Resistances of Commercially Available Dry Powder Inhalers (DPIs) – Edited protocol(s), Served as Medical Monitor – Perth, Australia Q3-4 2009

- **Respiratory Steering Committee (RSC)** - Medical Affairs & Clinical Medicine
- **UDB Leadership Team** – Medical Affairs & Clinical Medicine
- **AstraZeneca** – UDB & Respiratory Development Team Member

Chief Medical Officer & Vice President – Global Safety Pharmacovigilance - Jazz Pharma (1/06-9/08)
I built the entire Dept. of Medical Affairs including all services & departments, team of 30+ including Field-based and home office based Medical Affairs Group (MDs, PhDs, PharmDs), Safety & Pharmacovigilance Group – Supporting Both Marketed & Study drugs (US & ex-US arms). Jazz acquired and re-launched Xyrem (sodium oxybate), a controversial Scheduled 3 controlled substance with a single distribution pharmacy model and a highly restrictive REMS requirement to the sleep community for Narcolepsy. My role included working to gain the support and confidence of HCP/KOLs in the medical specialty area about the safe and effective use of Xyrem. We also supported a toxicology antidote to ethylene glycol and methanol poisoning (Antizol & Antizol Vet) and launched a novel SSRI for Obsessive

Compulsive Disorder (OCD) and Social Anxiety Disorder (SAD) – working closely with Psychiatrists. I also helped to launch the Phase 3 development program targeting Xyrem in the management of Fibromyalgia chronic pain.

Committees and Responsibilities Included:

- Clinical Trial Protocol Review Committee (PRC) – Medical representative
- Responsible for all CME (national/regional), Med Ed, Pub Planning
- Oversee Investigator Initiated Research Studies (IIT/IIS) – protocols
- Coordinate KOL / HCP engagement plans
- Med Affairs – publish monthly medical newsletters company-wide ("MAD" Bulletin)
- Medical Information Services – oversaw writing and updates of standard response letters
- International Medical Liaison – to Corp partners (aka UCB, Valeant)
- Regulatory Reviewer – Medical member of "CALM" committee
- Development Management Group – Medical/Clinical Member
- Fellowship Grant Programs – Sleep & Anxiety Programs – created & oversaw
- Manage and oversee independent budget of ~ 12+ million dollars/year
- Health and Safety Home office services – medical oversight
- New Product & Development programs (including due diligence, pre-clinical work through Phases I, II, III and IV post-marketing studies)
- Established virtual library services & electronic holdings
- Patent Review Committee – Medical/clinical member

Senior Director, Medical Affairs - MedImmune, Inc. (now AstraZeneca) Gaithersburg, MD (4/01-12/05)

This was my first Pharm/Bio industry job, and I took on a pivotal leadership role in this highly successful top 10 biotechnology company. I was responsible for 10+ direct reports (MDs, PhDs and PharmDs), while reporting into the VP of Medical Affairs who himself reported into the CMO. Served a central role in brand support for 3 marketed products – Synagis®, Cytogam® and FluMist®, and formerly Respigam®. Primarily responsible for Synagis – MedImmune's premier MAb (approx 1 billion in sales) – having created and executed yearly, the highly regarded, *International Congresses in Respiratory Viruses* – with published Proceedings and enduring educational materials, CME programs, Advisory Boards for both academic and clinically-oriented physicians and educational slide libraries with yearly updates. Besides building / overseeing all Medical Affairs functions my role and responsibilities expanded over time and included:

Translational Research: Worked intimately with all facets of MedImmune – from Marketing & Sales to Development, Legal and Regulatory Affairs, as well as Research and Development and Translational research collaborations with international thought leaders/key researchers.

- Publications/KOLs/Ad Bds: Development of Publication plans / Strategy, KOL engagement and Consultancy activities to help advance core brands and company.
- New Product Planning/R&D Support: Provided therapeutic, clinical and medical expertise in the areas of Pediatrics, Pulmonary Medicine, Critical Care, Infectious Diseases, Allergy and Immunology as well as Transplantation Medicine – to the Development / R&D teams – for new compounds and in-licensing opportunities.
- Regulatory Role: Responsible for development strategies and planning / execution of research activities and programs to meet the objectives of both the scientific and commercial aspects with regulatory rigor.
- International Work: Medical Affairs liaison responsibilities with both domestic (Ross Labs) and international (Abbott International) partnering companies. Worked intimately on Ph IV efforts, med Info, med inquiries etc.
- Patient Registry: Initiation and development of an enduring (x5+ years) Synagis patient registry with multiple abstracts, platform presentations and peer-reviewed publications associated with this work, as well as survey tools & investigator-initiated efforts engaging hundreds of clinicians & academic researchers.
- Fellowship Grant Program: Creation Fellowship Grant Program in Respiratory Infectious Diseases (providing $210K/yr) and PIDS Career Development Award ($150K over 3 yrs).
- Phase III/IV/IIT's: Direct involvement and responsibility for Phase IIIb, Phase IV and all Investigator Initiated Trials (IITs) relating to RSV / Synagis and CMV / Cytogam.
- Budgetary Responsibilities: Responsible for supporting the RSV & CMV franchises – incl IIT's, Phase IV & IIT budgets, CME and all other educational activities and programs.
- Publications: Authored and co-authored dozens of abstracts and manuscripts, as well as the creation of hundreds of educational slides – with many hundred successful and well-received lectures, didactics and

educational programs throughout the United States and abroad – in support of Ex-USA sales activities of Abbott International.

- Awards: Awarded **CEO Club** for Excellence in Medical Affairs '04-'05
- New Product Planning: Product Development Teams for RSV (Synagis & "NuMax"), hMPV (live vaccine and MAb) and the asthma / COPD development product - IL9 Mab.
- Regulatory Reviewer: Promotional & Regulatory Affairs - Materials Reviewer 3+ years
- Compliance: Compliance "Core Team" Member

MEDICAL PROFESSIONAL EXPERIENCE:

- **Stanford University School of Medicine** - **Clinical Instructor Adjunct (2006 – 2019)**
  Department of Pediatrics, Division of Pulmonary Medicine - I volunteered and serve as a member of the clinical teaching faculty at Lucille Packard Children's Hospital. I provided direct patient care to my own cohort of patients in addition to teaching medical students, residents, and fellows at Stanford University Medical Center.
- **Johns Hopkins University School of Medicine Assistant Professor Adjunct (2002 –2005)**
  Dept. of Pediatrics, Division of Pulmonary Medicine. While working at Medimmune fulltime, this was voluntary, pro bono clinical patient work in the Dept. of Pediatric Pulmonology. I cared for CF and other pediatric patients and taught medical students, residents, and fellows.
- **Morehouse School of Medicine – Assistant Professor – Adjunct**. Atlanta, GA **(1998-2001)**
- **Georgia Pediatric Pulmonology Associates (Private Practice Group)** – Atlanta, GA **(1998-2001)**

  Director of Clinical Research - which I established in this practice, which at the time was the largest and most well respected Pediatric Pulmonary Practice in the USA.
- **Washington University School Medicine,** St. Louis, MO **(1995-1998)**
  Assistant Professor of Pediatrics, Div of Allergy & Pulmonary Med

  Associate Director of Pediatric Lung/Heart-Lung Transplantation Program (Most active & the highly regarded Pediatric Lung / Heart-lung Transplant Program in North America at the time. I also served as Fellowship Director, Pediatric Pulmonary Medicine and Pediatric Residency Faculty Advisor.

EDUCATION:

• Undergraduate Training

- 7/78 – 5/82 University of Rochester, Rochester, New York
  B.S. Microbiology & **B.A.** History (1982)
- 9/82 – 6/83 Columbia University, New York, New York
- 8/83 – 6/84 Cornell University Medical College, New York, New York
  Department of Pharmacology, Research Assistant – Pain research w opiate agonists & antagonists.

• Graduate School Training

- 9/84 – 6/86 Sackler School of Medicine, New York State Program, NY, NY.
- 7/86 **–** 6/88 New York Medical College, Valhalla, New York - **M.D.** (1988)

• Post Graduate Training

- 6/88 – 6/91 Pediatric Internship and Residency
  - University of Colorado Health Sciences Center / The Children's Hospital
- 7/92 –6/95 Fellowship in Pediatric Pulmonology
  - University of Colorado / National Jewish Center for Immunology & Respiratory Disease / The Children's Hospital, Denver, Colorado

Board Memberships / Consultancies / Journal Reviewer:

- **Journal Reviewer - *Pharmaceutical Medicine Journal* -** Invited reviewer, 2021-onwards

- **American Thoracic Society (ATS) –** Leadership Committee Member – Drug Device Discovery Development (DDDD) ATS Committee and "BEAR Cage" Fellow & Junior Faculty Research Grant Reviewer (5/2016 – current)
- **BIO –** Bayer Corp Member - trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States plus 30 other nations (2019 - current)
- **INC (International Neonatal Consortium) Critical Path Institute –** Bayer Corp Member & Innovation Working Group Founding Member (2018 – onwards)
- **Brace Pharma Capital, Inc. –** VC Firm (Rockville, MD); EMS, Brazil US Group - Medical Advisor (2/16 – 12/19)
- **Wynd** (prev. Claireau) – Senior Clinical Consultant – Resp. Device Company (2015 – 2019)
- **GeNO (now Vero)** - **Chief Medical Officer** consultancy – part of Brace Pharma Capital, Inc holdings (1/17 – 4/17)
- **Anasa Therapeutics, Inc** – Clinical Consultant (2011 – 2014)
- **Novalos, LLC –** Clinical Consultant (2011 – 2014) Pharma company, Palo Alto, CA
- **SJ Pharmaceuticals, LLC** – Board of Director Member (2008 – 2011) Pharma company, Atlanta, GA
- **Phoenix Pharmaceutical Group** – Clinical Consultant (2010 – 2011) Pharma company start-up, Menlo Park,CA

Patents / Inventions:

- "Local Administration of Metals, Semi-Metals, and Se, Sb, or Bi Complexed with Hydroxypyridones, Hydroxypyridinones and Hydroxypyrones" – provisional application 61/284,724 (filed December 22, 2009).
- "Methods of Improving Microvascular Integrity" International Patent Application No. 14/771, 241 (GNE REF NO. P32771-US-1) - Provisional Patent Application No. 61/793,035 (filed 2014). EU Patent Application No./Patent No. 14767657.1 – 1453 PCT/US2014025895 (EU Patent Office 10/26/15 – filed 3/13/14)

Rare & Orphan Disease Experience:

I have served as a member at NORD (National Organization of Rare Disorders) for many companies as well as patient advocacy groups/support group work (Cystic Fibrosis Foundation, Premature baby Coalitions, Pulmonary Fibrosis Foundation, RARE etc) due to extensive work experience in the orphan drug disease space & patient advocacy arena.
Orphan drugs I have directly supported for Medical Launch/Commercialization & Post-Approval Registries include:

- **Synagis** – first in class anti-infective RSV mAb – launched and supported for BOTH **premature lung disease & congenital heart disease**: MedImmune – acquired by AZ
- **Cytogam** – first in class biologic targeting CMV infections in immunosuppressed hosts / **lung transplant recipients:** MedImmune – acquired by AZ
- **Xyrem** – first in class - CNS/sleep drug - **Narcolepsy** – excessive daytime sleepiness & cataplexy: Jazz Pharma
- **Pirfenidone (2 Orphan Indications)** first in class EU & US respiratory therapy for the interstitial lung disorder called **IPF (Idiopathic Pulmonary Fibrosis) PLUS 2nd Orphan target – SSc-ILD (systemic sclerosis with interstitial lung disease) -** InterMune: eventually acquired by Roche/Genentech
- **Nintedanib (2 Orphan Indications)** – US & EU approved & launched 2nd therapy for **IPF fibrotic lung disease** PLUS 2nd Orphan Target – **SSc-ILD (Systemic Sclerosis with Interstitial Lung Disease):** at BI (US & EU)
- **rhCC10** – (**3 Orphan Indications**) pulmonary delivered biologic (recombinant club cell protein) targeting: **Premature Lung Disease/BPD, Post Lung Transplant Bronchiolitis Obliterans (BOS) lung disease & Smoke Inhalation / Burn Injury Lung Disease (DoD funded project)**: at Therabron.
- **Eylea** – Pediatric Ophthalmology Orphan Disease program – started Q4 2019 globally: Bayer/Regeneron
- **Acoramidis (AG10)** – ATTR Amyloid-related Transthyretin Heart Failure (HF) and polyneuropathy (PN)
- **4D-710** – Cystic Fibrosis Lung disease – gene therapy delivered via breath-actuated nebulizer
- **4D-310** – Fabry Disease – systemically delivered (IV) gene therapy targeting cardiomyocytes

Clinical Trial Experience – Summary

Phase III/IV Studies/Programs:

- **Eidos/BridgeBio** – Acoramidis (*Attruby*™) is now approved for ATTR-CM (III); ATTR-PN (III – delayed)
- **Bayer – Eylea (VEGF inhibitor) for ROP/Premature eye disease (III)**

- Aridis – mAb for *S aureus* VAP/HAP (III)
- Aridis - mAb for *P aurginosa* for VAP/HAP (III)
- **Eddingpharm (EDP) – EDP-301 Telatinib for GI/stomach CA (US/China)**
- BI – Nintedinib – for IPF/ILD; SSc-ILD; Peds ILD
- **MAP – UDB (Unit Dose Budesonide) – for Pediatric asthma – global study (partnered AZ)**
- **Jazz – Xyrem – for Fibromyalgia**
- **Medimmune – palivizumab/Synagis (Registry/IV) – RSV premature infants and CHD**
- **InterMune – pirfenidone (IV) – registry/OLE – outcomes study**

Phase II Studies/Programs:

- **Aridis** – **inhaled gallium – CF lung disease/P aeruginosa pulm infections – drug/device combo**
- Bayer – Refractory cough P2X3 Antagonist (eliapixant)
- Bayer – SANDMAN Study - OSA/Excessive daytime sleepiness (BAY2253651)
- **Therabron** – **CC10 (club cell protein) – premature lung disease – drug/device combo (vibrating mesh)**

Phase I/FIH Studies/Programs:

- **4DMT** – 4D-710 – AAV-CFTR inhaled viral vector Gene therapy – targeting CF lung disease
- **4DMT** – 4D-310 – AAV – systemically delivered therapy, targeting cardiomyocytes in Fabry Disease
- **Aridis** – inhaled gallium – HV for *P aeruginosa* infections (CF target)
- Bayer – riociquat – chronic kidney disease (children)
- **Therabron** – CC10 – lung transplant patients (BOS)
- **Eddingpharm - EDP/Syndax** – Entinostat – Breast cancer
- **Eddingpharm - EDP 317** – "Basket" study – cancer program (DCRI)

Medical Affairs Teams:

- **Medimmune** – I created and oversaw our highly effective MSL/MSD team in the USA to support Synagis and FluMist products. I also worked with Abbott International on their Med Affairs support and activities in the EU and Asia. A bi-product of this work was the creation of: the ***International Congress of Respiratory Viruses*** – annual KOL meeting with development of academic slides and published supplement in *J Peds ID* x 4 years. I also created and launched an RSV/Synagis **Premature Patient Outcomes Registry** – yielding many publications, KOL med ed events and review articles
- **Jazz Pharmaceuticals, Inc** – after acquiring Xyrem from Orphan Medical – I was hired to create a new med affairs function with field MSLs and KOL engagement to re-launch this Narcolepsy therapy and to support Antizol and Luvox-CR. I created a new Dept from the ground up, built a KOL database and established an IIT program with numerous deliverables. We published a monthly "Newsletter' internally for the sales group and did journal clubs to educate, as well as created a med info function with standard response letters.
- **InterMune** – in preparation for both an FDA and EMA approval for Pirfenidone for IPF – I was hired to create a new Medical Affairs team and function and all supporting programs including a KOL database, F2F meetings with treatment leaders in USA, EU and Latin America, Publication strategy, advocacy and rare disease support groups (PFF, NORD etc), Life Cycle management and all post approval IIT/Investigator Initiated efforts (Phase 4) and Post Approval EMA Commitments (REMS).
- **Boehringer Ingelheim Pharma, Inc.** – I worked predominantly on Medical Affairs training and preparation for the IPF/Nintedanib pre-approval/post-approval and launch activities for this novel/orphan, ILD respiratory therapy. This included working with our established Respiratory Med affairs USA and EU teams on training modules/content, study results and competitive landscape. I also worked on support for our COPD and asthma therapies & development efforts (aka – expanded indication for Spiriva from exclusively COPD to both asthma and COPD use.
- **Eddingpharm, Inc** - I built and establish a Medical-focused & Medical Affairs organization in China given the need to more clearly separate roles for the sales force vs medical affairs, due to agreements we had with global partners (aka GSK etc.). This was a relatively new development for Pharma/Bio companies in China at this time and one that was welcomed but remained unfamiliar to most of my Chinese-based colleagues outside of the USA/EU operations.

- **Eidos Therapeutics, Inc**. – I was brought in to create a new and fully integrated Medical Affairs Dept from scratch including all related activities in support of both US and global development and medical/commercial support for both ATTR-CM and ATTR-PN amyloidosis drug development programs.

Product / Brand Support

I have worked closely with brand teams, reimbursement teams and marketing and sales groups at all of the companies I have worked with that had approved therapies as well as relaunching acquired therapies and all pre/post new launch activities in support of novel, first-to-market brands. That includes: Synagis, FluMist, Xyrem, Luvox CR, Antizol, Pirfenidone, Nintedanib and all 15+ products in China, including ALKs dust mite allergy Rx. I have helped to launch, brand and relaunch therapies, as well as work with Business Development teams and Marketing & Sales groups on life cycle management planning for drugs we supported and sold in USA, EU and ROW.

KOL & Advisory Board/Expert Engagement

In every company I have worked, I either was the person responsible for KOL/Ad Boards or I was asked to create them, develop them and oversee and run them and all their activities and collateral functions/needs. This included meetings, database creation, reporting, roundtables and publishing of expert panel reports in peer reviewed journals. I have also coordinated and overseen the submission and ultimate creation, review and editing of many scientific meeting posters, abstract submissions and platform presentation development, training and slide preparation. This includes Ad boards for new development programs, clinical trial support, DSMB teams, KOLs for speaker training, roundtable meetings, academic meeting events and programs, grand rounds programs and the creation of specialty meetings, slide set creation and publication of annual proceedings in the peer reviewed literature. I am particularly effective in this area, and I have mutually respectful professional relationships with many of the global leaders in Pulm/ID/critical care/sleep etc areas because of both my industry and professional/medical and academic-oriented work experience.

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49. McWilliams B, Glomb WB, Boron M, **Cohen A** and Rankin M. RSV Prevention: Preliminary Demographic & Risk Factor Data Regarding 1,155 Children with Chronic Lung Disease (CLD) Over The 2003-2004 Season. Chest 2004 (American College of Chest Physicians) October 23-28, 2004, Seattle, Washington. – Platform Presentation
50. Frogel M, Nerwen C, Boron M, **Cohen A**, Rankin M. Survey Results from the 2003-2004 Palivizumab Outcomes Registry Investigators Indicates Lack of Compliance With Needle Length Guidelines For Immunization Practice. 2004 American Academy of Pediatrics National Conference and Exhibition, October 9-13, 2004,
51. Oquist NL, Labella, JJ, **Cohen AH**, Ambrose C, Hess G, Lipskiy N. A National Community-based RSV Surveillance Program Using Rapid Assay Testing: Comparison of Findings and Seasonal Timing to NREVSS - 2004 American Academy of Pediatrics National Conf and Exhibition, October 9-13, 2004, San Francisco, CA. – Platform Presentation
52. Marcus M, Boron M, **Cohen A**, Rankin M and the Palivizumab Outcomes Registry Study Group. Adherence with RSV Prophylaxis among 19,548 High-Risk Infants & Children: Improved Outcomes with Homecare Administration. – Accepted for Presentation at the American Thoracic Society Meeting – San Diego, CA - 5/05
53. Gelfand A, Copenhaver S, **Cohen A**, Oquist N, Boron M and Rankin M. RSV Prevention: Demographic Data, Clinical Characteristics, and Outcomes from 6,150 High Risk Children Over the 2003-2004 Season. – Accepted for Presentation at the American Thoracic Society Meeting – San Diego, CA - 5/05
54. **Cohen AH**, Boron ML and Dingivan C; A Phase IV Study of the Safety of Synagis (Palivizumab) for Prophylaxis of Respiratory Syncytial Virus Disease in Children with Cystic Fibrosis. – ATS Meeting, San Diego, CA - 5/05
55. Speer M, **Cohen A**, Boron M, Rankin M and the Synagis Outcomes Registry Group. Results from the Palivizumab Outcomes Registry: Focus on Congenital Airways Abnormalities & Neuromuscular Disease – Presentation at the Society of Pediatric Research/Pediatric Academic Society, May 14-17, 2005, Meeting.
56. Speer M, Boron ML, McLaurin K, **Cohen AH**, Rankin M and the Synagis Outcomes Registry Group. Delayed Prophylaxis in Children at High Risk for RSV Disease. – SPR/PAS Presentation May 14-17, 2005, Meeting.
57. Frogel M, Nerwen C, Boron M, Oquist N, **Cohen A**, Rankin M and the Synagis Outcomes Registry Group. Impact of Medicaid Insurance Status Among 19,474 Infants Given RSV Monoclonal Antibody Prophylaxis – Poster Presentation at the Society of Pediatric Research/Pediatric Academic Society, May 14-17, 2005, Meeting. (2506) – General Peds & Preventative Peds: Disadvantaged Children – 5/15/05 number #43 poster.
58. Fisher-Owens SA, Turenne WM, Oquist N, **Cohen A** and Slonim AD. Special Medical Needs and RSV in Pediatric vs Community Hospitals – Presentation - Society of Pediatric Research/Pediatric Academic Society, May 2005 Meeting.
59. Frogel M, Nerwen C, Boron M, **Cohen A** and M Rankin. Homecare Administration of RSV Prophylaxis in 8,928 Infants on Medicaid: Improved Compliance and Outcome – Poster Presentation AAP Meeting – Wash DC - Oct 2005
60. **A H Cohen, MD**, J Tran, MD, P Uster, PhD, M Wang, PhD, S Shrewsbury, MD and D Kellerman, PharmD & the CASTLE I Study Group. Unit Dose Budesonide (UDB): A New Submicron Dispersion of Nebulizable Budesonide Studied in 361 Children 12 months to 8 years old with Mild to Moderate Persistent Asthma, Naïve to Inhaled Corticosteroids, A Phase III Clinical Trial - The CASTLE I Study – American Thoracic Society 2009 Annual Meeting, May 2009 – Poster presentation – Clinical Research Section.
61. Gadi Schoenheit, Ian Becattelli, **Alan H Cohen**. Living with Idiopathic Pulmonary Fibrosis (IPF): An In-depth Qualitative Survey of European Patients – ATS 2011 Annual International Meeting, Denver, CO May 2011

62. U Costabel, C Albera, **A Cohen**, W Bradford, T King, P Nobel, S Sahn, D Valeyre, R duBois. The Long-Term Safety of Pirfenidone in Patients with Idiopathic Pulmonary Fibrosis (IPF): Interim data from the RECAP extension study – European Respiratory Society Annual Congress, September 2011 – Amsterdam, NL – platform presentation.
63. **Alan H Cohen**, Williamson Z Bradford, Kenneth F Glasscock, Frank Weber. Interpreting Outcomes in Therapeutic Clinical Trials in Idiopathic Pulmonary Fibrosis (IPF): Benchmarks for Establishing a Clinically Meaningful Benefit, Presented - Pulmonary Fibrosis Foundation, IPF Summit Conference, December 2011, Chicago, IL.
64. **Alan H Cohen**, Williamson Z Bradford, Kenneth F Glasscock & Frank Weber **"**Defining Benchmarks for Clinical Outcomes in Idiopathic Pulmonary Fibrosis", British Thoracic Society Dec 2012 meeting – London, UK Dec 2012 65. A C Hernandez, P-F Laterre, M Kollef, A Torres, J Chastre, P Eggimann, B François & **A Cohen. "**Study Design: Placebo-Controlled, Double-Blind, Randomized Study of Human Monoclonal Antibody Aerucin as Adjunct Therapy to Antibiotics in the Treatment of *P. aeruginosa* Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia" Abstract #68113. ID Week Annual Meeting 2018, SF, CA
66. **Alan Cohen**, M Kankam*, P Mendelman, H Jafri, M Stevens-Brogan, C Plascencia, L Deans, A Kelson, P Lovalenti, J Woo, and Vu Truong POSTER 287 - Interim Results Of Phase 1/2a Clinical Study of AR-501, An Investigational Inhaled Formulation of Gallium Citrate being Evaluated as an Antibacterial in Cystic Fibrosis patients – **LATE BREAKER** – North American Cystic Fibrosis Conference (NACFC) October 2020. *Peds Pulm (2020) Vol 55 Issue 52 Supplement:* 34th Annual N American Cystic Fibrosis Conference Oct 7-23, 2020, Abstract #287 Page 151.
67. **Alan Cohen**, M Kankam, P Mendelman, H Jafri, M Stevens-Brogan, C Plascencia, L Deans, A Kelson, P Lovalenti, J Woo, V Truong. PHASE 1/2a RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY: INTERIM SAFETY AND PHARMACOKINETIC PROFILE OF AR-501, A NOVEL INVESTIGATIONAL INHALED ATIBACTERIAL, GALLIUM CITRATE BEING EVALUATED IN HEALTHY VOLUNTEERS AND CYSTIC FIBROSIS PATIENTS – ID Week Late Breaker – Submitted 9-2020/Presented 2020
68. **Alan H Cohen et al** – CFF Annual Meeting 11/2022 - INFECTION/MICROBIOLOGY Session: (RFPT06) RFPT06 - Rapid Fire Poster Talk Infection, Microbiology, & Immunity – Title: Phase 1/2a Randomized, Double-blind, Placebo-controlled Study, PK and Efficacy Outcome Measures of Inhaled Gallium Citrate (AR-501) in Cystic Fibrosis Patients – Poster Presentation & Rapid-Fire Talk 11-2022
69. **A. Cohen**, N. Lechtzin, S. Boas, T. Pena, K. McBennett, J. Gross, D. Dorgan, L. Couch, L. Hoffman, M. Saavedra, K. Hisert, M. Stevens-Brogan, C. Plascencia, L. Deans, A. Kelson, P. Lovalenti, J. Woo, V. Truong, H.S Jafri. PHASE 1/2a RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY: SAFETY, PK, AND EFFICACY OUTCOME MEASURES OF INHALED GALLIUM CITRATE (AR-501) IN P AERUGINOSA INFECTED CYSTIC FIBROSIS PATIENTS – Platform Poster Presentation - ECFS Annual Meeting, Vienna, Austria 6/2023.
70. Mark Thomas, Dau-Ming Niu, Nik Stoyanov, Jerry Vockley, Damara Ortiz, Nadine Jacquez, Carol Chung, Jinsong Shen, Theodore Sullivan, **Alan Cohen**, David Kirn. Phase 1/2 clinical trial evaluating 4D-310 in adults with Fabry disease cardiomyopathy: Interim analysis of cardiac and safety outcomes in patients with 10-32 months of follow-up. Platform Presentation - WORLD Symposium Feb 2024, San Diego, CA – Platform presentation & poster presentation
71. J Taylor-Cousar, J Mermis, A Gifford, T Sullivan, J Shen, **Alan H. Cohen**, D Kirn, S Donaldson, A Casey, R Jain, D. J. Dorgan, CFTR transgene expression in airway epithelial cells following aerosolized administration of the AAV-based gene therapy 4D-710 to adults with cystic fibrosis lung disease. Platform presentation - European CF Society (ECFS) Annual Meeting, Glasgow, UK 2024.
72. M Thomas, D Niu, N Stoyanov, J Vockley, D Ortiz, N Jacquez, C Chung, J Shen[d], T Sullivan, **A Cohen**, D Kirn: "Phase 1/2 clinical trial evaluating 4D-310 in adults with Fabry disease cardiomyopathy: Interim analysis of cardiac and safety outcomes in patients with 21–42 months of follow up" – WORLD Symposium Feb 2025, San Diego, CA – Platform presentation and poster presentation
73. B Long, J Holter, **A Cohen**, Z Sellers, C Vettermann, D Kirn, A Long. Low Pre-existing AAV-Neutralizing Titers Detected Using a Cell-Based Assay Did Not Impact 4D-310 Safety or Efficacy in Fabry Cardiomyopathy Patients – ASGCT 2025 Submitted

Attachment 2

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Deborah A. Eppstein, PhD

SUMMARY

Dr. Eppstein has 39 years of pharmaceutical research and development and business experience. Her experience encompasses biotechnology / pharmaceutical research and product development in anti-viral, anti-cancer, immunotherapies, stem cells and plant pathology, as well as pharmaceutical diagnostics. Dr. Eppstein has over 50 scientific publications and book chapters, and 25 patents.

EXPERIENCE

2006-2015 **Q Therapeutics, Inc.** Salt Lake City, UT
- President, CEO and Director
- Cell therapy products for neurodegenerative diseases
- Oversaw animal toxicology and efficacy studies and filings with FDA

1998-2005 **Altea Therapeutics, Inc.**, Atlanta, GA
- Founding CEO of Altea based on new technology for non-invasive delivery of proteins and small water soluble drugs from a skin patch (insulin patch, diabetes therapy patch, anti-coagulation patch in clinical development)
- 5 patents

1995-2005 **ATI Company,** Salt Lake City, UT and Atlanta, GA
- Co-Founder and Chairman
- Non-invasive glucose monitoring technology
- 4 patents

1999-2001 **Arcaris, Inc.,** Salt Lake City, UT
- Vice President, Corporate Development
- Functional genomics/anti-cancer drug discovery

1992-1999 **TheraTech, Inc.** (now Teva Pharmaceuticals), Salt Lake City, UT

- Vice President, Corporate Development and CBO
- Initiated, negotiated and managed 10 collaborations with major pharmaceutical companies that lead to two New Drug Approvals

1978-92 **Syntex Corporation** (now Roche Pharmaceuticals), Palo Alto, CA

- R&D Department Head ('78-87): vaccines, immunology, antiviral and anticancer research, drug delivery
- Over 50 publications and 16 US patents
- Director Corporate Development ('88-92): diagnostics, biotechnology and drug delivery

EDUCATION and TRAINING

1970	BA, Magna Cum Laude, Biology & Chemistry, Phi Beta Kappa: Grinnell College, IA
1974	PhD with honors, Biochemistry, University of Arkansas (NDEA research fellowship)
1975	Post-Doctoral Research, Plant Pathology, University of Arkansas
1976 - 78	Post-Doctoral Research, Virology, University of California at Santa Barbara (NIH fellowship)
1988 – 89	Stanford University program on Finance
1990 – 91	Harvard Law School Program on Negotiation

BUSINESS AWARDS

2008	30 Women to Watch, Utah Business Magazine
2009	Leadership Award, Women Technology Council
2009	Business Woman of the Year, Wasatch Woman Magazine
2008-11	Fittest Exec over 50, Utah Business Magazine
2009	Invited speaker, Utah State University, "Fitness benefits in the workplace"
2010	v100 Entrepreneur Award

PUBLICATIONS

Over 50 peer-review publications in scientific journals plus book chapters,
Over 25 US and international patents

Attachment 3

MARK L. KRAM, Ph.D., CGWP #471
7127 Hollister Ave., #25A-108
Goleta, CA 93117
(805) 899-8142

OBJECTIVE To utilize state of the art groundwater, chemical and GIS applications to assess and restore contaminated and over-drafted areas in the most fiscally responsible manner available.

EDUCATION Ph.D., Environmental Science and Management (UCSB, 2002); Thesis entitled "*DNAPL Contaminant Detection Using Optimized Fluorescence Methods*"; M.S., Geology (SDSU, 1988); Thesis entitled "*Fate and Distribution of Organotin in Sediments of Four U.S. Harbors*"; B.S., Chemistry (UCSB, 1983).

EXPERIENCE

Founder – CTO/CEO
Groundswell Technologies, LLC, since 4/08
Developed sensor technologies for real-time monitoring and reporting of environmental, water supply, security, and industrial data; emergency response and alarm systems.

Lecturer
University of California, Santa Barbara, 9/02 to 1/08
Taught graduate level Fate and Transport of Pollutants, Field Environmental Soil and Water Quality, and Geographical Information Systems.

Hydrogeologist
Naval Facilities Engineering Service Center, 6/89 to 5/08
Lead Research Scientist for DOD National Environmental Technology Test Site; Inventor of hydrogeologic, chemical assessment and well design technologies; West Coast Field Project Manager for SCAPS; Project Manager for remediation of groundwater and soil contamination, and contaminant fate and transport modeling efforts; Lead on dozens of environmental reports and remedial design specifications; Operator of laser spectroscopic cone penetrometer and other field analytical methods; Author of Navy, ASTM, ITRC, and EPA environmental quality assurance standard guidance.

Geochemist
Naval Oceans Systems Center, 9/86 to 12/88
Collected and analyzed environmental water and sediment samples for antifouling agent tributyltin; published articles contributed to Congressional legislation concerning marine pesticide applications.

Material Specialist
Decisive Testing, 2/86 to 9/86
Performed chemical, X-ray, and destructive analyses of industrial materials; administered engineering and welder certification examinations.

Geochronologist
San Diego State Foundation, 4/85 to 2/86
Mineral preparation, K-Ar age determination of terrestrial and extraterrestrial rock samples.

OTHER Recipient of the prestigious NGWA Technology Award and the 2014 ASTM International D18 Technical Editors Award; internationally recognized leader in innovative environmental technology development, demonstration, and technology transfer; holds several key patents for environmental assessment; published more than 50 peer-reviewed articles, several national standards and book chapters; participating ASTM member, Subcommittee D18.21 (current Chair), Committee E50; familiar with various modeling, and statistical packages.

BIOGRAPHICAL STATEMENT:

Dr. Mark Kram is the Founder and CTO for Groundswell Technologies, LLC, a group specializing in automated Cloud based monitoring and modeling of environmental sensor and analytical instrumentation networks. Dr. Kram earned his Ph.D. in Environmental Science and Management from the University of California at Santa Barbara, an M.S. degree in Geology from San Diego State University, and his B.S. degree in Chemistry from the University of California at Santa Barbara. He has over 40 years of experience using innovative environmental assessment techniques, has authored articles, national standards and book chapters on the subject, and has taught graduate level courses on related topics. Dr. Kram is an internationally recognized expert in site characterization and remediation, and has been instrumental in the areas of sensor development and implementation, innovative GIS applications, DNAPL site characterization, chemical field screening, well design, direct push well acceptance, mass flux/discharge based remediation performance, vapor intrusion, and groundwater basin yield and storage change assessment. Dr. Kram has patented inventions for automated sensor based contouring and multivariate analyses, automatic determination of groundwater basin storage change, water sustainability to protect from basin overdraft, seawater intrusion and stream depletion, and for in-situ measurement of groundwater contaminant flow rates and directions. Dr. Kram is credited with demonstrating that direct push monitoring wells perform as well as drilled wells, and his related published efforts served as critical ITRC, ASTM and regulatory references that resulted in industry and agency cost savings exceeding tens of millions per year. Dr. Kram is also credited with being the first to detect DNAPL source zones using induced fluorescence via direct push techniques. Dr. Kram has been featured in Forbes, is an active member of the National Ground Water Association (NGWA), American Society of Testing and Materials (ASTM Subcommittees D18.21 and E50.02; Chair of D18.21 on Groundwater and Vadose Zone Investigations), and the Interstate Technology Regulatory Council (ITRC), and is currently preparing national guidance for vapor intrusion and environmental characterization applications for ASTM, ITRC, and the Association of Vapor Intrusion Professionals (AVIP). Dr. Kram co-chaired an ASTM International symposium on continuous soil vapor chemical measurements, served as Editor for the ASTM International book entitled "*Continuous Soil Gas Measurement: Worst Case Risk Parameters*" (http://www.astm.org/BOOKSTORE/PUBS/STP1570.htm), is the recipient of the NGWA's prestigious Technology Award, and received the 2014 ASTM Committee D18 Technical Editors Award. Dr. Kram has also served as an expert witness on several high profile legal cases involving disputes surrounding groundwater quality and volatile contaminant emissions.

DR. KRAM'S 'INDUSTRY FIRSTS' (SELECTED):

1) Demonstrated how direct push wells perform as well as drilled wells (chemistry and hydraulics), and helped gain global approval for use of direct pushed wells for long term monitoring.
2) First to integrate sensors and GIS to automatically generate geospatiotemporal characterizations and responses.
3) First to directly locate Dense Non-Aqueous Phase Liquid source zones using optimized fluorescence.
4) First to automatically track changes in aquifer storage over time and space.
5) Part of team to first directly locate Light Non-Aqueous Phase Liquid source zones using fluorescence.
6) First to use direct push techniques (e.g., high resolution piezocone) to characterize hydrogeologic parameters (gradient, hydraulic conductivity, Darcy velocity, etc.).
7) First to use direct push techniques to generate solute mass flux and discharge distributions.
8) First to use sensors to automatically generate solute mass flux and discharge distributions.

9) Part of team to first document earth "breathing" and develop regulatory implications regarding vapor intrusion.
10) Part of team to first automate responses to acute vapor intrusion exposure risks.
11) Part of team to first use sensors and game theory for automated water resource sustainability management.
12) Part of team to first use machine learning to predict groundwater levels.
13) Part of team that discovered how barometric pumping influences bioremediation kinetics.
14) Part of team to first deploy gas chromatography for determining cannabis odor threshold.
15) First to develop building-specific vapor intrusion models to predict indoor air concentrations based on empirical correlations between climatic factors and indoor concentration measurements, machine learning, and NOAA climate records.
16) Part of team to demonstrate how groundwater extractions can impair Public Trust surface water resources (precedent-setting legal case in California).

Profound discoveries revealed through Dr. Kram's multivariate analytical monitoring include: bioremediation kinetics (allows practitioners to predict longevity of contaminant risks) where barometric pressure patterns correlate with microbial activity, barometric pressure patterns influence vapor intrusion risk, and the importance of differential pressure on vapor intrusion exposure intensity and duration. These are having significant financial, regulatory and legal impacts on the environmental industry.

MARK KRAM'S
UNITED STATES AND INTERNATIONAL PATENTS:

1. 6,208,940, March 27, 2001, Cone Tipped Cylindrical Probe For Use In Groundwater Testing, **Kram, Mark L**., Santa Barbara, California, Massey, James A., Ventura, California, The United States of America as represented by the Secretary of the Navy, Washington, District of Columbia, United States Government.

2. 6,235,941, May 22, 2001, Cone Tipped Cylindrical Probe For Use In Groundwater Testing, **Kram, Mark L**., Santa Barbara, California, Massey, Auldin James, Ventura, California, The United States of America as represented by the Secretary of the Navy, Washington, District of Columbia, United States Government.

3. 6,317,694, November 13, 2001, Method And Apparatus For Selecting A Sand Pack Mesh For A Filter Pack And Well Casing Slot Size For A Well, **Kram, Mark L.**, Santa Barbara, California, Farrar, Jeffrey A., Littleton, Colorado, The United States of America as represented by the Secretary of the Navy, Washington, District of Columbia, United States Government.

4. 6,915,211, July 5, 2005, GIS Based Real-Time Monitoring and Reporting System, **Kram, Mark L.**, Sirivithayapakorn, Sanya, Beighley, Edward.

5. 7,227,139, June 5, 2007, System And Method For Optical Detection Of Petroleum And Other Products In An Environment, **Kram, Mark L.**, Laverman, Leroy E.

6. 8,892,221, November 18, 2014, Integrated Resource Monitoring System with Interactive Logic Control**, Kram, Mark L. and Loaiciga, Hugo** (overseas issues initiated; NZ: 584482).

7. Submitted Application 09/10, Method and Apparatus for Groundwater Basin Storage Tracking, Remediation Performance Monitoring and Optimization, **Kram, Mark L** (overseas issues include NZ: 604020 and 700747; AU: 2011253144; Chile: 3147-2012).

8. BR 10 2019 014426 2, System with Multi-Way Valves for Gas Chromatography With Continuous Monitoring of Ambient Air and Vapors in the Soil, Negrao, Paulo, Hartman, Blayne, Kram, Mark L., and Frescura, Cliff, issued 9 April 2024.

NOTABLE EXPERT WITNESS EFFORTS:

Acosta, et al. *v.* Shell Oil, et al. (Case No: NC 053643)

Behar, et al. *v*. Northrup Grumman and Northrup Grumman Systems Corp. (Case No: 2:21-cv-03946)

Black, et al., v. Union Pacific Railroad (Case No: 6:23-cv-01218-EFM-ADM)

Bromley, et al. v. Amphenol Corp., et al., Marion County Superior Court (Case No: 49D02-1912-CT-050268)

California Coastkeeper Alliance *v*. County of Sonoma (Case No:SCV-268718)

City of Bethany, Oklahoma *v.* Rockwell Automation, Inc. and Gulfstream Aerospace Corp. (Case No: 5:16-cv-01005-PRW)

Denney, et al. v. Amphenol Corp., et al., United States District Court for the Southern District of Indiana (Case No: 1:19-cv-04757)

Shank, et al. v. Amphenol Corp., et al., Marion County Superior Court (Case No: 49D02-2010-CT-037131)

LEGAL CLIENTS HAVE INCLUDED:

California Coastkeeper Alliance
Cooper & Lewand-Martin
Environmental Energy & Natural Resources Advocates
Girardi & Keese
Lanier Law Firm, PC
Marc Chytilo, APC
Nidel & Nace, P.L.L.C.
Shute, Mihaly & Weinberger, LLC
Sycamore Law
Weitz & Luxenberg, PC

DR. MARK KRAM'S PUBLICATIONS

Bartlett, S.A., Robbins, G.A., Mandrick, J.D., Barcelona, M.J., McCall, W., and **Kram, M.L.**, 2004, Comparison of Hydraulic Conductivity Determinations in Direct Push and Conventional Wells, Naval Facilities Engineering Service Center Technical Report, TR-2252-ENV, October, 2004, 88pp.

Girty, Gary H. and **Mark L. Kram**, 1988. *Are Paleozoic Thrust Faults in the Shoo Fly Complex, Sierra Nevada, Related to the Antler Orogeny in Nevada?* Geological Society of America, Abstracts With Programs, Proceedings of the 84th Annual Meeting of the Cordilleran Section, Las Vegas, Nevada, March 29-31, 1988.

Hartman, B., **M. Kram**, and C. Frescura, 2019. Helping Lenders Resolve the Vapor Intrusion Pathway Within Days, *Environmental Bankers Association Newsletter*, January, 2019, p.16-17.

Hosangadi, V., B. Hartman, M. Pound, **M. Kram**, C. Frescura, B. Shavers, 2017. *High Frequency Continuous Monitoring To Track Vapor Intrusion Resulting From Naturally Occurring Pressure Dynamics*, Journal of Remediation, Spring, v.27, no.2, p.9-25.

James Jacobs, **Kram, Mark L**., and Stephen H. Lieberman, 2000. *Direct Push Technology Sampling Methods* in Standard Handbook of Environmental Science, Health, and Technology, Jay Lehr, ed., McGraw-Hill, 2000, pp.11.151 – 11.176.

Keller, Arturo A., Sanya Sirivithayapakorn, **Mark L. Kram**, and Michael Joy, 2000. *Innovative Treatment of MTBE in Groundwater, Soil and Air: A Case Study*, Soil Sediment and Groundwater, March 2000, pp. 92 - 93.

Keller, Arturo A., Britta Bierwagon, Sanya Sirivithayapakorn, and **Mark L. Kram**, 1999. *Advances in Groundwater Treatment to Remove MTBE*, Hazardous and Industrial Wastes, Proceedings of the Thirty-First Mid-Atlantic Industrial and Hazardous Waste Conference, pp. 199-208.

Keller, Arturo A. and **Mark L. Kram**, 1999. *Use of Laser Induced Fluorescence to Detect DNAPL and Fluorophore Mixtures In-Situ*, Proceedings of the XXVIII IAHR Congress, Graz, Austria, 22-27 August, 1999, p.6.

Keller, Arturo A., Sanya Sirivithayapakorn, and **Mark L. Kram**, 1999. *Remediation of MTBE-Contaminated Water and Soil*, Remediation, Winter 1999, pp. 55 - 68.

Keller, Arturo A. and **Mark L. Kram**, 1998. *Use of Fluorophore/DNAPL Mixtures to Detect DNAPLs In-Situ*, in Nonaqueous-Phase Liquids, Remediation of Chlorinated and Recalcitrant Compounds, Battelle Press, eds. Godage B. Wickramanayake and Robert E. Hinchee, pp.131-136.

Koglin, Eric N., Edward J. Poziomek, and **Mark L. Kram**, 1994. *Emerging Technologies for Detecting and Measuring Contaminants in the Vadose Zone* in Vadose Zone Characterization and Monitoring: Principles, Methods, and Case Studies, 896 pp., Lewis Publishers.

Kram, M. L. and R. Solgi, 2025. *Empirically-Derived Building-Specific Learning Models for Predicting Occupant Vapor Intrusion Exposures*, v.35, issue 2.

Kram, M. L., B. Hartman, M. Lahvis, B. Kahl, and G. DeVaull, 2025 (in review). *Empirical Building Specific Attenuation Factor Determination via Continuous Monitoring of Chemical and Physical Parameters*, in review.

Kram, Mark L., Hugo Loaiciga, Mark Widdowson, Eduardo Mendez, Ryan Solgi and Michael Lamar, 2023. "*Resolving the Water Crisis: There's a Way, But Is There the Will?*", Groundwater, v.61, issue 5, p.617-625; http://dx.doi.org/10.1111/gwat.13310

Kram, Mark L., Blayne Hartman, Cliff Frescura, 2022. "*Simultaneous Monitoring of VOC Concentration and Controlling Factors for VI Risk Evaluations – 2 Select Cases*", Remediation, v.32, issue 4, p.259-272.

Kram, Mark L., Blayne Hartman, Cliff Frescura, Paulo Negrao and Dane Egelton, 2020. "*Vapor Intrusion Risk Evaluation Using Automated Continuous Chemical and Physical Parameter Monitoring* ", Remediation, v.30, p.65-74.

Kram, Mark L., Blayne Hartman, and Nova Clite, 2019. "*Automated Continuous Monitoring and Response to Toxic Subsurface Vapors Entering Overlying Buildings – Selected Observations, Implications and Considerations*", Remediation, v.29, p.31–38.

Kram, Mark L., Lorne Everett and Arturo Keller, 2019*."Comments in Response to "DyeLIF™: A New Direct-Push Laser-Induced Fluorescence Sensor System for Chlorinated Solvent DNAPL and Other Non-Naturally Fluorescing NAPLs""*, Ground Water Monitoring and Remediation, Winter 2019, v.39, issue 1, p.73-74, DOI: https://doi.org/10.1111/gwmr.12313.

Kram, Mark L., Blayne Hartman, and Clifford Frescura, 2016. *Vapor Intrusion Monitoring Method Cost Comparisons: Automated Continuous Analytical vs. Discrete Time-Integrated Passive Approaches*, Journal of Remediation, Fall 2016, v.26, issue 4, p.41-52.

Kram, Mark L., 2016. *The Emperor's Old Cloths Revisited*, Guest Editorial Ground Water Monitoring and Remediation, Spring 2016, v.36, issue 2, DOI: 10.1111/gwmr.12150

Kram, Mark L., 2015. *The Emperor's Old Clothes: An Inconvenient Truth About Currently Accepted Vapor Intrusion Assessment Methods*, Guest Editorial, Ground Water Monitoring and Remediation, Fall 2015, v.35, issue 4, DOI: 10.1111/gwmr.12140.

Kram, Mark L., Peter Morris and Lorne G. Everett, 2013, *Dynamic Subsurface Explosive Vapor Concentrations,* in D18 Symposium on Continuous Soil Gas Measurements: Worst Case Risk Parameters, Eds.: Mark Kram and Lorne Everett, Special Technical Publication #1570.

Kram, Mark L., Peter Morris and Lorne G. Everett, 2011. *Dynamic Subsurface Explosive Vapor Concentrations – Observations and Implications*, Remediation Journal, Winter 2011, v.22, issue 1, p.59-69.

Kram, Mark L., Steve Airhart, Daniel Tyler, Amy Dindal, Andrew Barton, John L. McKernan, and Gregg Gustafson, 2011. *Web-Based Automated Remediation Performance Monitoring and Visualization of Contaminant Mass Flux and Discharge*, Remediation Journal, Summer 2011, v. 21, issue 3, p.89-101.

Kram, Mark L., Steve Airhart and Daniel Tyler, 2011. *Automated Monitoring and Visualization of Groundwater and Surface Water Interactions*, Sixth International Conference on Remediation of Contaminated Sediments (New Orleans, Louisiana; February 2011).

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Served as technical reviewer or contributing author for numerous additional reports, standards, books, and publications including the following:

ASTM D5088, *Standard Practice for Decontamination of Field Equipment Used at Nonradioactive Waste Sites*. Annual Book of ASTM Standards, v.04.08.

ASTM D5092, *Standard Practice for Design and Installation of Ground Water Monitoring Wells in Aquifers*. Annual Book of ASTM Standards, v.04.08.

ASTM D6001, *Standard Guide for Direct-Push Water Sampling for Geoenvironmental Investigations*. Annual Book of ASTM Standards, v.04.08.

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ASTM E2993, *Standard Practice for Evaluating Potential Hazard as a Result of Methane in the Vadose Zone*, Subcommittee E50 on Real Estate Assessment and Management.
ASTM WK#45360, *Standard Guide for the Development of Long-Term Monitoring Plans for Vapor Mitigation Systems*, in draft.
ASTM WK#57579, *Standard Practice for Environmental Site Assessments: Phase II Environmental Site Assessment Process*, revision of E1903, in draft.
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DR. MARK KRAM'S DISTINGUISHED THESIS COMMITTEE MEMBERS

Ph.D., Environmental Science and Management, University of California at Santa Barbara
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Dr. Arturo Keller; https://bren.ucsb.edu/people/arturo-keller
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M.S., Geological Sciences, San Diego State University
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DR. KRAM HAS SERVED ON MULTIPLE THESIS COMMITTEES, INCLUDING

Jan Bumberger, Ph.D., UFZ Helmholtz (Advisor, Dr. Hannes Topfer) - "Evaluation, Analysis, and Optimization of Direct-Push Sensor Systems", 2011.

Andrew D. Frazier, M.S., Virginia Tech (Advisor, Dr. Mark Widdowson) - "Groundwater Modeling of Managed Aquifer Recharge at the Regional and Local Scale", 2022.

Attachment 4

September 27, 2024

University of California, San Francisco

CURRICULUM VITAE

GENERAL INFORMATION

Name: George W. Rutherford, M.D., A.M., FAAP, FACPM, FIDSA, FRSM

Position: Professor Emeritus
Department of Epidemiology and Biostatistics
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Professor Emeritus of Epidemiology, Preventive Medicine, Pediatrics and History

Professor Emeritus, Department of Pediatrics (secondary)
Professor Emeritus, Department of Family and Community Medicine (secondary)
ProfessorvEmeritus, Department of Humanities and Social Sciences (secondary)
Adjunct Professor, School of Public Health, University of California, Berkeley (secondary)

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EDUCATION

1970-74	Stanford University, Stanford, CA	A.B.	Classics
1970-75	Stanford University, Stanford, CA	B.S.	Chemistry
1974-75	Stanford University, Stanford, CA	A.M.	History
1975-78	Duke University, Durham, NC	M.D.	Medicine
1978-79	University of California Medical Center, San Diego, CA	Intern (PL-1)	Pediatrics
1979-80	University of California Medical Center, San Diego, CA	Resident (PL-2)	Pediatrics

1980-81	Hospital for Sick Children, Toronto, Ontario	Resident (PL-3)	Paediatrics
1981	Children's Hospital and Health Center, San Diego, CA	Chief Resident (PL-4)	Pediatrics
1982	University of California Medical Center, San Diego, CA	Chief Resident (PL-4)	Pediatrics
1982-83	Epidemiology Office, Division of Viral Diseases, Center for Infectious Diseases, Centers for Disease Control, Atlanta, GA	EIS Officer	Epidemiology
1983-84	Division of Field Services, Epidemiology Program Office, Centers for Disease Control, Atlanta, GA	EIS Officer	Epidemiology
1994-95	Public Health Leadership Institute, Berkeley, CA	Scholar	Leadership
2001	American Society for Tropical Medicine and Hygiene, Intensive Review Course in Clinical Tropical Medicine and Travelers' Health, San Francisco, CA	Attendee	Clinical Tropical Medicine

LICENSES, CERTIFICATIONS

1979	Certified, National Board of Medical Examiners
1979	Physician's and Surgeon's License, California (G40928)
1980	College of Physicians and Surgeons of Ontario Educational License (O18976)
1983	Medicine and Surgery License, New York (157120-1)
1983	Certified, American Board of Pediatrics
1985	Fellow, American Academy of Pediatrics
1997	Certified, American Board of Preventive Medicine (Public Health and General Preventive Medicine)
1998	Fellow, Infectious Diseases Society of America
1998	Fellow, American College of Preventive Medicine

PRINCIPAL POSITIONS HELD

1983-85	Director, Division of Immunization, and Acting Director, Division of Tropical Diseases, Bureau of Preventable Diseases, New York City Department of Health, New York, NY
1984-85	Medical Epidemiologist, Division of Field Services, Epidemiology Program Office, Centers for Disease Control, Atlanta, GA (assigned to New York City Department of Health)
1985-86	Chief, AIDS Division, Bureau of Communicable Disease Control, San Francisco Department of Public Health, San Francisco, CA

1985-87	Medical Epidemiologist, AIDS Program, Center for Infectious Diseases, Centers for Disease Control, Atlanta, GA (assigned to San Francisco Department of Public Health)
1986-90	Director, AIDS Office, San Francisco Department of Public Health, San Francisco, CA
1990-92	Chief, Infectious Disease Branch, and State Epidemiologist, California Department of Health Services, Berkeley, CA
1992-95	Deputy Director, Prevention Services, and State Epidemiologist, California Department of Health Services, Berkeley, CA
1993-95	State Health Officer, California Department of Health Services, Berkeley, CA
1995-97	Associate Dean and Adjunct Professor of Epidemiology and Health Administration, School of Public Health, University of California, Berkeley, Berkeley, CA
1996-now	Director, Joint UCB-UCSF Residency Program in General Preventive Medicine and Public Health, School of Medicine, University of California, San Francisco, and School of Public Health, University of California, Berkeley
1997-now	Adjunct Professor (1997-2002), Professor in Residence (2002-2010); Professor (2010-now); Head, Division of Epidemiology and Prevention (1999-2001); Head, Division of Preventive Medicine and Public Health (2001-2013); Head, Division of Infectious Disease Epidemiology (2013-now); Salvatore Pablo Lucia Professor (2000-now), Vice Chair (2003-2018), Department of Epidemiology and Biostatistics, School of Medicine, University of California, San Francisco, San Francisco, CA
1998-2016	Director, Global Response Core, Center for AIDS Prevention Studies, University of California, San Francisco, San Francisco, CA
2002-2013	Director, Institute for Global Health, University of California, San Francisco, San Francisco, CA
2005-2021	Director, Prevention and Public Health Group, Institute for Global Health Sciences, University of California, San Francisco, San Francisco, CA
2010-2021	Director, Global Strategic Information, Institute for Global Health Sciences, University of California, San Francisco, San Francisco, CA
2021-now	Director, Center for Global Strategic Information and Public Health Practice, Institute for Global Health Sciences, University of California, San Francisco, San Francisco, CA
2021-2022	Acting Executive Director, Institute for Global Health Sciences, University of California, San Francisco, San Francisco, CA
2023-2024	Interim Executive Director, Institute for Global Health Sciences, University of California, San Francisco, San Francisco, CA

OTHER POSITIONS HELD CONCURRENTLY

1981	Transport Physician, Pediatric and Surgical Intensive Care Unit Children's Hospital and Health Center, San Diego, CA
1982-1983	Clinical Assistant Professor of Pediatrics Emory University, Atlanta, GA
1982-2010	Lieutenant (1982-83), Lieutenant Commander (1983-87), Commander (1987-93) (Active Reserve), Captain (1993-2010), U.S. Public Health Service Reserve
1984-1985	Clinical Assistant Professor of Pediatrics Cornell University, New York, NY

1986-now Assistant Clinical Professor (1986-92), Associate Adjunct Professor (1992-96), Professor and Attending Physician (1997-now) of Pediatrics and Pediatric Infectious Diseases, University of California, San Francisco, San Francisco, CA

1987-1997 Assistant Clinical Professor (1987-92), Associate Adjunct Professor (1992-95), Adjunct Professor of Epidemiology (1996-97), University of California, San Francisco, San Francisco, CA

1988-1990 Assistant Clinical Professor of Family and Community Medicine, University of California, San Francisco, San Francisco, CA

1990-1993 San Francisco Men's Health Study, Co-Investigator

1991-1995 Associate Clinical Professor of Community Health, University of California, Davis, Davis, CA

1997-now Adjunct Professor of Epidemiology and Health Administration, School of Public Health, University of California, Berkeley, Berkeley, CA

1997-2014 Coordinating Editor, Cochrane Collaborative Review Group on HIV Infection and AIDS

1997-2006 Senior Advisor on Public Health, California HealthCare Foundation, Oakland, CA

1999-2002 Senior Advisor, Institute for Global Health, University of California, San Francisco, San Francisco, CA

2000-2009 Research Director, Department of Emergency Medicine, Children's Hospital Oakland, Oakland, CA

2004-2021 Member, Haile T. Debas Academy of Medical Educators, University of California, San Francisco, San Francisco, CA

2005 Visiting Professor, University of Vermont, Burlington, VT

2006-2007 Visiting Professor, Andrija Štampar School of Public Health, University of Zagreb, Croatia

2006 Reviewer, U.S. Civilian Research and Development Foundation for the Independent States of the Former Soviet Union, Arlington, VA

2007-now Professor, Department of Anthropology, History and Social Medicine, School of Medicine, University of California, San Francisco, San Francisco, CA

2009-2012 Reviewer, Wellcome Trust, London, UK

2010 Reviewer, TREAT Asia HIV Observational Database, Bangkok, Thailand, and International Epidemiology Databases to Evaluate AIDS (IeDEA), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD

2013 Visiting Professor, Universidade Federal de Espirito Santo, Vitória, Brazil

2013 Visiting Professor, Universidade Federal de Sergipe, Aracajú, Brazil

2014-now Deputy Editor, Cochrane Infectious Disease Group

2015-now Visiting Professor, Andrija Štampar School of Public Health, University of Zagreb, Croatia

2016 Visiting Professor, School of Public Health of National University Kyiv-Mohyla Academy, Odessa, Ukraine

2021-now Sustaining Member, Haile T. Debas Academy of Medical Educators, University of California, San Francisco, San Francisco, CA

2022-now Member, Steering Group, John Snow Society

2022-now Member, Board of Directors, Wellness Equity Alliance

2022-23 Honorary Professor, London School of Hygiene and Tropical Medicine, London, UK

CONSULTANCIES

1987 The Pathfinder Fund, Brasilia and Recife, Brazil
1995 Association of State and Territorial Health Officials
1998-1999 Massachusetts Water Resources Agency (for Foley, Hoag & Eliot, LLP)
1998-1999 Pima County, Arizona County Attorney's Office
2001 Center for Health Leadership and Practice
2001-2002 Exponent, Inc.
2001-2004 Nancy Porter Productions
2001 The California Endowment
2001-2002 Touchstone Television
2002-2003 Orrick, Herrington & Sutcliffe, LLP (for American Home Products)
2002 University of Cape Town, South Africa
2002-now World Health Organization
2003 2005 Los Angeles County Department of Health Services
2003-2004 Maranga, Morgenstern, LLP (for Los Angeles County Department of Health Services)
2004 Milbank Memorial Fund
2004 The Degge Group, Ltd. (for Roche Pharmaceuticals)
2005-now Common Sense Media
2006-now Blood Systems Research Institute, Inc.
2006 Glaxo Smith Kline
2008-now Educate Girls Globally
2018 Malaysian AIDS Control Commission
2019 United States District Court, Central District of California (the Honorable Dolly M. Gee)
2020 Archdiocese of San Francisco
2020 Artisan Partners
2020 California Institute of Technology
2020-2021 California Department of Justice
2020-2021 Canaccord Genuity
2020 COVID-Watch
2020-now Dechert LLP
2020 Escuela Bilingüe Internacional
2020 Ethyl Walker School
2020 Fine Arts Museums of San Francisco
2020 Foster Farms
2020-2022 Golden State Warriors
2020 Hardly Strictly Bluegrass
2020 Interamerican Development Bank
2020 Latin American Development Bank
2020-now Medallia, Inc.
2020 Menlo College
2020 Milbrook School

2020 Myovant, Inc.
2020-2022 Piedmont Unified School District
2020 PreDxion Bio
2020 Private Medical
2020 Seacoast Capital
2020 San Francisco Exploratorium
2020-now San Francisco Hotel Council
2020-now San Francisco Opera
2020-now Sonoma Writers' Festival
2020 Tassajara Zen Center
2020 U.S. Rowing
2020 ZS Associates
2021 Community Hospital of the Monterey Peninsula
2021 Dechert LLP
2021 Samsung, Inc.
2021 West Contra Costa School District
2022 Princeton University COVID Scientific Advisory Committee
2024 City of Pasadena
2024 Kirkland and Ellis, LLP

HONORS AND AWARDS

1984 Foreign Duty Service Ribbon, United States Public Health Service
1998 Distinguished Alumnus Award, The Bishop's School, La Jolla, California
2000 Salvatore Pablo Lucia Chair in Preventive Medicine, University of California, San Francisco
2000 Eileen K. Taw, M.D., Memorial Public Health Lecturer, Riverside County Department of Public Health, Riverside, California
2000 Excellence in Teaching Award, California Department of Health Services, Preventive Medicine Residency Program
2000 Salvatore Pablo Lucia Symposium Lecturer, University of California, San Francisco
2002 Excellence in Research Award (Clinical), Children's Hospital Oakland Research Institute Annual Research Symposium
2002 F. Marian Bishop Educator of the Year Award, Association of Teachers of Preventive Medicine
2002 Excellence in Teaching Award, California Department of Health Services, Preventive Medicine Residency Program
2004 Member, Haile T. Debas Academy of Medical Educators, UCSF
2009 Holly Smith Award for Exceptional Service to the School of Medicine, University of California, San Francisco
2010 Fellow, Royal College of Medicine
2011 Lifetime National Associate, National Research Council, National Academy of Sciences
2021 Piedmont Citizen of the Year, *Piedmont Post*
2021 Commendation for Exceptional Volunteerism and University Service, University of California, San Francisco

2021 Chancellor's Award for Public Service (Faculty Category)
2021 White Coat Ceremony Speaker, University of California, San Francisco
2022 Salvatore Pablo Lucia Symposium Panelist, University of California, San Francisco
2023 Grand Marshall, Piedmont Fourth of July parade

KEYWORDS/AREAS OF INTEREST

HIV infection/epidemiology, HIV infection/prevention & control, public health, low- and middle-income countries, AIDS-related opportunistic infections/epidemiology, systematic reviews, meta-analysis, tuberculosis, coccidioidomycosis, immunization, bioterrorism/prevention & control, evidence-based medicine, preventive medicine, tropical medicine, coronavirus, Zika virus, Ebola virus, SARS-CoV-2 infection, COVID-19

CLINICAL ACTIVITIES

CLINICAL ACTIVITIES SUMMARY

As a member of the faculty in the Division of Pediatric Infectious Diseases, I attend monthly journal clubs; teach faculty, fellows, residents and students research methods; mentor fellows' research projects. As an attending physician in the Division of Emergency Medicine at UCSF Benioff Children's Hospital Oakland, I taught fellows research methods and mentored fellows' and junior faculty member's research projects.

CLINICAL SERVICES

Attending physician, Pediatric Infectious Disease Service, UCSF
Attending physician, Department of Emergency Medicine, UCSF Benioff Children's Hospital Oakland

PROFESSIONAL ACTIVITIES

PROFESSIONAL ORGANIZATIONS

MEMBERSHIPS

1975-2015 American Association for the History of Medicine
1980-2015 American Society of Tropical Medicine and Hygiene
1984-now American Academy of Pediatrics (Fellow)
1990-now Section on Epidemiology
1995-now Section on Infectious Diseases
1984-2010 Section on Uniformed Services
1984-now American Public Health Association
1985-95 Bay Area Communicable Disease Exchange
1987-2009 California Medical Association
1987-now California Public Health Association - North
1987-now Infectious Diseases Society of America (Fellow)
1987-1990 Northern California AIDS Epidemiology Consortium
1987-1990 San Francisco Medical Society
1988-now International AIDS Society
1989-now Society for Epidemiologic Research
1989-1995 Society for Pediatric Epidemiologic Research
1990-1995 California/Baja California Binational Health Council
1990-1995 Conference of State and Territorial Epidemiologists
1990-1995 Southern California Public Health Association
1990-1995 United States-Mexico Border Health Association
1991-1995 AIDS and Reproductive Health Network

1991-2008 Alameda-Contra Costa Medical Association
1991-now Bay Area Infectious Disease Society
1993-now Association of State and Territorial Health Officials
1994-now California Academy of Preventive Medicine
1996-now American College of Preventive Medicine (Fellow)
1996-2009 Association of Teachers of Preventive Medicine
1996-2001 American College of Physician Executives
2002-now John Snow Society
2004-now Global Health Council
2008-now Royal Society of Medicine (Overseas fellow)

SERVICE TO PROFESSIONAL ORGANIZATIONS

1987-90 American Academy of Pediatrics, California Chapter 1Member, Committee on Infectious Diseases
1987-90 San Francisco Medical Society, AIDS Task Force
1988-now International AIDS Society, Local Organizing Committee and Epidemiology and Prevention Subcommittee (Co-Chair, 1988-90); International Programme Committee (1989-90), International Scientific Committee (1995-96, 1998, 2000); International Scientific Advisory Committee (2001-02), International Abstract Review Committee (2004, 2006, 2008, 2010, 2012, 2014, 2016, 2018, 2020, 2022, 2024)
1988-89 Northern California AIDS Epidemiology Consortium, President
1993-95 U.S.-Mexico Border Health Association, Co-President, State Health Officers Group
1994-95 Association of State and Territorial Health Officials, Committee on Federal Health Care Reform, Work Group on the Future of Public Health
1994-95 Association of State and Territorial Health Officials, HIV Committee
1994-95 Immunizations Committee, Association of State and Territorial Health Officials
1995-2008 American Academy of Pediatrics Member (1995-99) and Chair (2004-2008), Section on Epidemiology Executive Committee (2004-08)
1995-2001 California Academy of Preventive Medicine, Board Member, President-Elect (1996), President (1997-98), Immediate Past President (1998-99), Nominating Committee (2000-01)
1995-2008 California Medical Association, Scientific Advisory Board on Preventive Medicine and Public Health; Technical Advisory Committee on HIV (1997-2008)
1996-2008 Public Health Committee, Alameda-Contra Costa Medical Association
1996-now American College of Preventive Medicine and Association of Teachers of Preventive Medicine, Joint Preventive Medicine Residency Directors Council
1998-now American College of Preventive Medicine, Graduate Medical Education Committee
2001-04 Annual Meeting Planning Committee, Public Health Practice Subcommittee (Vice Chair, 2002-03), American College of Preventive Medicine
2001 Infectious Diseases Society of America and HIV Medical Association, Chair, Session on What are Suitable Monitoring Approaches? Conference to Develop an HIV/AIDS Therapeutic Research Agenda in Resource-Limited Countries
2004-2006 National HIV/AIDS Clinicians Consultation Center, Advisory Committee

2014-now California Public Health Leadership Forum
2018-now John Snow Society, President, Northern California Chapter
2020-now International Antiviral Society-USA, Podcast speaker
2022-now John Snow Society, Member, Board of Directors

SERVICE TO PROFESSIONAL PUBLICATIONS

1988-now *Ad hoc* referee for *African Journal of AIDS Research, AIDS, AIDS and Behavior, AIDS Research and Human Retroviruses, American Journal of Epidemiology, American Journal of Preventive Medicine, American Journal of Public Health, American Journal of Tropical Medicine and Hygiene, Annals of Internal Medicine, Annals of Neurology, Archives of Industrial Medicine and Toxicology, BMC Health Services Research, BMC Infectious Diseases, BMC Public Health, BMJ, Clinical Evidence, Clinical Infectious Diseases, Collegium Anthropologium, Drug and Alcohol Dependence, Emerging Infectious Diseases, Environmental Health Perspectives, European Journal of Epidemiology, Expert Review of Anti-Infective Therapy, Global Public Health, Hastings Law Journal, Health Affairs, International Journal of Dermatology, International Journal of Epidemiology, International Journal of Environmental Research and Public Health, International Journal of Gynaecology and Obstetrics, International Journal for Quality in Health Care, Iranian Journal of Pediatrics, JAMA Pediatrics, Journal of the Acquired Immune Deficiency Syndromes, Journal of the American Medical Association, Journal of General Internal Medicine, Journal of the National Medical Association, Journal of Rural Health, Journal of Urban Health, Lancet, Lancet HIV, Lancet Infectious Diseases, Medical Care, New England Journal of Medicine, Paediatric and International Child Health, Pediatric Infectious Disease Journal, Pediatrics, PLoS Medicine, PLoS One, Revista Brasileira de Psiquiatría, Systematic Reviews, Traffic Injury Prevention, Transactions of the Royal Society of Tropical Medicine and Hygiene, Tropical Medicine and International Health, Virus Research, Western Journal of Medicine*

1988-1995	*California AIDS Update*	Editorial Board
1990-1992	*California Morbidity*	Editor in Chief
1993-9197	*Current Reviews in Public Health*	Section Editor
1994-now	*SIDA: Revista Cientifica de Información Nacional e Internacional (Argentina)*	Editorial Board
1997-2016	*Cochrane Collaborative Review Group on AIDS and HIV Infection*	Coordinating Editor
1997-now	*HIV InSite*	Contributing Editor
2002-now	*Jornal Brasileiro de Doenças Sexualmente Transmissiveis*	International Scientific Committee
2003-now	*Evidence-Based Preventive Medicine*	Honorary Editorial Board
2004-now	*Global Public Health*	International Advisory Board
2006-now	*LiveMed Journal HIV/AIDS*	Editorial Board
2010-now	*Research and Reports in Tropical Medicine*	Editorial Board

2016-now	Cochrane Infectious Disease Group	Associate Editor
2022-now	*East African Journal of Applied Health Monitoring & Evaluation*	Editorial Board
2023-now	*International Journal of Public Health Science*	Editorial Board
2024-now	*Tropical Medicine and Infectious Diseases*	Editorial Board

INVITED PRESENTATIONS

INTERNATIONAL

1985 International Conference on AIDS, Atlanta, Georgia
1986 International Conference on AIDS, Paris, France
1987 Caring for AIDS Sufferers in the Community, University of London, London, UK, (plenary speaker)
1987 Congres de l'Association Canadienne-Francaise pour l'Avancement des Sciences, Ottawa, Canada
1987 International Conference on AIDS, Washington, D.C.
1987 Pan-American Teleconference on AIDS, Quito, Ecuador
1987 Simpôsio Nacional de Reprodução Humana, Universidade de Brasília, Brasília, Brazil (plenary speaker)
1988 AIDS/ARC Update, University of British Columbia, Vancouver, Canada
1988 Congreso Nacional sobre el Sindrome de Inmunodeficiencia Adquirida, Mexican Ministry of Health, Cocoyoc, Mexico
1988 International Conference on AIDS, Stockholm, Sweden (reviewer and moderator)
1988 Pan-American Teleconference on AIDS, Rio de Janeiro, Brazil
1988 Symposium on the Economic Impact of HIV Infection, McGill University, Montreal, Canada
1989 Congresso Brasileiro de Pediatria, Recife, Brazil
1989 Consultation on Partner Notification for Preventing HIV Infection, World Health Organization, Geneva, Switzerland (rapporteur)
1989 International Conference on AIDS, Montreal, Canada (reviewer)
1989 Pan-American Teleconference on AIDS, Santo Domingo, Dominican Republic
1990 International Conference on AIDS, San Francisco, California (reviewer and moderator)
1990 International Symposium on AIDS and Reproduction, Università di Genoa, Genoa, Italy
1990 United States-Mexico Border Health Association Annual Meeting, Saltillo, Coahuila, Mexico
1991 International Conference on AIDS, Florence, Italy (reviewer and moderator)
1992 United States-Mexico Border Health Association Annual Meeting, Phoenix, Arizona
1992 International Conference on AIDS, Amsterdam, The Netherlands (reviewer)
1992 United States-Mexico Border Health Statistics Meeting, El Paso, Texas
1993 International Conference on AIDS, Berlin, Germany
1993 Primer Congreso Argentino sobre el SIDA, Universidad de Rosario, Rosario, Argentina

1994 Border Governors' Conference, Phoenix, AZ
1994 International Conference on AIDS, Yokohama, Japan
1994 United States-Mexico Border Health Association Annual Meeting, Ciudad Victoria, Tamulipas, Mexico
1996 International Conference on AIDS, Vancouver, Canada (reviewer and moderator)
1997 Cochrane Colloquium, Amsterdam, The Netherlands
1997 II Congresso Brasileiro de Prevenção das DST/AIDS (plenary speaker), Brasília, Brazil
1997 HIV Trialists' Collaborative Working Group, London, UK
1998 Cochrane Colloquium, Baltimore, Maryland
1998 Conference on Retroviruses and Opportunistic Infections, Chicago, Illinois
1998 International Conference on AIDS, Geneva, Switzerland (reviewer)
1999 Cochrane Colloquium, Rome, Italy
2000 Cochrane Colloquium, Cape Town, South Africa
2000 Conference on Retroviruses and Opportunistic Infections, San Francisco, California
2000 Curso Curto sobre Métodos de Pesquisa Clínica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil
2000 International Conference on AIDS, Durban, South Africa (reviewer)
2001 California-Mexico AIDS Initiative Consensus Meeting, Tijuana, Mexico
2001 Cochrane Colloquium, Lyon, France
2001 Conference on Retroviruses and Opportunistic Infections, Chicago, Illinois
2001 Global Forum for Health Research Forum 5, Geneva, Switzerland
2001 International Conference on AIDS in Asia and the Pacific, Melbourne, Australia
2002 Cochrane Colloquium, Stavanger, Norway
2002 Conference on Retroviruses and Opportunistic Infections, Seattle, Washington
2002 Curso Curto sobre Métodos de Pesquisa Clínica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil
2002 International Conference on AIDS, Barcelona, Spain (reviewer, rapporteur and Track D organizing committee)
2002 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Nairobi, Kenya
2003 Cochrane Colloquium, Barcelona, Spain
2003 Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts
2003 Curso Curto sobre Métodos de Pesquisa Clínica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil
2003 Encontro Gaúcho de Saúde Genital: Organizando Serviços Resolutivos de Atenção a Pessoas com DST, Porto Alegre, Brazil (keynote speaker)
2003 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Pretoria, South Africa
2003 Wilton Park conference on Financing Global Public Goods for Health, U.K Foreign and Commonwealth Office, Steyning, UK
2003 Workshop on Clinical Research Methods, University Hospital for Infectious Diseases and Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2004 Cochrane Colloquium, Ottawa, Canada
2004 Conference on Retroviruses and Opportunistic Infections, San Francisco, California

2004 Curso Curto sobre Análise de Dados e Redação Científica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Brazil
2004 International Conference on AIDS, Bangkok, Thailand (reviewer)
2004 New Strategies for HIV/AIDS surveillance in resource-constrained countries, Addis Ababa, Ethiopia (rapporteur)
2004 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Guatemala City, Guatemala
2004 South Asian Conference on Systematic Reviews, Christian Medical College, Vellore Vellore, India
2004 Wilton Park conference on Scaling Up Health Investments in Developing Countries: Lessons about what Works, U.K Foreign and Commonwealth Office, Steyning, UK
2004 Workshop on Clinical Research Methods, University Hospital for Infectious Diseases and Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2004 Workshop on Scientific Writing for HIV, Entebbe, Uganda
2005 Curso Curto sobre Análise de Dados e Redação Científica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Brazil
2005 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Accra, Ghana
2005 Seminário de Investiagación y controle de brotes de enfermedades infecciosas. Universidad Peruana Cayetano Heredia, Lima, Peru
2005 Strategic Information and Monitoring and Evaluation Field Officer Training for Southern Africa, National Centre for Infectious Diseases, Johannesburg, South Africa
2005 Vigilancia epidemiológica e intervenciones de salud pública para VIH/SIDA y ETS. Universidad Peruana Cayetano Heredia, Ministério de Salud de Perú, Instituto Nacional de Salud Peruano, Naval Medical Research Center, Lima, Peru
2005 Wilton Park conference on Improving the Effectiveness of Health Investments in Developing Countries: How is Performance-Based Funding Working? U.K Foreign and Commonwealth Office, Steyning, UK
2005 Workshop on Scientific Writing, University Hospital for Infectious Diseases and Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2005 Workshop on Scientific Writing for HIV, Entebbe, Uganda
2006 Cochrane Colloquium, Dublin, Ireland (plenary speaker)
2006 Biological HIV/AIDS Surveillance: New Concepts and Methods in Estimating Burden of Disease and Response to Treatment, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia
2006 International Conference on AIDS, Toronto, Canada (reviewer)
2006 Workshop on Scientific Writing, University Hospital for Infectious Diseases and Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2006 Workshop on Scientific Writing for HIV, Kampala, Uganda
2006 Workshop on Scientific Writing for HIV Bangkok, Thailand
2007 Curso Curto sobre Métodos de Pesquisa Clínica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

2007 Curso Curto sobre Métodos de Pesquisa Clínica, Universidade Federal de Bahia, Salvador, Bahia, Brazil, 2007
2007 Encontro da Associação Latino-Americana para Controle das DST, Porto Alegre, Brazil (plenary speaker)
2007 Triangulation Training Workshop for Analysis and Use of Strategic Information, Cavtat, Croatia
2007 Workshop on National Triangulation, Maputo, Mozambique
2007 Workshop on Revision of HIV Surveillance Training Manuals, WHO Eastern Mediterranean Regional Office, Cairo, Egypt
2007 Workshop on Scientific Writing for HIV, Kampala, Uganda
2008 Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts
2008 Curso Curto sobre Análise de Dados e Redação Científica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Brazil
2008 International Conference on AIDS, Mexico City, Mexico (reviewer)
2008 Leading Practices in Monitoring and Evaluation, KPMG Global Grants Program, New Delhi, India
2008 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Luxor, Egypt
2008 Public Health Surveillance for AIDS, HIV and Sexually Transmitted Infections, Cavtat, Croatia
2008 Workshop on National Triangulation, Maputo, Mozambique
2008 Workshop on Scientific Writing for HIV, Mombasa, Kenya
2008 Workshop on Size Estimation for Populations at Risk for HIV Infection, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia
2008 World Health Organization, Consultation on Prevention and Treatment of Malaria in Children with HIV, Geneva, Switzerland
2009 Africa Influenza Scientific Symposium, Johannesburg, South Africa
2009 New Strategies for HIV/AIDS surveillance in resource-constrained countries, Bangkok, Thailand, 2009 (rapporteur)
2009 Workshop on National Triangulation, Windhoek, Namibia
2009 Workshop on Monitoring and Evaluation of HIV/AIDS Public Health Programmes, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2009 Workshop on Scientific Writing for HIV, Mombasa, Kenya
2009 Workshop on Scientific Writing for HIV, Guatemala City, Guatemala
2009 Workshop on Scientific Writing for HIV, Morogoro, Tanzania
2009 Workshop on Scientific Writing for Influenza Surveillance, Johannesburg, South Africa
2009 World Health Organization, Consultation on Adult and Adolescent Antiretroviral Treatment Guidelines, Geneva, Switzerland
2009 World Health Organization, Consultation on Pediatric Antiretroviral Treatment Guidelines, Geneva, Switzerland

2009 World Health Organization, Consultation on Prevention of Mother-to-Child Transmission of HIV, Geneva, Switzerland
2009 World Health Organization, Consultation on Prevention and Treatment of Diarrhoea and Pneumonia in Children with HIV, Geneva, Switzerland
2010 Curso Curto sobre Análise de Dados e Redação Científica, Centro de Estudos de AIDS de Rio Grande do Sul, Porto Alegre, Brazil
2010 Triangulation Training Workshop for Analysis and Use of Strategic Information, Moscow, Russia
2010 Workshop on National Triangulation, Dar es Salaam, Tanzania
2010 International Conference on AIDS, Vienna, Austria (reviewer and moderator)
2010 Workshop on Advanced HIV Surveillance Methods, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health Cavtat, Croatia
2010 Workshop on Scientific Writing for HIV, Kampala, Uganda
2010 Workshop on Scientific Writing, University Hospital for Infectious Diseases and Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia
2010 Workshop on Scientific Writing for HIV, Nairobi, Kenya
2010 Workshop on Scientific Writing for Influenza Surveillance, Nairobi, Kenya
2011 Cochrane Colloquium, Madrid, Spain
2011 East Africa HIV Case Reporting Workshop, Addis Ababa, Ethiopia
2011 International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy (reviewer, speaker),
2011 Triangulation Training Workshop for Analysis and Use of Strategic Information, Kiev, Ukraine
2011 Workshop on Programme Evaluation in Key Populations at Higher Risk of HIV, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, Cavtat, Croatia
2011 Workshop on Scientific Writing for Influenza Surveillance, Bangkok, Thailand
2011 World Health Organization, Consultation on Couples Counselling and Testing, Harare, Zimbabwe
2011 World Health Organization Consultation on the Diagnosis, Prevention and Treatment of HIV-Related Cryptococcal Infection, Geneva, Switzerland
2012 Curso Curto sobre Análise de Dados e Redação Científica, Universidade Federal de Bahia, Salvador, Bahia, Brazil
2012 Curso Curto sobre Análise de Dados e Redação Científica, Fundação de Medicina Tropical Doutor Heitor Vieira Dourado, Manaus, Amazonas, Brazil
2012 HIV/AIDS Cochrane Review Progress School, South African Cochrane Centre, Cape Town, South Africa
2012 International Conference on AIDS, Washington, D.C. (reviewer),
2012 Workshop on Scientific Writing for HIV, Kigali, Rwanda
2012 Workshop on Scientific Writing for HIV, Naivasha, Kenya
2012 Workshop on Scientific Writing for HIV, Morogoro, Tanzania
2012 Workshop on Surveillance for Sexually Transmitted Diseases, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia

2012 World Health Organization, HIV/AIDS Department, Consolidated Antiretroviral Guidelines 2013, Adult Guidelines Development Group Meeting, Geneva, Switzerland
2012 World Health Organization, HIV/AIDS Department, Consolidated Antiretroviral Guidelines 2013, Maternal and Child Health Guidelines Development Group Meeting, Geneva, Switzerland
2012 World Health Organization, HIV/AIDS Department, Consolidated Antiretroviral Guidelines 2013, Organization of Care Guidelines Development Group Meeting, Geneva, Switzerland
2013 Atelier sur le synthesis de donnees: developpement de fiches epidemiologiques, Programme National de la Lutte contra le SIDA, Kishasa, Democractic Republic of the Congo
2013 Cochrane Colloquium, Quebec, Canadad
2013 Implementation Science, Andrija Štampar School of Public Health, University of Zagreb, Cavtat, Croatia, 2013
2013 International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Kuala, Lumpur, Malaysia (reviewer)
2013 International Workshop on HIV Observational Databases, Cavtat, Croatia, 2013
2013 Seminário de Pesquisa Epidemiológica, Programa de Pós-Graduação em Doenças Infecciosas, Centro de Ciências de Saúde, Universidade Federal do Espírito Santo, Vitória, Brazil
2013 Workshop on Scientific Writing for HIV, Naivasha, Kenya
2013 Workshop on Scientific Writing for HIV, Nakuru, Kenya
2013 Workshop on Scientific Writing for HIV, Stonetown, Zanzibar, Tanzania
2014 African Federation for Emergency Medicine, 2nd Biannual Conference, Addis Ababa, Ethiopia
2014 National Workshop on Regional Triangulation Results, International Alliance for HIV/AIDS in Ukraine, L'viv, Ukraine, 2014
2014 Curso de Redacção Científica, Bilene, Mozambique, 2014
2014 Global Adult Tobacco Survey Writing Retreat, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia
2014 International Conference on AIDS, Melbourne, Australia (reviewer),
2014 International Workshop on HIV Observational Databases, Sitges, Spain
2014 Investigación y formación en VIH/ITS en marcha y prospectivas: colaboración con la Universidad de California en salud pública mundial, Universidad Peruana Cayetano Heredia, Lima Peru
2014 Longitudinal Surveillance of Paediatric HIV Care and Treatment in Kenya (L-SPTCTIK), Manual Development Workshop Series, 1: Data Analysis, Nairobi, Kenya
2014 Mentorship Skills Development Workshop, Kenya Field Epidemiology and Laboratory Training Program, Nairobi, Kenya, 2014
2014 New Strategies for HIV/AIDS surveillance in resource-constrained countries, Bangkok, Thailand (moderator)

2014 Training Course in Implementation of HIV Surveillance Using Time Location sampling (TLS) and Random Sampling, World Health Organization, Baku, Azerbaijan
2014 Workshop on Poster Presentations, Kenyan Ministry of Health, Nairobi, Kenya
2014 Workshop on Study Design and Population Size Estimates among "Bridge Populations", International HIV/AIDS Alliance, Tbilisi, Georgia, 2014
2015 Adolescent Transition Workshop, Collaborative Initiative for Paediatric HIV Education and Research, International Epidemiologic Databases to Evaluate AIDS, Giardino Naxos, Italy
2015 Conference on Retroviruses and Opportunistic Infections, Seattle, Washington
2015 Curso de capacitação para programação de ações de prevenção combinada para a redução da tranmissão do HIV, Departamento de DST, Aids e Hepatites Virais, Ministério de Saude, Brasília, Brazil, 2015
2015 Global Fund for AIDS, TB and Malaria, 26th Technical Evaluation Review Group Meeting, Geneva, Switzerland
2015 Global HIV Cascade Workshop: measuring and tracking people along the HIV health sector cascade, World Health Organization, Marrakech, Morocco, 2015.
2015 HIV Cascade Analysis Workshop, Eastern Mediterranean Regional Office, World Health Organization, Beirut, Lebanon
2015 Improving HIV Programmes through the Use of Cohort Data: ART Cohort Data Analysis, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia, 2015
2015 International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Vancouver, Canada (reviewer)
2015 International Workshop on HIV Observational Databases, Giardino Naxos, Italy
2015 Training Course in HIV Prevention and Treatment Cascade Analysis, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia
2015 World Health Organization HIV/AIDS Department, Consolidated Antiretroviral Guidelines, Geneva, Switzerland
2015 World Health Organization, Global HIV Cascade Workshop: Measuring and Tracking People along the HIV Health Sector Cascade, Marrakech, Morocco
2016 19º Congresso de Infectologia Pediátrica, Fortaleza, Ceará, Brazil (plenary speaker)
2016 Dubrovnik Institute for Bioethics Summer School, Dubrovnik, Croatia (keynote speaker)
2016 Global HIV Cascade Workshop: measuring, using and tracking cascade progress towards treat all and the 2020 targets, World Health Organization, Cavtat, Croatia
2016 Adolescent Transition Workshop, Collaborative Initiative for Paediatric HIV Education and Research, International Epidemiologic Databases to Evaluate AIDS, Budapest, Hungary
2016 International Conference on AIDS, Durban, South Africa (reviewer and moderator),
2016 International Workshop on HIV Observational Databases, Budapest, Hungary
2016 Introduction to Epidemiology and Biostatistics, Ukraine Public Health Certificate Programme, Ukrainian Center for Family Medicine, Bogomolets National Medical University, Kyiv, Ukraine

2016 Measurement and Surveillance of HIV Epidemics (MeSH) Consortirum Think Tank, Tallinn, Estonia, 2016.
2016 Public Health Leadership Seminar, Ukrainian Center for Family Medicine, Bogomolets National Medical University, Kyiv, Ukraine, 2016.
2016 Training Workshop in HIV Prevention, Diagnosis, Treatment and Care for Key Populations and Programme Evaluation, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia, 2016
2016 Workshop on HIV Continuum of Care Data Analysis for Key Populations, Centers for Disease Control and Prevention Eastern Caribbean Regional Office, Bridgetown, Barbados
2016 World Health Organization, Global HIV Cascade Workshop: Measuring, Using and Tracking Cascade Progress towards Treat All and the 2020 Targets, Cavtat, Croatia
2017 Conference on Retroviruses and Opportunistic Infections, Seattle, Washington
2017 International AIDS Society Conference on HIV Science, Paris, France (reviewer)
2017 International Workshop on HIV Observational Databases, Lisbon, Portugal
2017 Measurement and Surveillance of HIV Epidemics (MeSH) Consortium, II International Scientific Symposium, Muldersdrift, South Africa, 2017
2017 Training Course in HIV Case-Based Surveillance and Patient Monitoring, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia
2017 Training Couse in Writing Up Results of Research Studies, Alliance for Public Health, L'viv, Ukraine
2017 Training Workshop on HIV Data Quality Improvement, Programme Quality Improvement and Data Use, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia, 2017
2017 Workshop on HIV Prevention, Diagnosis, Treatment and Care in Key Populations and Programme Evaluation, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia
2017 World Health Organization, HIV Cascade Workshop: Using Data as an Intervention to Close Gaps in the Cascade. Evidence for Programme Improvements from the Use of Health Sector, Key Population and Sub-National Cascades in Africa, Harare, Zimbabwe
2018 HIV Care and Treatment HIV Cascades to Improve 90-90-90 Targets, Malaysian AIDS Control Commission, Kuala Lumpur, Malaysia
2018 International Conference on AIDS, Amsterdam, The Netherlands (reviewer)
2018 Namibia Population-Based HIV Impact Assessment (NAMPHIA) Final Report Writing Workshop, Centers for Disease Control and Prevention and Columbia University, Walvis Bay, Namibia, 2018
2018 Reaching the 90-90-90 Targets in Key and Priority Populations: Cascade-Driven Programmes to Improve Engagement in HIV Prevention and Care, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia

2018 Workshop on Using HIV Care and Treatment Cascades to Improve 90-90-90 Targets, WHO Collaborating Centre for HIV Strategic Information, Andrija Štampar School of Public Health, University of Zagreb, Dubrovnik, Croatia, 2018

2018 World Health Organization, Guideline Development Group, Consultation on New and Updated Guidance on Male Circumcision for HIV Prevention, Johannesburg, South Africa

2019 Act Against AIDS Workshop, Taiwan Center for Disease Control, Taipei, Taiwan

2019 Conference on Retroviruses and Opportunistic Infections, Seattle, Washington

2019 HIV Epidemic Control: Measuring Progress Toward 2020 and 2030, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia

2019 HIV Epidemic Control: Moving Toward 2020 and 2030, Jamaican Ministry of Health and Wellness, Meliã Braco Village, Jamaica

2019 HIV Surveillance Systems to Improve HIV Case Finding, Ukrainian Public Health Centre, Kiev, Ukraine

2019 International AIDS Society Conference on HIV Science, Mexico City, Mexico (reviewer)

2020 Ciclo de Debates Pré-Congresso EPI 2021, 11º Congresso Brasileiro de Epidemiologia, Fortaleza, Brazil (plenary speaker)

2020 Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts

2020 COVID-19 Update, Iranian Ministry of Health and Medical Education, Tehran, Iran (speaker)

2020 International Conference on AIDS, Amsterdam, San Francisco, California (reviewer)

2020 International Frontiers in COVID-19 Research, Symposium, Stanford University Center for Health Education, Stanford, California (plenary speaker)

2020 Malawi Recent HIV Infection Testing & Surveillance. Data Use and Public Health Response Workshop, Lilongwe, Malawi

2020 Measuring Service Coverage and Impact on HIV Interventions in Key and Vulnerable Populations, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia

2020 Regional Workshop on Advancing Implementation Science on HIV and Viral Hepatitis in Eastern Europe and Central Asia, World Health Organization European Regional Office, Berlin, Germany

2020 Strengthening COVID-19 tracing for Trinidad and Tobago, Banco de Desarrollo de América Latina, Port-of-Spain, Trinidad.

2020 Trazibilidad (rastreo) de contactos para COVID-19: lecciones desde San Francisco, Banco de Desarrollo de América Latina and Organismo Andino de Satud-Convenio Hipólito Unanue, Lima, Peru.

2021 International AIDS Society Research for Prevention Conference, Geneva, Switzerland

2022 Global Initiative on Children's Surgery, Abuja, Nigeria

2022 International AIDS Conference, Montreal, Quebec, Canada (reviewer, satellite moderator)

2022 Namibia Recency Surveillance, Recency Public Health Response and Data Review Workshop, Windhoek, Namibia

2022 HIV Surveillance in Key Populations, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia (workshop faculty)
2022 The Future of Public Health in Europe, Public Health and the Future of Healthcare, Conference on Public Healthcare through the Vision and Principles of Andrija Stam Štampar, Father of Modern Public Health on the Occasion of the 95th Anniversary of the Andrija Štampar School of Public Health, European Parliament, Brussels, Belgium (panel discussant)
2023 30th Conference on Retroviruses and Opportunistic Infection, Seattle, Washington (themed discussion moderator)
2023 HIV Surveillance in Key Populations, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia (workshop faculty)
2023 TRACE Regional Best Practices Workshop, Bangkok, Thailand (plenary lecturer)
2023 TRACE Regional Best Practices Workshop, Dar es Salaam, Tanzania (plenary lecturer)
2023-24 World Health Organization, Guideline Development Group, Consultation on Guidelines for HIV Post-Exposure Prophylaxis, Geneva, Switzerland (methodologist)
2024 31st Conference on Retroviruses and Opportunistic Infections, Denver, Colorado
2024 HIV Strategic Information and Programme Monitoring in Key Populations, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia (workshop faculty)

NATIONAL

1982 Epidemic Intelligence Service Conference, Centers for Disease Control, Atlanta, Georgia
1983 Epidemic Intelligence Service Conference, Centers for Disease Control, Atlanta, Georgia
1983 American Public Health Association Annual Meeting, Dallas, Texas
1984 American Public Health Association Annual Meeting, Anaheim, California
1984 Epidemic Intelligence Service Conference, Centers for Disease Control, Atlanta, Georgia
1984 National Immunizations Conference, Boston, Massachusetts
1985 American Society for Tropical Medicine and Hygiene Annual Meeting, Denver, Colorado
1985 National Immunizations Conference, Dallas, Texas
1986 American Academy of Dermatology, Las Vegas, Nevada
1986 American Public Health Association Annual Meeting, Las Vegas, Nevada
1986 American Society for Tropical Medicine and Hygiene, Denver, Colorado
1986 Duke University Medical Alumni Invitational Symposium, Durham, North Carolina
1987 American Public Health Association Annual Meeting, New Orleans, Louisiana
1987 HIV Seroprevalence Workshop, Centers for Disease Control, Atlanta, Georgia
1987 Interscience Conference on Antimicrobial Agents and Chemotherapy, New York, New York
1987 National AIDS Conference (plenary speaker), San Francisco, California
1987 National Sexually Transmitted Disease/HIV Prevention Conference, Atlanta, Georgia

1987 The Role of HIV Antibody Testing in the Prevention and Control of AIDS, Centers for Disease Control, Atlanta, Georgia
1987 Surgeon General's Workshop on AIDS, Children with HIV Infection and their Families, Philadelphia, Pennsylvania
1988 American Orthopsychiatric Association, New York, New York
1988 American Public Health Association Annual Meeting, Boston, Massachusetts
1988 Forum on AIDS Partner Notification Strategies, Association of State and Territorial Health Officials, Atlanta, Georgia
1988 Infectious Disease Society of American Annual Meeting, Los Angeles, California
1988 Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, California
1988 National AIDS Conference (plenary speaker), San Francisco, California
1989 Advances and Controversies in Clinical Pediatrics, Monterey, California
1989 American Psychiatric Association, San Francisco, California
1989 American Public Health Association Annual Meeting, Chicago, Illinois
1989 Duke University Medical Alumni Invitational Symposium, Durham, North Carolina
1989 Medical Ethics and Pediatric AIDS, Hastings Center, Hastings-upon-Hudson, New York
1989 National AIDS Update, San Francisco, California
1989 Society of Behavioral Medicine Annual Meeting, San Francisco, California
1989 Symposium on the Epidemiology of AIDS-Associated Kaposi's Sarcoma, University of California, San Francisco, Center for AIDS Research (moderator)
1991 Advances and Controversies in Clinical Pediatrics, Monterey, California
1991 Chronic Fatigue Syndrome: Current Theory and Treatment, Miami, Florida
1991 Conference of State and Territorial Epidemiologists Annual Meeting, Minneapolis, Minnesota
1991 National Sexually Transmitted Disease/HIV Prevention Conference
1991 Retrovirology of Chronic Fatigue Immune Dysfunction Syndrome,
1992 Access to Children's Health Care Symposium, Women in Government,
1992 Advances and Controversies in Clinical Pediatrics, Monterey, California
1992 American Association of Physicians for Human Rights, San Francisco, California
1992 Conference of State and Territorial Epidemiologists Annual Meeting
1992 Infectious Disease Society of American Annual Meeting, Orlando, Florida
1992 Legionella: Biology, Evaluation, and Control
1992 National AIDS Update, San Francisco, California
1993 American Public Health Association Annual Meeting, San Francisco, California
1993 Conference of State and Territorial Epidemiologists Annual Meeting,
1994 American Association for Chronic Fatigue Syndrome (plenary speaker), Miami, Florida
1994 Association of State and Territorial Health Officials Annual Meeting,
1994 HIV Seroprevalence Workshop, Centers for Disease Control, Atlanta, Georgia
1994 Infectious Disease Society of American Annual Meeting
1994 Coccidioidomycosis Study Group, Stanford, California
1994 Conference of State and Territorial Epidemiologists Annual Meeting, Vail, Colorado
1995 American Public Health Association Annual Meeting, San Diego, California

1995 National Immunizations Conference (plenary speaker),
1995 West Virginia Public Health Association Regional Meeting (plenary speaker), Charleston, West Virginia
1996 American Academy of Pediatrics National Conference and Exhibition,
1996 American Association for Chronic Fatigue Syndrome, Cambridge, Massachusetts
1996 American Public Health Association Annual Meeting, New York, New York
1996 Navy Occupational Health and Preventive Medicine Workshop (plenary speaker), Virginia Beach, Virginia
1996 Prevention 96, Dallas, Texas
1997 American Academy of Pediatrics National Conference and Exhibition
1997 American Public Health Association Annual Meeting, Indianapolis, Indiana
1997 Coccidioidomycosis Study Group, San Diego, California
1997 Prevention 97, Atlanta, Georgia
1997 Prevention in Managed Care: Joining Forces for Value and Quality (workshop speaker)
1998 American Academy of Pediatrics National Conference and Exhibition
1998 American Public Health Association Annual Meeting, Washington, D.C.
1999 Annual Conference on Vaccine Research,
1998 Coccidioidomycosis Study Group, Visalia, California
1998 Globally Emerging Viral Infections
1998 Partners in Prevention Research
1998 Prevention 98, San Francisco, California
1999 American Academy of Pediatrics National Conference and Exhibition
1999 Coccidioidomycosis Study Group, Tijuana, Baja California, Mexico
1999 Mycoses Study Group, National Institute of Allergy and Infectious Diseases, Bethesda, Maryland
2000 American Academy of Pediatrics National Conference and Exhibition
2000 American Public Health Association Annual Meeting, Boston, Massachusetts
2000 Annual Conference on Vaccine Research, Washington, D.C.
2000 Coccidioidomycosis Study Group, Berkeley, California
2000 Mycoses Study Group, National Institute of Allergy and Infectious Diseases, Bethesda, Maryland
2000 Prevention 2000,
2001 Annual Conference on Vaccine Research
2001 Coccidioidomycosis Study Group, Tucson, Arizona
2001 Conference to Develop an HIV/AIDS Therapeutic Research Agenda for Resource-Limited Countries, Infectious Diseases Society of America/HIV Medical Association (session chair), San Francisco, California
2001 Infectious Disease Society of American Annual Meeting
2002 American Public Health Association Annual Meeting, Philadelphia, Pennsylvania
2002 Association of Teachers of Preventive Medicine Annual Meeting, Washington, D.C.
2002 Annual Conference on Vaccine Research, Bethesda, Maryland
2002 Coccidioidomycosis Study Group, Davis, California

2002 National Sexually Transmitted Disease/HIV Prevention Conference, San Diego, California
2002 Pediatric Academic Societies Annual Meeting, Baltimore, Maryland
2003 Annual Conference on Vaccine Research, Arlington, Virginia
2003 Association of Teachers of Preventive Medicine Annual Meeting, Albuquerque, New Mexico
2003 Coccidioidomycosis Study Group, Scottsdale, Arizona
2003 National Sexually Transmitted Disease/HIV Prevention Conference, Atlanta, Georgia (Co-chair, Track C)
2005 American Academy of Pediatrics National Conference and Exhibition
2005 National Sexually Transmitted Disease/HIV Prevention Conference, Atlanta, Georgia
2005 Pediatric Academic Societies Annual Meeting
2006 American Academy of Pediatrics National Conference and Exhibition
2006 American Society for Microbiology, Conference on Dimorphic Fungi, Denver, Colorado
2006 Pediatric Academic Societies Annual Meeting, San Francisco, California
2007 American Academy of Pediatrics National Conference and Exhibition
2007 Pediatric Academic Societies Annual Meeting
2008 American Academy of Pediatrics National Conference and Exhibition
2008 Coccidioidomycosis Study Group, San Diego, California
2008 Pediatric Academic Societies Annual Meeting
2011 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Community Health, Communities Putting Prevention to Work, Writing Workshop, Decatur, Georgia
2012 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Community Health, Communities Putting Prevention to Work, Writing Workshop, Atlanta, Georgia
2013 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Community Health, Manuscript Development Training Series, Scientific Writing Workshop, Decatur, Georgia
2014 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Community Health, Manuscript Development Training Series for Community Transformation Grants, Atlanta, Georgia
2014 Research Priorities to Inform Public Health and Medical Practice for Domestic Ebola Virus Disease: a Workshop, Institute of Medicine, Washington, D.C.
2016 Consortium of Universities in Global Health Annual Meeting, San Francisco, California
2020 American Society of Echocardiography Virtual Experience, San Francisco, California (speaker)
2020-2021 COVID-19: What We Know Today Series, International Antiviral Society-USA, San Francisco, California (podcast interviewee)
2020 Diabetes Technology Society, Virtual COVID-19 and Diabetes Summit, San Mateo, California (speaker)

2020-2021 Digital Orthopaedics Conference, San Francisco, California (speaker)
2020 Disparities in COVID-19 Infection Rates and Mortality: System Issues, Human Factors and Ergonomics Society, San Francisco, California (webinar speaker)
2020-2021 National Oceanographic and Atmospheric Administration, Northwest Regional Laboratory, Seattle, Washington (webinar speaker, 3 sessions)
2020 United States Department of Justice, Washington, DC (webinar speaker)
2020 VLAB Founder Series, Mountain View, California (speaker)
2021 American Public Health Association/National Academy of Science. The Fourth Wave: Vaccines, Variants and the Future (panelist)
2021 National Academy of Science, Engineering and Medicine, Systematizing the One Health approach in preparedness and response efforts for infectious disease outbreaks
2022 Council of Former Federal Executives (speaker)
2022 Society of Actuaries Annual Meeting (panelist)
2023 Western Regional Valley Fever Workshop: Emerging Public Health Problem and Mitigation Strategies, University of Arizona College of Medicine, Phoenix, Arizona (moderator)
2024 Consortium of Universities in Global Health Annual Meeting, Los Angeles, California

REGIONAL AND OTHER INVITED PRESENTATIONS:

1988-1991 California Medical Association Annual Meeting
1989 United Nations Association of San Francisco, Model United Nations Workshop
1990-1993 AIDS on the Front Line, Orange County Health Services Agency, 1990 (plenary speaker), 1993 (plenary speaker)
1990 West Coast Epidemiologists Annual Meeting
1991-1995 California Association of Public Health Laboratory Directors Annual Institute
1991 California Department of Health Services, Annual Maternal-Child Health Conference
1991-1999 California Public Health Association North Annual Meeting, 1991 (moderator), 1999 (keynote speaker)
1991 California Sexually Transmitted Disease Controllers Association Annual Meeting
1991-2011 California Tuberculosis Controllers Association Annual Meeting
1991-1997 Health Officers Association of California Annual Meeting
1991 Symposium on the Prevention of Hepatitis B in Infants and Children
1992 Consensus Meeting regarding the Transmission of Blood-Borne Pathogens in Health Care Settings (co-chair)
1992 Revolt Against Tobacco Conference
1993-1994 California Childhood Injury Prevention Conference (plenary speaker)
1993-1994 California Conference of Local Health Officers Annual Meeting, 1993 (plenary speaker), 1994 (plenary speaker)
1993 California Mosquito and Vector Control Association (plenary speaker)
1994-2001 Epidemiology and Control of Infectious Diseases Continuing Medical Education Course, University of California, San Francisco (plenary speaker)
1995-2000 Children's Hospital Oakland, Grand Rounds speaker

1995	Prenatal HIV Testing and Counseling Training Conference, Alameda County Health Care Services Agency
1995	Santa Clara Valley Medical Center, Medical Grand Rounds
1995	Statewide Preventive Medicine Residency Conference (plenary speaker)
1995	Surveillance for Pediatric HIV Infection and AIDS in Northern California 6th Annual Update, Lucille Packard Children's Hospital (plenary speaker)
1996	American Academy of Pediatrics, California Chapter 1 Annual Meeting (plenary speaker)
1997	Loma Linda University School of Public Health, Dean's Conference
1998	California Department of Corporations Annual Conference (plenary speaker)
1998-2000	California Department of Health Services, AIDS Surveillance Conference (plenary speaker)
1999	American Academy of Pediatrics, Advances and Controversies in Pediatrics (lecturer)
2000	California Department of Health Services, 2000 HIV Prevalence Consensus Meeting (moderator)
2012	County of Santa Cruz Health Services Agency, Public Health Division Grand Rounds
2013	California Department of Public Health, The Century Ahead: Tuberculosis Science, Public Health and Policy (plenary speaker)
2014	University of California, Berkeley, Haas School of Business, Business of Health Care Conference (panel moderator)
2015	UC Hastings College of the Law, LAW 515: Global Health and Policy (panel member
2019-2020	San Francisco Fleet Week, Center for Humanitarian Assistance, Annual Medical Peer to Peer Exchange, plenary speaker and panelist
2019	State of Child Health in the World, Natividad Medical Center, Salinas
2019	Stanford's Annual Health Hackathon, health++, plenary speaker
2020	California El Camino Real Association of Occupational Health Nurses, webinar speaker
2020	California Medical Association-California Health and Human Services Agency, grand rounds speaker
2020-2022	Coastside Women's Club/Rotary Club of Half Moon Bay, webinar speaker (3 sessions)
2020	Chan Zuckerberg BioHub Workshop for Bay Area Departments of Public Health Community, speaker
2020	The Daily Californian Live!, featured speaker
2020	California Department of Public Health, Disease Investigation Specialist Summit, speaker
2020-2021	Digital Orthopaedics Conference (DOC SF)
2020-2021	Imperial County Public Health Department, Updates on COVID-19 (10 sessions)
2020-2021	International Antiviral Society-USA
2020-2022	Kaiser Permenente Regional Medical Center, San Francisco, Medicine Grand Rounds (3 sessions)
2020	Marin Healthcare District & MarinHealth Medical Center, webinar speaker
2020-2021	Piedmont League of Women Voters (4 sessions)

2020-2022 San Diego Superior Court, Judge George "Woody" Clarke Science and the Law Lecture (3 sessions)
2020 San Francisco Consular Corps, webinar speaker
2020-2021 San Francisco Hotel Council (2 sessions)
2020 San Francisco Opera Town Hall
2020 San Francisco Surgical Society, webinar speaker
2020-2021 Santa Clara Valley Medical Center, Department of Pediatrics Grand Rounds (2 sessions)
2020-2022 University of California, San Francisco, Department of Epidemiology and Biostatistics, Faculty Meeting (24 sessions)
2020-2022 University of California, San Francisco, Department of Medicine Grand Rounds (26 sessions)
2020-2021 University of California, San Francisco, Department of Medicine, Management of the Hospitalized Patient (CME course, two conferences, speaker)
2020 University of California, San Francisco, Osher Mini-Medical School (3 sessions)
2020-2021 University of California, San Francisco, Department of Pediatrics Grand Rounds
2020-2022 University of California, San Francisco, Department of Surgery Grand Rounds (4 sessions)
2020 University of California, San Francisco, School of Nursing Town Hall
2020-2022 University of California, San Francisco, UCSF Health Affiliates (4 sessions)
2020-2022 University of California, San Francisco, UCSF Health and Incident Command System town halls (80 sessions)
2020 World Affairs Council, Technology and Privacy in the Time of COVID (panelist)
2021 Alameda Teachers Association, town hall speaker
2021 Alice B. Toklas LGBT Democratic Club
2021 Asana, Inc.
2021 California Department of Public Health, CA Notify Symposium
2021-2022 California Department of Public Health, Virtual Town Hall (3 sessions)
2021 Chabot Space and Science Center
2021 California HealthCare Foundation
2021 Contra Costa County Health Services Agency, Community of Practice
2021 Curative Medical
2021 East Bay Municipal Utilities District
2021 Gladstone Institute
2021 Hill Physicians Medical Group
2021 ICONIQ Capital
2021 Intuit, Inc.
2021 Las Positas College, Livermore, California
2021 Northern California Chapter, American Society of Microbiology
2021 Pisces, Inc.
2021 Palo Alto Unified School District Town Hall
2021 Rossmoor Rotary Club, webinar speaker
2021 Rotary International
2021 San Diego Epidemiology Exchange

2021 San Francisco Chamber of Commerce
2021 Santa Clara County Board of Supervisors
2021 Stanford Alumni Association
2021 University of California Agricultural and Natural Resources
2021 University of California, San Francisco, Asian Health Institute
2021 University of California, Berkeley, Public Health Alumni Association (panelist)
2021 University of California, San Diego, School of Public Health, graduation speaker
2021 University of California, San Francisco, CARES Collaborative
2021 University of California, San Francisco, COVID-19: The Path Forward. Mapping a Post-Pandemic World (panelist)
2021 University of California, San Francisco, Department of Medicine, Cardiology Council
2021 University of California, San Francisco, Department of Medicine, Division of Pulmonary, Critical Care and Sleep Medicine Retreat
2021 University of California, San Francisco, Department of Medicine, UCSF Primary Care Medicine: Update 2021 (2 sessions)
2021 University of California, San Francisco, Department of Neurology, MS and Neuroinflammation Center Patient Town Hall
2021 University of California, San Francisco, Department of Otolaryngology, Head and Neck Surgery, Otolaryngology Update (plenary speaker)
2021 University of California, San Francisco, Department of Pediatrics, Advances and Controversies in Clinical Pediatrics
2021 University of California, San Francisco Foundation Board Meeting
2021 University of California, San Francisco, Institute for Global Health Sciences, Grand Rounds
2022 Bay Area Global Health Alliance, Monkeypox Symposium
2022 California Travel Association, California Comeback Task Force
2022 Cosmos Club of Washington, DC
2022 Stanford Sierra Camp (faculty lecturer)
2022 Stanford University, EPI 297, History of Epidemiology (lecturer)
2022 State of California, Virtual Training Academy, Community of Practice for Small and Rural Counties (2 sessions)
2022 Università di Sienna, Santa Chiara Laboratory and Institute for Global Health, Master in Vaccinology and Drug Development (lecturer)
2022 (webinar speaker)
2022 University of California, San Francisco Emeriti Faculty Association (lecturer)
2022 University of California, San Francisco Global Health Interest Group
2022 University of San Francisco, MPH 609H, Global Perspectives on Public Health (lecturer)
2023 University of California, San Francisco. Department of Pediatrics, 55th Annual Advances and Controversies in Clinical Pediatrics (lecturer)
2024 University of California Global Health Institute Annual Meeting, Los Angeles, California

CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2001 American Society for Tropical Medicine and Hygiene, Intensive Review Course in Clinical Tropical Medicine and Travelers' Health, San Francisco, CA

GOVERNMENT AND OTHER PROFESSIONAL SERVICE*:*

International

1986-89	Pan American Health Organization	Consultant (Rio de Janeiro and Sao Paulo, Brazil, 1986), Quito, Ecuador (1987), and Santo Domingo, Dominican Republic (1988-1989)
1990-1992	Pan American Health Organization, Project CONSENSO	Member
1993	Medical Research Council of Canada	Reviewer
2000	Australian Commonwealth Department of Health and Aged Care	Australasian Cochrane Collaboration Review Groups Selection Committee, Reviewer
2001-now	United Kingdom Medical Research Council	Reviewer
2004-07	United Kingdom Department for International Development	Reviewer
2004	World Bank	Consultant
2006	Chinese Academy of Engineering, Chinese National Influenza Centre, International Risk Governance Council	Consultant
2006-now	Programa Nacional de Doençcas Sexualmente Transmissiveis e Aids, Brazilian Ministry of Health	Consultant and Reviewer
2007-now	World Health Organization	Consultant, Department of HIV/AIDS and Department of Maternal, Child and Adolescent Health (2007-now); Global Programme on AIDS (1988-1990); Task Force on Congenital Syphilis Elimination (2007-now)
2007-now	World Health Organization, European Regional Office, Andrija Štampar School of Public Health, University of Zagreb, Zagreb, Croatia	HIV Knowledge Hub for Strategic Information, Advisory Advisory Board (Chair)
2008	Hong Kong Research Grants Center	Reviewer
2011	Natural Sciences and Engineering Research Council of Canada/Network Centres of Excellence	Expert review panel member
2015	World Health Organization Country	Consultancy on ensuring

	Office, Tehran, Iran	adherence to treatment based on new treatment guidelines of WHO with focus on IDU
2016	Canadian Institutes of Health Research	HIV Implementation Science Peer Review Committee
2020	Western-Eastern European Partnership Initiative on HIV, Viral Hepatitis and TB, Copenhagen, Denmark	Reviewer
2020	Ministry of Health and Medical Education, Tehran, Iran	Webinar speaker

National

1987-now	Centers for Disease Control and Prevention	Consultant; Research Agenda Steering Group (2005-2006)
1995-2004	United States Department of Veterans Affairs	Veterans Health Administration Research Realignment Committee (Chair) (1995-1996); National Research Advisory Committee (chair) (2000-2004)
2001-now	United States Public Health Service	Research Officers Group, Reviewer
2003-now	Institute of Medicine/National Academy of Medicine, U.S. National Academies of Sciences, Engineering and Medicine	Committee on the Ryan White CARE Act (2003-2004), Committee on HIVNET 012 (2004-2005), Committee on Gulf War and Health: Review of the Medical Literature Relative to Gulf War Veterans' Health (2005-2006), Committee on Gulf War and Health: Infectious Diseases (review coordinator) (2006), Committee on Disabilities in America (review coordinator) (2007), Committee on HIV Prevention Research Methods (2007-08), Committee on Gulf War Syndrome: Traumatic Brain Injuries (chair) (2007-08), Committee on Readjustment Needs of Returning Veterans (chair) (2009-2013), Board on Population Health and Public Health Practice (2008-11), Board on Select Populations (2011-

		2013), Committee on VA Disability Examinations for Traumatic Brain Injury (2018-19), Committee Conducting an Independent Analysis of Department of Defense's Comprehensive Autism Demonstration Program (chair) (2023-now)
2009-2012	National Institutes of Health, National Institute of Mental Health	Reviewer, Loan Repayment Program (2009-2012); Reviewer, R-13 Conference Grants Panel (2009)
2010-2014	National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development	National Advisory Council
2018	National Institutes of Health, Fogarty International Center	Member, Review Group ZRG1 BDCN-S 02
2019	National Institutes of Health, Fogarty International Center	Member, Review Group ZRG 1 IDM-Z (55) R
2020	Naval Studies Board, National Academy of Sciences, Engineering and Medicine	Consultation on Science, Policy, and Operational Considerations for the U.S. Marine Corps' Campaign Plan in Responding to the COVID-19 Pandemic and Subsequent Infectious Disease Outbreaks
2020-2021	National Academy of Social Insurance	Interdisciplinary Task Force Epidemiology Working Group

State

1987-1990	California Department of Justice	Attorney General's AIDS Fraud Task Force
1987-now	California Department of Health Services California Department of Public Health	*Ad Hoc* Lyme Disease Steering Group (1990-1991); AIDS Vaccine Research and Development Advisory Committee (1990-1995); California AIDS Education Campaign Steering Committee (1987-1989); California AIDS Leadership Committee, Health-Care Resources and Financing Subcommittee (Co-Chair) (1988-1989); Childhood Lead Poisoning

		Prevention Implementation Task Force (Chair) (1994-1997); Committee on Integration of New Clinical Laboratory Technology into Healthcare Delivery (Chair, 1996); Hepatitis C Strategic Plan Working Group (2000-2001); HIV Surveillance Workgroup (2000-2001); Medi-Cal Managed Care Leadership Committee (Co-Chair, Program Design Subcommittee, Chair, Work Groups on Clinical Preventive Services and Future of Public Health) (1992-1994); Preventive Medicine Residency Committee (Chair) (1992-1995); Tobacco Education and Research Oversight Committee (1994-2001, Governor's Appointee, 1994-2001); Tuberculosis Elimination Advisory Committee (Chair, 1994-now)
1992-1995	California Environmental Protection Agency	Comparative Risk Project Interagency Management Committee (1992-1994), Proposition 65 Working Group (1993-1995)
2004-2005	California Health and Human Services Agency	California Performance Review Work Group on Public Health] (Chair, 2004)
1992-1994	State of California	Interagency Work Group on Prevention of Legionellosis (1992-1994), Interagency Work Group on Tuberculosis (Chair) (1992-1994)
2020-now	California Department of Justice	Consultant
2022-now	California Department of Public Health	Monkeypox Scientific Advisory Group
Local		
1995	City and County of San Francisco, Board of Supervisors	Cryptosporidiosis Task Force
1985-now	City and County of San Francisco, Department of Public Health	AIDS Committee (Chair) (1987-1990), AIDS Community Advisory Committee (1985-1989), AIDS

		Health Resources and Services Community Advisory Committee (1989-1990), AIDS Medical Advisory Committee (Chair) (1985-1990), AIDS Minority Advisory Committee (1987-1990), AIDS Prevention Community Advisory Committee (1989-1990), Committee on Ambulatory Services for Persons with HIV Infection (1988-1989), Committee for Non-Acute Services for Persons with AIDS (1988-1989), Pediatric and Perinatal AIDS Advisory Committee (1985-1990), Director's Advisory Group on COVID-19 (2020-now)
1985-1990	City and County of San Francisco, Office of the Mayor	Mayor's AIDS Advisory Task Force
1990-2005	County of Los Angeles County Department of Health Services D	Consultant (2003, 2005), eputy Health Officer (without salary) (1984), Sexually Transmitted Disease Professional Advisory Committee (1990-92), Kaiser Family Foundation Advisory Group (1996)
1998	County of San Diego, Department of Health Services	Consultant
2022	City of Los Angeles Health Commission	Invited speaker

Attachment 5

SRINIVASAN "SRINI" VENKATESHWARAN, Ph.D.

Providing Effective Executive Leadership and Innovative Pharma Strategies

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PROFESSIONAL SKILLSET

- ✓ Entrepreneurship
- ✓ Strategic Planning
- ✓ Investor/Board Presentations
- ✓ Fund Raising
- ✓ Product Development
- ✓ Team Leadership
- ✓ FDA/Regulatory Strategy
- ✓ Intellectual Property
- ✓ Product Licensing
- ✓ CRO/CMO Mgmt
- ✓ Partner Management
- ✓ Contracts Negotiation

CAREER HIGHLIGHTS

- Innovatively identified and patented selective muscarinic antagonist NRX 101 for the treatment of sialorrhea and co-founded NeuRx Pharmaceuticals LLC to develop compound
- Completed NRX 101 Phase 1 study under US IND
- Executive catalyst in taking Lipocine (NASDAQ: LPCN) public via a reverse merger and raising $52M in a PIPE and a fully underwritten follow-on offering; advanced and completed Phase 3 studies with lead product candidate
- Successfully completed several product licensing agreements at Lipocine with pharma companies resulting in over $20M in equity investment, upfront license fee, R&D reimbursements and milestone payments
- Built and led Lipocine R&D team of 10 scientists, advancing and managing over 12 R&D programs ranging from early stage to successful Phase 3 completion
- Formulated and spearheaded filing of Mylan's fentanyl patch ANDA (first to file to J&J Duragesic®) in 15-months, one of Mylan's most successful generic products
- Managed external (acquired) metered dose and dry powder inhalation device technology development program and initiated and led in-house dry powder formulation technology development program

LEADERSHIP EXPERIENCE

NeuRx Pharmaceuticals LLC, San Antonio, TX — January 2015 – Present

Co-Founder, President & CEO

Key Accountabilities:

- Founded and operated NeuRx as a virtual company handling all aspects including IP filing/prosecution, preclinical development, PIND meeting with FDA, and completing a Phase 1 study under IND in 3 years

Key Achievements:

- Identified muscarinic agent selective to the salivary glands for the treatment of sialorrhea (excessive uncontrolled drooling), founded company, developed business plan and filed method of use patent
- Completed preclinical studies and pre-IND meeting with FDA Division of Neurology Products in <1 year; defined 505(b)(2) development pathway for NCE with 5 years exclusivity
- Completed Phase 1 formulation selection study under US IND

Vestan, Inc., Salt Lake City, UT — May 2015 – April 2017

President & CEO

Key Accountabilities:

- Responsible for business plan, fund raising, product development strategy

Key Achievements:
- Innovatively developed single-use (drug+device) combination product concept for lymph node visualization during breast cancer surgery
- Developed business plan and product development strategy
- Authored Vestan's NIH-SBIR Phase IIB grant application

Lipocine Inc., Salt Lake City, UT November 2001 – November 2014

CTO & VP R&D

Key Accountabilities:
- Built and led R&D group of 10 scientists with 4 direct reports including VP Product Development, Director Clinical R&D, Associate Director Regulatory Affairs, and Manager Analytical R&D
- Led all aspects of early stage product development including identification/selection of drug candidates, formulation development, IP/FTO, analytical R&D, proof of principle clinical studies
- Led all aspects of late-stage product development including 505(b)(2) regulatory strategy and filings, interactions with FDA, Phase 2/3 clinical studies conduct, and senior stakeholder communication
- Managed multiple partnered product development programs

Key Achievements:
- Key executive leadership role in taking Lipocine (NASDAQ: LPCN) public via a reverse merger; Raised $52M in a PIPE and a fully underwritten follow-on offering
- Completed Phase 3 clinical study with lead product candidate; Conducted End of Phase 2 FDA meeting defining the 505(b)(2) NDA requirements; Hired/managed CRO for Phase 3 study and CMO for scale-up/production
- Key executive leadership role in product licensing agreements with AbbVie, Reckitt Benkiser and UCB resulting in over $20M in equity investment, upfront license fees, R&D reimbursements and milestone payments
- Selected pipeline drug candidates, developed formulation, IP and regulatory strategy and advanced over 12 drugs into clinical development
- Developed business plan for Lipocine's JV with Elan and managed JV operations and product development, resulting in ~$2M in funding during very early stage of company

Mylan Technologies, Inc., St. Albans, VT May 2000 – October 2001

Executive Director R&D

Key Accountabilities:
- Led R&D group of 12 scientists with 4 direct reports including Director Product Development, Director Formulation Development, Manager Regulatory Affairs, and Manager Analytical R&D

Key Achievements:
- Formulated and spearheaded filing of Mylan's first to file fentanyl patch ANDA in 15 months and coordinated Paragraph IV patent challenge efforts with attorneys

TheraTech Inc. (TEVA), Salt Lake City, UT August 1989 – April 2000

Executive Director Transdermal & Inhalation Research

Key Accountabilities:
- Built and led R&D group of 20 scientists with 3 direct reports including Manager Product Development, Senior Scientists, and Manager Analytical R&D

- Led all aspects of early-stage product development including identification/selection of drug candidates, formulation development, IP/FTO and analytical R&D
- Managing partnered programs with Pfizer, Proctor & Gamble

Key Achievements:

- Spearheaded early-stage development of several commercialized transdermal patches for male hormone replacement (AndroDerm®), female hormone replacement (Alora®), incontinence (Oxytrol®)
- Managed external (acquired) metered dose and dry powder inhalation device technology development program and initiated and led in-house dry powder formulation technology development program

University of Utah, Salt Lake City, UT October 1986 – August 1989

Post-Doctoral Fellow

- Spearheaded research on iontophoretic transport mechanisms
- Authored a NIH research grant proposal on iontophoretic transport that was ranked in the 97th percentile and received $750,000 in funding; two successive competitive renewals

EDUCATION

Ph.D. in Chemical Engineering, University of Utah

Bachelor of Technology in Chemical Engineering, Indian Institute of Technology

AWARDS | PUBICATIONS | PATENTS

- Ebert Prize for best manuscript published in the Journal of Pharmaceutical Sciences in 1990, awarded by the American Pharmaceutical Association (APhA)
- Lead author/co-author on 15 publications in peer reviewed journals (list available upon request)
- Over 30 issued US patents with corresponding foreign counterparts (list available upon request)

CONSULTING ASSIGNMENTS

- Provided CMC, regulatory, preclinical and clinical development consulting services to client for a drug/device combination iontophoretic patch development project
- Evaluated acquisition opportunity and advised client on key issues relating to technology, product pipeline, IP portfolio and strategy for potentially enhancing value of acquisition
- Evaluated generic transdermal patch product in-licensing opportunities and advised client on technology, capabilities, development and paragraph IV related issues

Exhibit 3

June 27, 2025

Board of Supervisors
County of Sonoma
575 Administration Drive
Room 100A
Santa Rosa, CA 95403

RE: Beta-Myrcene (BM) Exposure and Toxicity

Dear Supervisors

The Neighborhood Coalition of Sonoma County has asked me to review its document titled "Cumulative Levels of Beta-Myrcene Inhaled by Humans Living Near Outdoor Cannabis Cultivation Sites May be Toxic and Carcinogenic" from a scientific perspective.

I am a PhD in Chemical Engineering and completed a post-doctoral fellowship in the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. I have had a 35-year career in the pharmaceutical industry in the research and development of drugs that has led to several products being commercialized. My work has primarily focused on administering drugs via the oral, transdermal, topical, buccal (oral mucosal) and inhalation routes to maximize bioavailability (i.e., the amount of drug that actually enters the blood stream) for optimal therapeutic effect while minimizing adverse effects. I have many publications in peer-reviewed journals and am the inventor or co-inventor of over 30 issued US patents with corresponding issued international patents. I have also consulted with several companies on the development of drug products. I have enclosed my curriculum-vitae which elaborates on my educational, academic and professional background in greater detail.

I have reviewed the document authored by Dr. Deborah Eppstein titled "Cumulative Levels of Beta-Myrcene Inhaled by Humans Living Near Outdoor Cannabis Cultivation Sites May be Toxic and Carcinogenic". I find the assumptions, reasoning and calculations to be scientifically accurate, credible and consistent with standard industry practices. I completely agree with the conclusions. Specifically:

- Beta-myrcene ("BM") is toxic and carcinogenic at all doses tested in animals (using oral gavage dosing technique) and that a non-toxic, non-carcinogenic dose has not been established in animal studies.

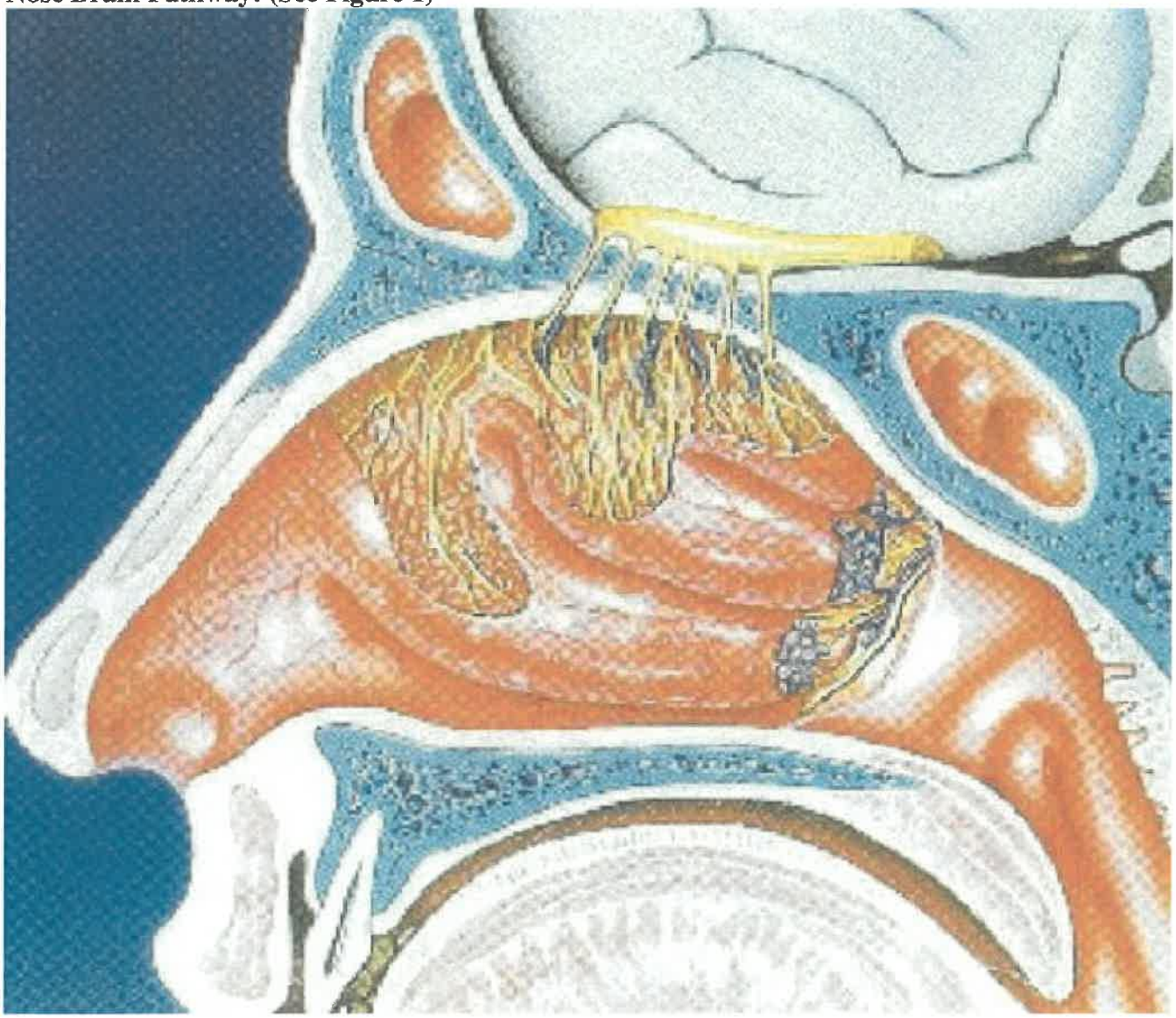
- The toxic doses of BM are <0.1 g/day in young children and <0.4 g/day in adults, based on projections from animal studies.
- Chronic inhalation of BM at 100 parts per billion (ppb) for 3-6 months each year can expose young children to the projected toxic dose in 5 years (15-30 months exposure) and adults after 10 years (60 months exposure). However, since those projected toxic doses were calculated from the lowest dose tested in the animal studies, which was still carcinogenic, a reduction by factor of 10 was also used. That lower-level projects toxicity to young children after 3 months exposure, and to adults after 6-12 months exposure. Chronic inhalation at higher concentrations, as occurs during flowering and harvesting of cannabis, can lead to toxic exposure significantly earlier in adults and children. At 1000 ppb, toxic doses are reached in much less than 3 months.

An area that deserves additional consideration is the potential direct brain exposure of BM via inhalation. As shown in Figure 1 below, the olfactory bulb (yellow region in the figure) is located at the apex of the nasal cavity and is responsible for our sense of smell [1]. It is lined by olfactory cells with olfactory receptors. Any molecule binding to the olfactory receptors is transported directly to the brain [1, 2]. Direct uptake to the brain via the olfactory pathway can lead to significantly higher brain exposure of a compound as compared to brain exposure via the blood. Toxicity studies using the oral gavage technique only lead to exposure to the brain from drug in the bloodstream. Brain exposure of a molecule via the blood can be significantly lower than exposure resulting from direct brain exposure of the molecule by inhalation because of metabolism, distribution into other body organs/tissues and difficulty in crossing the blood brain barrier [3], which is a natural protective mechanism that prevents many molecules from entering the brain. Toxicity studies with BM using inhalation route of administration would lead to a better understanding of potential brain toxicity and carcinogenicity due to chronic BM inhalation. Those studies have not been done. Exposing people to BM exposure by inhalation may cause brain toxicities not seen in the rodent toxicity studies.

BM being a lipophilic molecule is highly likely to bind to the olfactory receptors and be taken up directly into the brain. The fact that residents living downwind near outdoor cannabis cultivations can smell odors associated with cannabis cultivation suggests that BM and other volatile organic compounds are probably being taken up by the olfactory pathway leading to direct brain exposure. Given that they breathe in these vapors continuously for prolonged periods (as much as 3 months during a single growing season and 6 months/yr with two growing seasons) and BM concentrations

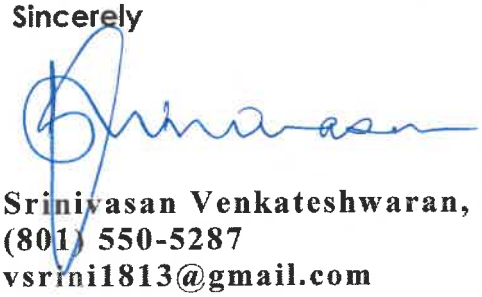
could be in the range of 100-1000 ppb, direct brain exposure to BM in adults and children could be very substantial, with proportionally greater cumulative exposure over multi-year periods. The potential for brain toxicity and carcinogenicity from direct uptake of BM to the brain should be seriously considered in allowing outdoor cultivation of commercial cannabis.

Nose Brain Pathway: (See Figure 1)



In summary, I am in complete agreement with Dr. Eppstein's scientific analysis that potential BM exposures from outdoor commercial cultivation poses a serious health hazard to adults, children and fetuses. Furthermore, as inhalation of BM not only provides greater levels of BM in the body than does oral ingestion, it also provides a direct route to the brain. No safety studies, neither acute nor chronic, have been done on the toxicities of BM on the brain after inhalation. This is another major reason to apply the precautionary principle to prevent exposure of the public, especially of children, to inhaled BM from outdoor cannabis cultivation.

Sincerely



Srinivasan Venkateshwaran, PhD
(801) 550-5287
vsrini1813@gmail.com

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Exhibit 4

Alan H Cohen, MD
283 Solstice, Box 518
The Sea Ranch, CA
95457-0518

June 25, 2025

To Whom it May Concern,

My name is Alan H Cohen, MD and I am a board-certified pediatric pulmonologist and former lung transplant physician, most recently on the clinical and teaching faculty at Stanford University School of Medicine and Lucille Packard Children's Hospital.

I am a California licensed and practicing pulmonary physician as well as a researcher and scientist who has focused my 35+ year-long career on the respiratory health and well-being of children and adults. My professional experience includes working at several internationally recognized centers of excellence, including the National Jewish Center for Immunology and Respiratory Diseases in Denver, CO, Washington University / Barnes Jewish Medical Center in St Louis, MO and Johns Hopkins Medical Center in Baltimore, MD. I have also had the honor and privilege to work on numerous therapeutically significant medicines, while employed at leading biotechnology and pharmaceutical companies responsible for many important respiratory-centric therapeutic advances, including first-in-class treatments for asthma, COPD and fibrotic lung diseases like idiopathic pulmonary fibrosis, as well as heart failure and pneumonia. Many of these drugs are administered via inhalation or aerosol delivery to the lungs of newborns, young children, chronically ill adults and elderly. As such, pulmonary delivery of small molecules, biologics and virally mediated gene therapies is something I am very experienced in, whether it be relevant to environmental exposure or as a means of delivering therapies and drug substances to the lungs.

I now live and work in the agricultural area of Sonoma County with my family. I have become aware of the proposal being considered that would allow large unenclosed cannabis cultivation to be established in alarmingly close proximity to family homes, local daycares, places of worship, elder care facilities and schools where chronic, daily airborne inhalation exposure would endanger the health and well-being of vulnerable populations like pregnant woman with unborn infants, newborns, school-aged children as well as chronically infirmed and elderly community members on a daily basis. High risk members of our communities would be unknowingly exposed and unnecessarily breathing in unhealthy levels of b-myrcene day and night, because of the potential allowance for under-regulated and under-managed outdoor cultivation of cannabis in Sonoma County to nearby homes and schools. This is a matter that I find deeply worrisome and concerning enough to motivate me to write to you to please seriously reconsider this dangerous and unnecessary potential community health risk, especially knowing that simple safeguards can be implemented to meaningfully mitigate these risks altogether.

Please understand, I have no issue with cannabis being grown for both medicinal and personal use, nor do I take issue with the legalization and commercialization of cannabis in California or elsewhere in the United States. What I take issue with is the proposal to allow for cannabis farming within only a few hundred feet or less from private residences, and places where children and the elderly will be knowingly exposed chronically, at estimated levels of b-myrcene which we already understand represents a human health hazard, despite being represented in cited reports (e.g. "SafeBridge" and "Trinity") as seemingly modest levels of daily exposure in the air and soil around us.

As you already know, b-myrcene is listed under Proposition 65 by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) as a chemical well established by the State of California to cause cancer and reproductive harm (1). Inhalation, ingestion and topical

exposure by agricultural workers has been clearly associated with causing nausea, headache, cough, respiratory diseases and asthma (2), including in the death of two cannabis workers (3, 4). Residents living near outdoor cannabis fields in Sonoma County have also experienced these deleterious health impacts (5, 6, 7). In animal studies, prolonged exposure to b-myrcene has been shown to cause renal cancer in mice and liver cancer in rats (8). Significantly, no lower safe level of b-myrcene was determined. It is worth noting that this evidence was sufficient for the Food and Drug Administration to constitute b-myrcene exposure in agricultural settings as having sufficient "clear evidence" of being responsible for these worrisome degrees of medically significant harm. This subsequently led the OEHHA to appropriately list b-myrcene under Proposition 65. Additionally, b-myrcene has also subsequently been removed from the FDA's list of approved food additives as recently as 2018 (9). Clearly, b-myrcene's are not innocuous substances that simply make the air smell "skunky" and unpleasant, they carry meaningful health risks that need to be cautiously accounted for when considering allowances for commercial level cultivation of cannabis in unenclosed agricultural areas, alongside dairy farms and other existing farm and livestock related businesses as well as homes where children and other at-risk members reside and work.

Some important observations can and should be considered when setting future regulations on where and how outdoor commercial scale cannabis manufacturing can be done more safely for everyone in our rural and agricultural communities. Based on the published scientific literature, medically significant and toxic levels of b-myrcene exposure can be achieved at levels that are as low as 0.1 g per day in young children and 0.4 g per day in adults. This is important to keep in mind because the environmental exposure to b-myrcene from outdoor, unenclosed grow areas can achieve and exceed these levels of human exposure over even a few months, increasing with longer exposures of a year or more. Sonoma County currently issues 5-year cannabis cultivation permits, but is now proposing to make these permits permanent, with no expiration, meaning that residents could be exposed to toxic levels of b-myrcene for the rest of their lives. The chronic daily inhalation of b-myrcene at 100 parts per billion (ppb) can expose young children to the projected toxic levels of this natural byproduct of cannabis cultivation in as little as three months (i.e., just one growing and harvest season (10). With two harvests each year as occurs with outdoor hoop houses, exposure doubles, and even at only 10 ppb (thus at undetectable odor levels), children can experience cumulative toxic levels in several years. At 1000 ppb of exposure, toxic levels can be reached in three months even in adults.

Higher ambient levels can be anticipated to occur during flowering and harvesting periods, which can cycle multiple times annually in commercial settings. Given that these much more dangerous and elevated levels of b-myrcene exposure can be reached much more quickly, this is why – considering the proximity of these cannabis grow fields when placed too close to residential communities and schools - it is important to accurately estimate and understand the cumulative exposure risks over time, to accurately monitor b-myrcene levels and to consider future population shifts into these agricultural areas of Sonoma County.

The "SafeBridge" report made several assumptions regarding human exposure which I do not believe are remotely fair-balanced and accurate. This is especially relevant as it relates to exposure of children and more vulnerable infirmed and elderly adults who are important not to ignore when making decisions regarding the community impact on health and well-being. This report refers to a so-called average adult in Sonoma County being exposed to b-myrcene only for 8 hours per day even though most vulnerable populations are homebound and less likely to travel away from their homes. Even healthy adults average far more than 8 hours each day at their homes. The true exposure time for the vulnerable populations would be closer to 24 hours per day not eight, meaning that the "safe dose" would be 3-fold lower when inhaled for 24 hours a day. Additionally, this report only calculated what they referred to as a "safe dose" of b-myrcene for a "typical" 70 kg (154 lb) healthy adult, ignoring those most vulnerable, including children and infants, who certainly weigh significantly less and as such their true exposure risks are many

magnitudes higher due to their smaller size, weight and 24-hour per day exposure in their homes. By not properly considering the significantly greater exposure risks to a small child (e.g. 14 kg, or 31 pounds) this so-called “safe” dose would be 5-fold lower for 8 hours daily exposure, or 5 x 3 =15 fold lower with 24 hr daily exposure. When considering an infant, the actual “safe dose” would be 20-fold lower for 8 hours of daily exposure, which is 20 x 3 = 60 fold lower for 24 hours daily exposure, and for an unborn fetus, the so-called “safe dose” would realistically be closer to 100-fold lower or more. By ignoring the real risks and harm posed to children and infants, this report fails to accurately characterize the true magnitude of harm being proposed by allowing unenclosed commercial cannabis grow areas to reside in communities only a few hundred feet from those at greatest risk of irreversible harm, infants, children and the elderly.

Even more fundamentally as discussed above, the “SafeBridge” report, by under-reporting and mis characterizing the actual exposure risks to those most greatly at risk for harm - pregnant woman, high-risk elderly and children living and attending school nearby and inhaling b-myrcene contaminated air 24 hours per day, these so-called daily “safe” doses would be closer to 3-fold higher exposure risk daily. As such, a more accurate calculated exposure dose over a full 24-hour period is actually 1.7 mg/m3/day for a 154-pound adult, 0.36 mg/m3/day for a 33-pound child, and 0.08 mg/m3/day for an infant. It is important to understand that SafeBridge derived the OEL from the lowest dose tested in rats, which was still highly carcinogenic, as no safe lower dose was determined. In addition, SafeBridge assumed that oral delivery of b-myrcene provided the same bioavailability as from inhalation although they provided no data, whereas other reports with cannabis compounds show that inhalation has much higher bioavailability, ranging from 3-5 fold higher (11). This unsupported assumption by SafeBridge would also result in a 3-5 fold higher calculated OAL if the greater bioavailability of b-myrcene by inhalation was considered. Although the Trinity air dispersion report being used for exposure calculations divided the “SafeBridge” OEL dose by 10 to account for 24 hr daily and chronic exposure, as noted above the OAL should already be reduced by a minimum of 10-fold to account for 24 hr exposure (3-fold reduction) and the higher bioavailability of inhalation over oral delivery of b-myrcene (>3-fold reduction), in addition to further reduction for those less than 154 pounds (e.g., children, babies and developing fetuses). The lowest calculated safe dose is further reduced by a factor of 10 when testing in humans to account for potentially greater toxicity in humans. In this case, since the lowest dose tested in rats was still carcinogenic, even assuming a 1/10 factor is arbitrary and may not represent a non-toxic dose. However, if applying a 1/10 factor to the calculations to estimate a safe dose, this would result in an OEL of 0.17 mg/m3/day for a 15 4-pound adult, 0.036 mg/m3/day for a typical child, and 0.008 mg/m3/day for an infant. Note that these calculations do not include an estimated further 3-fold reduction in OEL due to the known higher bioavailability of inhalation vs oral exposure. These are important and alarming calculated exposure risks because what they highlight is that even when employing clearly flawed assumptions and calculations from the Trinity air dispersion report, using the above OELs the b-myrcene levels far exceed the so called “safe limits” using the Trinity model being proposed. So, the exposure-risk data, when employed 24 hours per day instead of 8 hours per day and when applied to the actual sizes and weights of those most vulnerable among us in our communities, show that the true exposure risks are clearly significantly unhealthy, highly problematic and unsupportable if we are asked to defend the proposed plan as stated.

As you know, enclosed, indoor cultivation can more effectively mitigate high levels of exposure by workers, with the use of industrial air purifiers and personal protective equipment, such as respirators, protective clothing and goggles (6), which are standardly employed to protect adult employees involved in indoor manufacturing of cannabis and b-myrcene. Short of mandating all Sonoma County cannabis cultivation to indoor setting, what can be done is to limit the size and proximity of future proposed cannabis cultivation in unenclosed parcels at sufficient distances to make them less likely to harm the community at large, especially those in nearby schools, residential community settings and places of worship. Fortunately, our legislative leadership can proactively mitigate this clear harm and risk to

ourselves, our neighbors and community members by putting our health and well-being ahead of commercial interests and let science help to better inform our community-related decision-making.

We cannot and should not ignore the evidence which clearly documents the observed carcinogenic effects of b-myrcene and the real risk we would be knowingly supporting by allowing unenclosed commercial cannabis grow areas to be situated just a few hundred feet from homes, daycares and schools, despite the clear evidence of potential harm we would be doing to Sonoma County residents who would be exposed involuntarily on a daily basis at levels that will be irreversibly harmful in as little as 3-12 months. We need to act in a responsible manner to protect Sonoma County residents' public health interests first and foremost. Just like the oath I took when I became a licensed and practicing medical physician, we need to be sure that we knowingly do no harm.

Clearly, striking a balance between proactively helping the free market thrive and flourish in our communities, while protecting and serving the public good is what we are all striving for, and I am here to argue on behalf of those people in our communities that often have no voice, the unborn fetuses, pregnant woman, young school-aged children, the infirmed and elderly, all at the greatest risk for harm. I would ask you all to err on the side of evidence-based science and make an informed decision that is one that prioritizes the health and well-being of all the constituents in Sonoma County, especially those we often fail to acknowledge, our children.

Respectively,

Alan H Cohen, M.D.

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Exhibit 5

Mark L. Kram, Ph.D.

Environmental Consulting Services
7127 Hollister Ave., Suite 25A-108
Goleta, CA 93117

July 9th, 2025

To: Sonoma County Board of Supervisors

Subject: Sonoma County Cannabis Ordinance; Draft Environmental Impact Report; Sonoma County Comprehensive Cannabis Program Update, May, 2025.

Dear Supervisors,

As requested by Save Our Sonoma Neighborhoods, I have reviewed the Draft Environmental Impact Report (DEIR) generated by Sonoma County and their consultants to address the subject listed above and have provided my general and specific comments below. I am offering these opinions to a reasonable degree of scientific certainty based on my review of the DEIR as well as my education, training, and experience that spans more than four decades in the fields of environmental assessment and remediation, chemical fate and transport measurement and modeling, and specifically, my extensive volatile chemical measurement and high-frequency multivariate monitoring experiences.

General Comments:

1) The DEIR is well-written, comprehensive, and well-organized.
2) The DEIR does not include several key model assumptions. For instance, specific model input for wind speed range, cannabis varietals, plant age, and vapor dispersion related assumptions for each model iteration are not provided. A model is only as reliable as its weakest assumption. As such, it would be helpful to be transparent about every assumption used in each simulation, and to perform sensitivity analyses to understand critical controlling factors and impacts on exposure predictions.
3) The models are generic and have not been calibrated. For instance, terrain and topography are assumed to be flat, and it appears that a very calm wind speed has been assumed. In addition, different cannabis varietals emit very different terpene concentrations and profiles. As such, it is not possible to apply the simulations and predictions to specific operations and downwind receptors. While models can be helpful for understanding process, empirical evidence is far more reliable. Calibrated simulations based on data collected from a few select operations either within Sonoma County or from other regions with similar characteristics would have been useful and potentially more applicable.
4) The model results regarding predicted exposure point concentration are inconsistent with empirical field measurements. More specifically, the predicted terpene concentrations at key distances from operations are lower than those measured by my team as well as those reported by others based on odor threshold relationships to terpene concentrations (e.g., Kern County, 2017; Nevada County, 2019). As such, if the objective is to avoid impacts associated with odors and terpene exposures, the proposed setbacks are insufficient.

Specific Comments:

Comments below are organized in a manner consistent with the order of items contained within the document under review. As such, several comments are presented more than once for completeness.

- P.3.3-12: The following is stated: "*Currently, there is not a clear or consistent numerical threshold to use for cannabis odors. Because odor is a perception-based phenomenon and involves complex mixtures of substances rather than single chemically defined substances, it is important to evaluate odors comprehensively rather than breaking down individual chemical constituents of the odor*." My colleagues and I have derived a human odor detection threshold (ODT) by identifying a correlation between human detection and the combined concentration of three common cannabis terpenes, including Myrcene. **When these terpene concentrations range between 20 and 50 ppbv, greater than 50% of the participants report odors. This criterion has been successfully used for more than 40 projects in Santa Barbara County.** These projects included baseline screening, emission tracking during harvest, evaluation of odor testing and mitigation technologies, and compliance testing as required in legal settlements. The technology we deployed consisted of a laboratory grade gas chromatograph customized to automatically track select terpene concentrations from multiple locations along with weather conditions. Data was delivered to a web dashboard in near real-time for reporting and automated response. Note that Nevada County (2019) described a Myrcene ODT of 13 ppbv in their EIR. Myrcene is one of the terpenes we track and use to determine whether an odor will be detected by the public.
- P. 3.3-12: The following is stated: "*The results of modeling by Kern County indicated that specific cannabis compounds may be detectable at a distance of 2 miles or more depending on weather conditions (Kern County 2017). Nevada County released an EIR (State Clearinghouse No. 2018082023) for its Commercial Cannabis Cultivation Ordinance in 2019 and identified in their odor detection modeling that cannabis odors could be detected in some circumstances between 100 feet and as far as 1 mile from the source of the odor (Nevada County 2019)*." **When combined with our consistent odor threshold observations, this shows that terpene compounds can range from 20 to 50 ppbv as far as one to two miles from the source. In many cases, Myrcene is the dominant terpene detected downwind of emission sources.**
- P. 3.3-14: The DEIR describes setbacks and proposes 100 feet separation from property lines, 600 feet from residential zoned parcels, and 1,000 feet from sensitive use properties. As stated above, the reports described by Kern County (2017) and Nevada County (2019) suggest that when odors are detected at one or two miles downwind, terpene concentrations can at times range from 20-50 ppbv at those distances from the operation. When these models are considered along with the outdoor grow example presented in Case Study #1 below (e.g., where 440 ppbv Myrcene was measured approximately 2,600 feet downwind of the operation), **it is highly probable that residential neighbors and sensitive receptors will experience odors and exposures to Myrcene concentrations above the risk exposure level (REL) at distances farther than the proposed setbacks.** This will most likely occur when specific combinations of conditions are met (e.g., spatial and topographic context, cannabis varietal mix and age, wind speed and direction, and operational activities such as harvest, etc.). **As such, this unavoidable impact must be appropriately addressed**.

Mark L. Kram, Ph.D.
Environmental Consulting Services
7127 Hollister Ave., Suite 25A-108
Goleta, CA 93117

- P.3.3-15: The following is stated: "*According to Appendix G of the State CEQA Guidelines and standard practice, an impact on air quality would be significant if implementation of the project would…result in other emissions (such as those leading to odors) adversely affecting a substantial number of people*." This would be operation-specific. **As such, a clear definition of "*substantial number of people*" will be required**.
- P.3.3-21: The following is stated: "*Operation of existing and new cannabis uses could generate objectionable odors with adverse effects for residents and other sensitive land uses. This impact would be significant*." Also, "*The furthest distance cannabis odors from cultivation uses may be recognizable or detectable is approximately 2 miles, depending on topography and meteorology (Kern County 2017)...The distance for odor detection is very site-specific and can be affected by many variables, including meteorology, topography, and plant stages of plant growth*." Our studies are consistent with these comments. We also note that the detection of odors commonly occurs when select terpenes (including Myrcene) range in concentration from 20-50 ppbv. We did not perform studies related to health risks, but instead refer to Prop 65 which classifies Myrcene as a carcinogen.
- P.3.3-22: The following is stated: "*Sonoma County commissioned Trinity Consultants to evaluate the potential for toxics risk and community exposure of beta-myrcene related to cannabis cultivation (Appendix C). The study included the development of an occupation exposure level (OEL), with the intent of determining the potential to adversely affect members of the public with proximity to cannabis cultivation. Based on a review of readily available clinical and nonclinical data an OEL of 5 mg/m^3 as an 8-hour time-weighted average was recommended. The OEL provides a threshold at which no adverse effects would occur in an exposed worker (i.e., somebody within proximity to the chemical in question for the duration of a normal 8 hours work day). The OEL considers pharmacological and other adverse effects (e.g., sneezing, itching, nasal congestion and irritation, drowsiness, moderate skin and eye irritations), as well as nonclinical effects (reproductive and developmental effects at extremely high doses). To address public exposure, the OEL was lowered by a factor of 10 to develop the chronic risk exposure level (REL), which was used as a threshold in consideration of protecting the general public, which may experience exposure 24 hours per day, 7 days per year, year round. Thus, this analysis assumed an REL of 0.5 mg/m3 or less would not present an adverse effect*." Given that 1 ppbv Myrcene equals 6.1 x 10^{-6} mg/L (see below), then **an REL of 0.5 mg/m^3 is equal to 82 ppbv** (e.g., 0.5 mg/m^3 x (ppb/6.1 x 10^{-6} mg/L) x (m^3/1000L) = 82 ppbv). This REL value is very close to the upper end of the odor threshold (e.g., 20 – 50 ppbv for 50% of participants to report odor detection) my team has consistently documented. **As such, when community members report smelling odors, they are often being exposed to Myrcene levels that are close to or above the REL**.
- P. 3.3-22: The following is stated: "*To determine the potential for exposure on the general public, air dispersion modeling was completed to estimate ground-level beta myrcene concentrations at a distance of 100 feet for two hypothetical outdoor cannabis growing operations: a 1-acre facility and a 10-acre facility. These scenarios were modeled to estimate the ground-level concentration of beta-myrcene from a cannabis growing area at various distances using the US*

EPA regulatory model, AERSCREEN…The results showed that the maximum concentration of airborne beta-myrcene generated by 1-acre and 10-acre cannabis fields at a distance of 100 feet from the edge of a field would be 0.1 mg/m3 (23 percent of REL) and 0.3 mg/m3 (64 percent of REL), respectively. Additionally, at 600 feet, the setback required for residential zoning under the Cannabis Program Update, airborne concentrations of beta myrcene would be reduced to 0.04 mg/m3 for a 1-acre site and 0.1 mg/m3 for a 10-acre site. Levels at Cannabis Program defined sensitive land uses, which would be setback at least 1,000 feet from a cannabis premises under the Cannabis Program Update, would be reduced further." **When we convert this to units of ppbv, the models suggest that at 100 feet from the edge of a field, one would encounter approximately 16.4 ppbv Myrcene for a 1-acre operation and approximately 49.2 ppbv Myrcene for a 10-acre operation (Table 1). At 600 feet from the operation, the model concludes that one would encounter approximately 6.6 ppbv Myrcene for a 1-acre operation and 16.4 ppbv for a 10-acre operation (see table below). The Trinity modeling numbers are inconsistent with what our team has measured in the field as well as the Kern County (2017) and Nevada County (2019) reports.** Detailed modeling assumptions have yet to be shared, so we do not know the user input for all controlling factors, and it appears that the model has yet to be calibrated. However, **we have directly measured Myrcene at much higher levels at greater distances from operations (e.g., ~440 ppbv Myrcene at 2,600 feet downwind of a 4-acre outdoor operation)**. In addition, as stated above, if someone reports odors, they are most likely encountering at least 20 ppbv of select terpenes which can typically be dominated by Myrcene. As such, when Kern County describes odors as far as 2 miles from an operation, this suggests that the folks reporting odors are being exposed to levels comparable to what the model suggests at 100 feet from a 1-acre facility and at 600 feet from a 10-acre facility. **These inconsistencies point to the critical need for site-specific empirical assessments with confirmation testing**.

Table 1. Myrcene Concentration over Distance; Trinity Model Simulations vs. Field Evidence

	Operation Size	Distance from Operation (ft)	Maximum Myrcene (mg/m3)	Maximum Myrcene (ppbv)
Trinity Model	1-acre	100	0.10	16.4
	1-acre	600	0.04	6.6
	10-acre	100	0.30	49.2
	10-acre	600	0.10	16.4
Empirical Field Observations	4-acre	2,600	2.68	439.5*
Kern County (2017)	?	10,560	0.12-0.30	20-50
Nevada County (2019)	?	5,280	0.12-0.30	20-50
* Maximum reported/measured does not represent maximum occurrence due to spatiotemporal constraints.				

- P.3.3-22: The following is stated: "*Because site-specific conditions can determine the effectiveness of buffers, identifying a standard buffer distance at which odors could not be*

perceived for outdoor and mixed-light cannabis cultivation operations not contained within buildings or greenhouses is not considered feasible." **I agree with this acknowledgement. As such, and since each operation will have site-specific impacts (if any) on neighbors, it is essential that the model and analysis represent realistic conditions and outcomes**. At present, the simulations and conclusions are inconsistent with our work as well as the fate and transport related conclusions reported in Kern County (2017) and Nevada County (2019). **Concentrations of Myrcene are expected to be higher at larger distances from operations than the current Trinity model predicts. If a person smells odors at 1,000 feet or greater from an operation, there is an elevated probability that they are inhaling levels of Myrcene that exceed exposure point concentrations predicted by the Trinity models**.

- P.3.3-24, Figure 3.3-3, the Trinity dispersion model: The following is stated: "*Based on dispersion modeling, odors emitted from outdoor cannabis cultivation facilities decrease substantially for the first approximately 500 to 600 feet from a cultivation site (see Figure 3.3-3). Past this point, up to 1,000 feet, odors become less detectable at a slower rate. Past 1,000 feet, odor perceptibility tends to decrease further with distance at a slower rate compared to the first 1,000 feet from a cultivation site. Modeling indicates a direct relationship between odor emissions levels and cultivation area size, and in turn, a decreased rate of odor dissipation as cultivation area increases within a given site. While odors would be substantially reduced at 1,000 feet from a 1-acre cannabis cultivation site they would remain perceptible and may be considered objectionable (note that the maximum area of cultivation on the smallest allowable parcel size under the proposed Cannabis Program Update is 0.5 acres) (Trinity Consultants 2020)*." A few pages earlier, they state: *Because site-specific conditions can determine the effectiveness of buffers, identifying a standard buffer distance at which odors could not be perceived for outdoor and mixed-light cannabis cultivation operations not contained within buildings or greenhouses is not considered feasible*." We agree with the second statement (e.g., the model does not address site-specific conditions), and need to know more about the assumptions before commenting in detail about the first statement beyond the fact that the applicant acknowledges that there can be Myrcene detected beyond 1,000 feet of the operation. As such, and since each operation will have site-specific impacts on neighbors, it is essential that the model and analysis represent realistic conditions and outcomes. The specific model assumptions have not yet been shared. However, **given that people report odor detections when terpenes (including Myrcene) reach concentrations of 20 - 50 ppbv, if a person smells odors (in this case at or beyond 1,000 feet from the operation), there is an elevated probability that they are breathing levels of Myrcene that exceed exposure point concentrations predicted by the simulations**. More specifically, the proposed policy based on the Trinity model suggests that 600 feet is an appropriate residential setback, when in fact, terpene levels will still exceed odor thresholds at least out to 1,000 feet (see below). This is consistent with what we've documented regarding Myrcene and odor, and with what Kern County (2017) has reported.
- <u>Myrcene Concentration Estimate Based on Empirical Data Combined with Trinity Dissipation Model</u>: Below, I estimate the Myrcene concentration at key proposed setback distances by applying field observations from a 4-acre outdoor operation located in Buellton, California, to

the Trinity dissipation model in Figure 3.3-3. Table 2 (see Case Studies) represents a summary of these results.

- Myrcene Concentration Estimate at 600 feet from Source Using Empirical Data Combined with Trinity Dissipation Model: Figure 3.3-3 suggests that at 2,500 feet, only about 6.25% of source remains (e.g., 2.5 divided by 40) and that at around 600 feet, only about 20% remains (e.g., 8 divided by 40). We can use this relationship to calculate a Myrcene concentration for the Case 1 effort described below. For instance, we measured approximately 440 ppbv Myrcene at 2,600 feet from the emission source. if 440 ppbv = 6.25%, then the source concentration would be 7,040 ppbv (e.g., 440 ppbv/.0625) Myrcene. Figure 3.3-3 suggests that we would encounter 20% of the source concentration 600 feet from the source. As such, 20% of 7,040 ppbv suggests that 1,408 ppbv Myrcene would occur 600 feet from the source for the Case 1 situation described below. **This estimate is more than an order of magnitude higher than what the Trinity model predicts at 600 feet from a source for a grow operation more than twice the size (e.g., 4-acre: 1,408 ppbv Myrcene vs. Trinity Model 10-acre: 16.4 ppbv). This is also more than 17 times the REL set by SafeBridge/Trinity (e.g., 0.5 mg/m^3 or 82 ppbv).**
- Myrcene Concentration Estimate at 1,000 feet from Source Using Empirical Data Combined with Trinity Dissipation Model: Using the same logic (e.g., empirical evidence combined with the Trinity dissipation model; Figure 3.3-3) for a location 1,000 feet from the source, we note that the Trinity dissipation model predicts that 12.5% of source remains (e.g., 5 divided by 40). **This translates to a concentration of Myrcene equal to 880 ppbv (e.g., 12.5% of 7,040 ppbv) 1,000 feet from an operation, which is more than 10 times the REL set by SafeBridge/Trinity**.
- Myrcene Concentration Estimate at 100 feet from Source Using Empirical Data Combined with Trinity Dissipation Model For completeness, the predicted Myrcene concentration at 100 feet from the 4-acre outdoor operation is calculated. Applying the same logic as the earlier examples, we note that the Trinity dissipation model suggests that (conservatively) 50% of the source remains at 100 feet from the operation (e.g., 20 divided by 40 at the source). As such, 50% of 7,040 ppbv suggests that 3,520 ppbv Myrcene would occur 100 feet from the source for the Case 1 situation described below. **This estimate is more than an order of magnitude higher than what the Trinity model predicts at 100 feet from a source for a grow operation more than twice the size (e.g., 4-acre: 3,520 ppbv Myrcene vs. Trinity Model 10-acre: 49.2 ppbv). This is approximately 43 times the REL set by SafeBridge/Trinity (e.g., 0.5 mg/m^3 or 82 ppbv).**

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Conclusions:

1) The Trinity model predictions are inconsistent with empirical evidence as well as observations reported by Kern County (2017) and Nevada County (2019). More specifically, concentrations of Myrcene will most likely be much higher than the Trinity model predictions at specific criteria distances from cultivation operations.
2) The proposed REL will be exceeded much farther from grow facilities than the Trinity model results predict.
3) Given #1 and #2 above, the proposed setback requirements should be increased.

Regards,

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Case Studies:

We used a laboratory grade gas chromatograph to measure key cannabis odor related terpenes (including Myrcene) along with wind speed and direction. The analytical system was multiplexed to allow for automated continuous sampling and analysis from multiple locations with a single instrument. Case Study 1 is more applicable to the Sonoma DEIR because the monitoring was performed downwind of an outdoor cannabis operation. Given that Alternative 2 includes indoor operations, Case Study 2 is also described below.

Case Study 1: 4-Acre Outdoor Grow Operation; Buellton, Santa Barbara County
Our team documented 440 ppbv Myrcene approximately 2,600 feet downwind of the facility. Wind was approximately 7 mph from the West. This was a randomly timed sample, so it does not represent the maximum occurring concentration.

Conclusions:

1) The Myrcene concentration at 2,600 feet downwind (e.g., 440 ppbv) is almost an order of magnitude higher that what the Trinity model predicts at 100 feet for a 10-acre operation (e.g., 0.3 mg/m^3, or 49.2 ppbv).
2) Figure 3.3-3 suggests that at 2,500 feet, only about 6.25% of source remains (e.g., 2.5 divided by 40) and that at around 600 feet, only about 20% remains (e.g., 8 divided by 40). We can use this relationship to calculate a Myrcene concentration for the Case 1 effort. For instance, we measured approximately 440 ppbv Myrcene at 2,600 feet from the emission source. If 440 ppbv equals 6.25%, then the source concentration of Myrcene would be 7,040 ppbv (e.g., 440 ppbv/.0625). Figure 3.3-3 (the Trinity dissipation model) suggests that approximately 50% of the source remains at 100 feet from the operation (e.g., 20 divided by 40 at the source). As such, 50% of 7,040 ppbv suggests that 3,520 ppbv Myrcene would occur 100 feet from the source (Table 2). Similarly, Figure 3.3-3 suggests that we would encounter 20% of the source concentration 600 feet from the source. As such, 20% of 7,040 ppbv suggests that 1,408 ppbv Myrcene would occur 600 feet from the source. Furthermore, the Trinity dissipation model would imply that 880 ppbv would occur at 1000 feet from the operation.
3) **The Trinity model compliance point predictions are inconsistent with empirical evidence. More specifically, the model represents an underestimate of downwind Myrcene concentrations at 600 feet from the source (e.g., 16.4 ppbv for a 10-acre model prediction versus 1,408 ppbv for a 4-acre operation).**

Table 2. Empirical Observations (Buellton, 4-Acre Grow) Combined with Trinity Dissipation Model.

	Trinity Model	Buellton Case 1	
Distance from Operation (ft)	Percent Remaining	Predicted Myrcene Concentration (ppbv)*	REL Multiple**
100	50.0	3520	42.9
600	20.0	1408	17.2
1,000	12.5	880	10.7
* Source concentration = 7,040 ppbv			
** REL = 82 ppbv			

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Case Study 2: Greenhouse Emissions; Carpinteria, Santa Barbara County

Our team tracked Myrcene (and other terpene) levels at a roof vent of a 3-acre greenhouse and at other locations at varying distance downwind from the greenhouse. Wind speed ranged from approximately 3 to 7 mph from the Southwest when maximum downwind concentrations were recorded. The maximum Myrcene concentration recorded at the greenhouse vent was 122,149 ppbv. Maximum Myrcene concentrations were recorded downwind from the greenhouse vent location and included the following:

- 227 feet from roof vent to a downwind flagpole:
  - Maximum concentration at flagpole = 2,495 ppbv Myrcene
- 520 feet from roof vent to a downwind Foothill Rd point:
  - Maximum concentration at Foothill Rd point = 2,025 ppbv Myrcene

Downwind dissipation rates were calculated using maximum values observed. Assuming a linear dissipation rate over these distances (conservative), we estimate that at 100 feet downwind of the vent, dissipation ranged from 19 to 43 percent. Myrcene concentrations ranged from 69,625 ppbv to 98,941 ppbv, which corresponds to a range of 57 to 81 percent of the source concentration remaining (see calculations below).

#1) (*122,149 ppbv-2,495 ppbv)/227' = 527 ppbv/ft*
98% drop over 227' = 0.43%/ft
100' = 43% dissipated (57% remains); 69,625 ppbv remains
#2) (*122,149ppbv-2,025ppbv)/520' = 231ppb/ft*
98% drop over 520' = 0.19%/ft
100' = 19% dissipated (81% remains); 98,941 ppbv remains

Conclusions:

1) While dissipation is most likely non-linear past a specific distance (consistent with the Trinity model), these values suggest that Myrcene concentrations 100 feet downwind of the facility will be much higher than what the Trinity model predicts.
2) The Myrcene concentration at 227 and 520 feet downwind are several orders of magnitude higher that what the Trinity model predicts at 100 feet.
3) While these values represent the maximum values we documented, higher values could have occurred when the system was sampling at other locations when the true maximum passed by the monitoring points.

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Conversion of 1ppbv Myrcene to mg/L

Facts:

- Avogadro's number is 6.022×10^{23} molecules/mole of compound; a mole is defined as the molecular weight in grams [1].
- Myrcene (Myr) has a molecular weight of 136.23 g/mole [2].
- The volume of a mole of a gas (e.g., air) at Standard Temperature and Pressure (STP) is 22.4 L [3].

Thus: the number of molecules in one Liter of air is calculated as:

- $(6.022 \times 10^{23}$ molecules/mole of air) x (1 mole of air/22.4 Liters) = 0.27×10^{23} molecules air per 1 Liter air

1ppb (part per billion) of Myr is 1 molecule Myr per billion (10^9) molecules of air.

Number of molecules of Myr, at 1 ppb, per L of air, is:

- (1 molecule Myr/10^9 molecules air) x (0.27×10^{23} molecules air/1L of air) = 0.27×10^{14} molecules Myr/L air at 1 ppb

Converting to g of Myr at 1 ppb of air:

- (0.27×10^{14} molecules Myr/L air) x (136.23 g B-Myr/6.022×10^{23} molecules/mole Myr) = 6.1×10^{-9} g Myr/L air at 1 ppb of Myr
- 1000 mg = 1 g

As such, **6.1×10^{-6} mg Myr/L air = 1 ppb**

References:

1. Britannica, Avogadro's number.
2. National Institute of Standards and Technology, NIST chemistry webbook SRD 69,B-Myrcene.
3. Testbook

Exhibit 6

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November 6, 2024

Board of Supervisors
County of Sonoma
575 Administration Drive
Room 100A
Santa Rosa, California 95403

Dear Supervisors:

RE: BETA-MYRCENE EXPOSURE

I was asked by the Neighborhood Coalition to review its very measured responses to Sonoma County's proposed amendments to the Cannabis Health Ordinance that comes before the Board of Supervisors on November 12, 2024.

I am a pediatrician and epidemiologist and have spent the large majority of my 42-year career dealing with diseases of public health significance. I am a professor emeritus of epidemiology, preventive medicine, pediatrics and history at the University of California, San Francisco, where among other responsibilities lead the Center for Global Strategic Information and Public Health Practice. I am also an adjunct professor of epidemiology at the School of Public Health at the University of California, Berkeley. While my work has mostly focused on infectious diseases, my interest extends farther and includes toxicologic events, such as the 1984 release of methyl isocyanate gas during an industrial accident in Bhopal, India, and the 1991 derailment of a train at the Cantara loop near Dunsmuir, in which 19,000 gallons of the herbicide metam sodium were spilled directly into the Sacramento River. I have been both the State Epidemiologist and the State Health Officer for California, and in those posts was responsible for the public health, including the environmental health, of the state of California. I have enclosed my curriculum vitae.

One area that I believe deserves additional discussion by the Board is exposure to the chemical b-myrcene in the outdoor cultivation of cannabis in the County. b-myrcene is a naturally occurring chemical present in many plant species, including hops, lemongrass, verbena, bay leaves, carrots, and cannabinoids (1). It is used as a fragrance additive to cosmetics, detergents, and soaps. It, however, has been listed under Proposition 65 by the

1. Surendran S, Qassadi F, Surendran G, Lilley D, Heinrich M. Myrcene – What are the potential health benefits of this flavouring and aroma agent? Front Nutr 2021; 8:699666.

California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) in 2015 as a chemical known to the State of California to cause cancer or reproductive harm (2). Inhalation, ingestion or dermal exposure in agricultural workers is associated with nausea, headache, cough, respiratory diseases and asthma (3). In animal experiments, prolonged exposure to b-myrcene has been shown to cause renal cancer in male mice and hepatic cancer in male rats (4); this constitutes "clear evidence" of harm according to the Food and Drug Administration (4). This determination, in turn, triggered OEHHA's decision to list b-myrcene under Proposition 65. B-myrcene was also removed from the Food and Drug Administration's list of approved food additives in 2018 (5).

At issue here is whether naturally occurring levels of b-myrcene associated with the outdoor cultivation of cannabis in Sonoma County represents a human health hazard. Exposure during indoor cultivation can presumably be mitigated by personal protective equipment, such as safety glasses, personal respiratory devices, and protective clothing, and through hand and face washing (6), which are the standards used for industrial production of b-myrcene.

I have reviewed Dr. Epstein's logic, calculations and conclusions (7), and I find them to be credible and important. I will draw your attention to three of her conclusions:

1. The toxic doses of b-myrcene are less than 0.1 g per day in young children and 0.4 g per day in adults.
2. Environmental exposure to b-myrcene can reach these levels over a period of months to years.

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2. California Office of Environmental Health Hazard Assessment (OEHHA). Beta-Myrcene. Available at https://oehha.ca.gov/proposition-65/chemicals/beta-myrcene. Accessed September 9, 2024.
3. Beckman S, Castañeda X. Rivas L, Schenker MB. California cannabis cultivation and processing workers: a qualitative analysis of physiological exposures and health effects. Am J Indus Med 2002; 66:75-84.
4. National Toxicology Program. *Toxicology and Carcinogenesis Studies of β-Myrcene (CAS No. 123-35-3) in F344/N Rats and B6C3F1 Mice (Gavage Studies)*. Technical Report Series No. 557. NIH Publication No. 11-5898. U.S. Department of Health and Human Services, National Toxicology Program, Research Triangle Park, NC, 2010. Available at http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/TR557.pdf.
5. Department of Health and Human Services. Food and Drug Administration. 21 CFR §172 and 177, 5 October 2018. Available at: federalregister.gov/documents/2018/10/09/2018-21807/food-additive-regulations-synthetic-flavoring-agents-and-adjuvants#:~:text=James%20Huff%2C%20by%20amending%20the,substances%20for%20use%20in%20food. Accessed 27 October 2024.
6. Sigma-Aldrich. Safety data sheet: b-myrcene. Available at https://www.sigmaaldrich.com/US/de/sds/ALDRICH/W276200?userType=undefined. Accessed 20 September 2024.
7. Neighborhood Coalition. Cumulative levels of beta-myrcene inhaled by humans living near outdoor cannabis cultivation sites are likely to be toxic and carcinogenic. 18 October 2024.

3. Chronic inhalation of b-myrcene at 100 parts per billion (ppb) can expose young children to the projected toxic dose after five years and adults after 10 years. At higher doses, as, for instance, occur during flowering and harvesting, these levels can be reached much more quickly (for instance, at 1000 ppb of exposure, toxic levels can be reached in three months in young children and 15 months in adults).

I conclude that there is an urgent need to design mitigation plans to reduce involuntary exposure to b-myrcene. Monitoring of ambient levels is a first step, but the bottom line is that I am fully in agreement with Dr. Epstein's implicit recommendation that the Board seriously consider the toxic and carcinogenic effects of b-myrcene to which residents are exposed involuntarily and act in a way to protect the public health.

Sincerely,

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