

IN THE SUPREME COURT OF THE STATE OF NEVADA

SANDRA CAMACHO; AND ANTHONY
CAMACHO,

Petitioners,

vs.

THE EIGHTH JUDICIAL DISTRICT COURT OF
THE STATE OF NEVADA, IN AND FOR THE
COUNTY OF CLARK; AND THE HONORABLE
NADIA KRALL, DISTRICT JUDGE,

Respondents,

and

PHILIP MORRIS USA, INC., a foreign
corporation; R.J. REYNOLDS TOBACCO
COMPANY, a foreign corporation, individually,
and as successor-by-merger to LORILLARD
TOBACCO COMPANY and as successor-in-
interest to the United States tobacco business of
BROWN & WILLIAMSON TOBACCO
CORPORATION, which is the successor-by-
merger to THE AMERICAN TOBACCO
COMPANY; LIGGETT GROUP, LLC., a foreign
corporation; and ASM NATIONWIDE
CORPORATION d/b/a SILVERADO SMOKES &
CIGARS, a domestic corporation; LV SINGHS
NC. d/b/a SMOKES & VAPORS, a domestic
corporation,

Real Parties in Interest.

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*PETITIONERS' APPENDIX
VOLUME 5 (Nos. 898-1032)*

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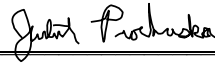
DECLARATION OF JUDITH PROCHASKA, Ph.D., M.P.H.

I, Judith Prochaska, Ph.D., M.P.H., declare as follows:

1. My name is Judith Prochaska. My address is 3180 Porter Drive, Palo Alto, CA 94304
2. The opinions rendered in my expert report (attached to this declaration) represent my opinions, all held to a reasonable degree of scientific certainty, and are based on a reasonable scientific probability and scientifically reliable evidence.
3. I reserve the right to amend my opinions if further information is provided in any form.

Pursuant to NRS 199.120, under penalty of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

Dated: June 6, 2022.



JUDITH PROCHASKA, Ph.D., M.P.H.

Expert Witness Report of: Judith J. Prochaska, PhD, MPH

**In Re: Sandra Camacho, individually, and Anthony Camacho, individually,
(Plaintiffs)**

vs.

Philip Morris USA, Inc.; R.J. Reynolds Tobacco Company; et al. (Defendants)

**District Court Clark County, Nevada
Case No. A-19-807650-C**

I. Background and Qualifications

My name is Judith J. Prochaska, PhD, MPH. I am the Deputy Director and a tenured Professor of Medicine with the Stanford Prevention Research Center in the Department of Medicine and the School of Medicine at Stanford University. I am a licensed clinical psychologist and hold addiction medicine privileges with Lucile Packard Children's Hospital at Stanford and with Stanford Health Care where I direct Stanford Cancer Center's Tobacco Treatment Service and treat patients who have nicotine addiction, including patients addicted to JUUL.¹ I am a member of the Stanford Cancer Institute and direct Stanford Cancer Center's tobacco treatment service, which has received institutional awards and is part of the National Cancer Institute's Moonshot Initiative. I train and supervise psychology student interns in treating tobacco use in patients diagnosed with cancer. I am a faculty member of the Stanford Child Health Research Institute and the Stanford Woods Institute for the Environment.

I also am a faculty member with the Stanford Research into the Impact of Tobacco Advertising (SRITA) collaborative. SRITA is a research group that studies the effects of tobacco advertising, marketing, and promotion. The SRITA online library consists of more than 50,000 tobacco and e-cigarette advertisements (tobacco.stanford.edu). I am the Faculty Director for Stanford's Master of Science (MS) Program in Community Health and Prevention Research. I also co-direct Stanford's Postdoctoral Fellowship on Cardiovascular Disease Prevention, which has been funded for 45 years by the National Heart, Lung and Blood Institute. I have received multiple teaching and mentoring awards.

I joined Stanford in 2012. Prior to that, I was a faculty member for 8 years (2004-2012) in the Department of Psychiatry at the University of California, San Francisco (UCSF), appointed from Assistant through to Full Professor, and held medical privileges at the Langley Porter Psychiatric Institute. I completed my undergraduate studies in psychology at Duke University in 1995; my master's degree in public health at San Diego State University in 2001; my clinical psychology doctoral degree at the University of California, San Diego and San Diego State University in 2002, and my internship (2002) and postdoctoral fellowship (2002-2004) training at UCSF, before joining the UCSF faculty in 2004.

I have been a Principal Investigator on multiple research awards from the National Institutes of Health, the American Cancer Society, and the State of California Tobacco-Related Disease Research Program. My research program centers on studies of tobacco use, including e-cigarettes, and treatments for nicotine addiction in diverse and vulnerable populations with high smoking prevalence. To date, I have conducted 11 clinical tobacco treatment trials with over 3000 people who smoke, spanning adolescents to older adults. I also study the impact of tobacco product marketing, tobacco policies, and mass media tobacco control campaigns and have conducted research on cigarette design and tobacco industry documents. I

¹ CK Johnson, Never too late: Cancer centers push patients to quit smoking. AP News July 26, 2021
<https://apnews.com/article/science-health-cancer-smoking-dda02a87195436afaa03275193a5d295>

received outstanding early career research awards from the National Institute on Drug Abuse (2010) and the Society for Research on Nicotine and Tobacco (2007). Thus far, in my professional career, I have received more than 20 grants with research funding totaling over \$25 million. I chair grant review sections for the National Institutes of Health.

I am a past-President and Fellow of the Society for Research on Nicotine and Tobacco (SRNT), the international scientific society aimed at stimulating the generation and dissemination of new knowledge concerning nicotine and tobacco from bench to bedside and through to health policy. I am an appointed member of the American Academy of Pediatrics (AAP) Tobacco Consortium. I am on the Editorial Boards of the journals *JAMA Internal Medicine* and *Health Psychology* and have served on the boards of *Tobacco Regulatory Science* and the *Cochrane Tobacco Addiction Review Group*. I have authored or co-authored over 250 peer-reviewed publications in the areas of smoking cessation, nicotine dependence, e-cigarettes, smoking and disease, tobacco marketing, psychiatric disorders, medical education, multiple risk behavior change, measurement development and psychometrics, dissemination, and quantitative methods. The journals in which I have published include *NEJM*, *JAMA*, *JAMA Internal Medicine*, *JAMA Psychiatry*, *BMJ*, *Addiction*, *Tobacco Control*, *Nicotine and Tobacco Research*, *Tobacco Regulatory Science*, *Journal of Adolescent Health*, *Journal of Addiction Medicine*, *Addictive Behaviors*, *Addiction Science & Clinical Practice*, *Circulation*, and *Oncology*. I have led and collaborated on highly cited meta-analyses related to tobacco use and its treatment. To advance the treatment of tobacco use and addiction in medical practice, I developed, evaluated, and disseminated the *Rx for Change* tobacco treatment curricula (<http://rxforchange.ucsf.edu>), with focus on psychiatry and cardiology care providers. Collaboration with the World Heart Federation extended the training materials to providers in China, the Middle East, and South America.

I was a contributing author to the 2020 Surgeon General's Report on *Smoking Cessation*. I served as a consultant to the World Health Organization's (WHO) *Expert Committee on the Selection and Use of Essential Medicines* with a focus on tobacco cessation treatment and continue to consult to the WHO during my sabbatical year. I have consulted as a scientific expert with the Centers for Disease Control and Prevention on their TIPS from former smokers campaign; the National Comprehensive Cancer Network (NCCN) on their Smoking Cessation Clinical Practice Guidelines in Oncology; with the Food & Drug Administration's (FDA) Center for Tobacco Products PhenX panel to identify best measures in tobacco regulatory research; with the National Cancer Institute, Division of Cancer Control and Population Sciences, advising on tobacco control research priorities for the next 10 years; the Congressionally-mandated Federal Advisory Interagency Committee on Tobacco and Health with focus on tobacco addiction, mental illness, and other addictions; and with the Federal Trade Commission (FTC) in their consumer division on deceptive advertising practices. I regularly serve as a grant reviewer for the National Institutes of Health and have served as a scientific advisor to Pfizer and Achieve Life Sciences regarding their smoking cessation medications. I served on the advisory board for the nation's largest purveyor of tobacco quitline services (Optum) and am the editor for the Merck Manuals professional and consumer content relating to tobacco use, nicotine addiction, and tobacco cessation.

My academic training and professional experience have provided me with expertise in the fields of cancer and cardiovascular disease prevention, particularly as they relate to tobacco epidemiology, tobacco use behaviors, nicotine addiction, consumer risk perceptions, tobacco product marketing, cigarette design, tobacco industry documents, and tobacco industry conduct.

I am aware that in acting as an expert in this case, I am to provide assistance to the court and that I am not to act as an advocate for any party to the dispute. My duty to the court is to provide fair, objective, unbiased, and non-partisan opinions on the issues for which I have been asked to opine. I certify that this report has been made in conformity with this duty. Furthermore, I will, if called on to give oral or written testimony, give that testimony in conformity with this duty.

A current copy of my curriculum vitae is attached to this report as Appendix A.

II. Prior Testimony

In Appendix B, I have listed all tobacco cases for which I have been disclosed and my prior deposition and court testimony since 2014. To date, I have testified as an expert on the same topics as outlined in this report, including 16 times at trial in state courts and over 50 times by deposition. Factors that influence the development and maintenance of addiction to tobacco are complex, including the pharmacologic effects of nicotine; tobacco product design, including the additive menthol and alternative nicotine delivery devices like electronic cigarettes (i.e., e-cigarettes, vapes); genetics; learned factors conditioned to the drug nicotine; and sociocultural exposures including use by family and peers and marketing. Based upon my education, training, research program, and clinical experience, as well as my previous testimony in tobacco litigation, I would be expected to provide opinions related to tobacco epidemiology and tobacco use behaviors, including: youth tobacco use susceptibility, use initiation, and lasting use effects on the developing adolescent brain; use transitions; use cessation, attempted cessation, and cessation attempt methods; nicotine addiction, including the physiological, psychological, and neurological mechanisms of nicotine addiction; cigarette design, including safer alternative designs; the cigarette as an efficient nicotine delivery (addiction-sustaining) device; e-cigarette design and use, including marketing to and use by youth, marketing as a therapeutic, and dual use; the co-occurrence of nicotine with other substances of abuse and the risk for gateway effects and cross-addiction; consumer knowledge and risk perceptions related to smoking; tobacco product marketing influences on brand, and sub-brand, choices and smoking behaviors; cigarette toxin exposures; cigarette-smoking related disease risk; and tobacco industry public denials relating to smoking, health, and addiction issues; tobacco industry documents; and tobacco industry conduct.

III. Basis for Opinions

The opinions that I will offer in this case are based on my more than 20 years of experience and expertise in the tobacco control field, including research of tobacco industry documents. The basis for my opinions includes but is not limited to: (1) original data from my own research; (2) published scientific literature and official reports (e.g., Surgeon General Reports, National Cancer Institute Monographs, FDA); (3) prior court decisions (e.g., United States vs. Philip Morris [D.O.J. Lawsuit]); (4) internal documents of tobacco manufacturers and their affiliated organizations (e.g., TIRC, CTR, TI) revealed through publication or on the internet (e.g., Truth Library); (5) statements of cigarette industry officials related to public appearances, litigation and congressional testimony; (6) advertisements and advocacy statements authored by the cigarette industry and appearing on television and radio, in pamphlets, in public speeches, in newspapers, in magazines, and on the internet (many cataloged on the SRITA website); (7) medical records, interrogatories, and deposition testimony pertaining to Sandra Camacho; and (8) my own interview, and assessment, of Sandra Camacho.

IV. Structure of this Report

I have organized this report with generic opinions presented first followed by case specific evidence concerning Sandra Camacho. The generic opinions include a review of the addictive nature of nicotine as delivered via cigarette smoking, the implications of becoming addicted to nicotine at an early age, the reinforcing effects of cigarette smoking that create and sustain addiction, the effect of nicotine addiction and exposure to nicotine in adolescence on the ability to discontinue smoking; and the significant health harms and risk of premature death due to exposure to carcinogens with regular smoking. I review leading, evidence-based methods for assessing nicotine dependence and addiction. Also reviewed are actions by the tobacco industry to market (and sample) cigarette smoking as a normative, attractive, enjoyable,

lifestyle choice while knowingly denying to the American public the addictiveness of nicotine and the adverse health consequences from regular smoking. Tobacco companies failed to warn the public of the true risks of their product and instead fueled a campaign of misinformation that minimized perceived risks and dissuaded individuals from quitting smoking. Further, rather than addressing defects in cigarette design that result in an addictive, inhalable product, the tobacco companies instead marketed design features (e.g., filtration, low tar, lights/ultralights, menthol) as harm reducing innovations that in truth were not realized. That is, these cigarette modifications were a marketing ploy that provided no reduction in their harmfulness to health, and there is scientific evidence that they even created greater harms.

The tobacco industry has intentionally designed cigarettes with enough nicotine to create and sustain addiction and has controlled the impact and delivery of nicotine in many ways. The use of menthol as an additive in cigarettes increased smoking initiation among youth and young adults, particularly African American youth and young adults, leading to greater addiction and decreased success in quitting smoking. Safer cigarette design alternatives include, but are not limited to, those that actually reduce the nicotine level in the cigarette rod to substantially minimize the addictiveness (i.e., very low nicotine content cigarettes) and those that reduce inhalability. Safer design alternatives can substantially reduce the addictiveness of cigarettes in adults and adolescents who smoke and in nicotine naïve individuals. Minimizing the addictiveness of cigarettes thereby reduces the compulsion -- the need and drive to smoke -- and ultimately the harm that results from repeated toxin exposure caused by heavy, sustained cigarette smoking.

I reserve my right to amend this report based on additional relevant facts as they become available to me.

My reliance materials as used in previous tobacco cases and as represented in this report have been notated in this report as footnotes and with BATES numbers and are publicly available and/or are in the scientific domain. The case specific materials are detailed in Section VII-1.

V. Methodology for General and Specific Opinions

In writing this report, I have synthesized the evidence following a systematic methodology with attention to bias and consideration of the credibility of the data sources. Within each individual opinion section, I identify the sources of material upon which the opinions are based, including my own research where relevant. I explain why certain facts were found, why certain evidence was credited, and why other evidence was either discredited as not believable or, in most instances, outweighed by other more convincing and credible evidence.

Consistent with my approach to the research literature, the methodology I undertook in developing my case specific opinions was similarly comprehensive, rigorous, and analytic and adhered to established measures and methods in determining nicotine dependence and addiction. Specifically, I reviewed the materials available (i.e., medical records, interrogatories, fact witness deposition testimony, interview); considered the timeframes of contact with Sandra Camacho, in relation to her smoking behavior; assessed reliability in recall and reporting; examined (in)consistencies within and between the sources of evidence; met with and interviewed Sandra Camacho regarding her smoking history and behaviors; and mapped the case specific evidence to established measures of nicotine dependence and addiction. Further details on my methods in formulating case specific opinions are found in Section VII-2.

In making an assessment of Sandra Camacho's addiction to nicotine, the methodology I applied was the same as that which I apply in my clinical practice, teaching, and research. The assessment tools I used are commonly used measures in the peer-reviewed medical literature, and in applying these tools I considered the strengths and weaknesses of each finding and considered the commonalities and differences in findings between the measures. With regard to assessment of tobacco and nicotine addiction, there are

general agreed-upon requirements for generating competent and reliable scientific opinions. Namely, assessment tools ought to have demonstrated adequate validity and reliability,² briefly reviewed here:

Validity of an assessment tool is the degree to which the tool measures what it purports to measure. In this case, the degree to which the assessment captures the phenomenon of tobacco and nicotine addiction. The four main types of validity are face, content, criterion and construct validity. Face validity concerns whether the assessment “on the face of it” relates to the phenomenon of interest. For example, one would expect a measure of tobacco addiction to include assessment of intensity of use. Content validity

Types of Validity	
CONTENT-RELATED (appropriate content)	CRITERION-RELATED (relationship to other measures)
face validity: degree to which the test appears to test what it aims to test	concurrent validity: degree to which the test relates to similar measures taken at the same point in time predictive validity: degree to which the test predicts later performance on a related criterion
content validity: extent to which the test “covers” the construct of interest	construct validity: extent to which the test relates to underlying theoretical constructs
Types of Reliability	
test-retest reliability: degree to which the test yields similar values with repeat administration	internal consistency: extent to which items within the test relate to each other
inter-rater reliability: extent to which different clinicians administering the test with the same individual obtain similar values	

is the extent to which the measure “covers” the construct of interest. Content validity is typically assessed by carefully checking the measurement method against the conceptual definition of the construct. For example, a definition of addiction from the National Institute on Drug Abuse (NIDA) is “compulsive drug seeking despite negative consequences.”³ Hence, measurement of addiction would be expected to assess a drive to use the drug. Criterion validity is the extent to which scores on a measure correlate with other measures with which they would expect to be correlated (i.e., criteria) measured either at the same time (i.e., concurrent validity) or in the future (i.e., predictive validity). Examples for nicotine addiction would be correlation with a biological indicator of tobacco use (e.g., cotinine⁴) or predicting future difficulty or failure to quit smoking. Construct validity is the degree to which an assessment relates to underlying theoretical concepts. Examples would be the relationship of nicotine addiction severity to the development of tobacco-related diseases, such as lung cancer, and death. **Reliability** refers to the consistency of a measure. With clinical assessments, three types of consistency are of interest: over time (test-retest reliability), across items (internal consistency), and across different clinicians (inter-rater reliability). Consistency is expected in repeat applications of a test for phenomena that are fairly stable and particularly if administered close in time; items in a measure assessing a common construct are generally expected to relate to each other; and interviewer effects are ideally minimized to avoid undue influence (or bias) introduced by the clinician’s administration style and practice of interpretation. Consideration of the validity and reliability of the tools I use to assess nicotine and tobacco addiction in my research, clinical, and forensic practice are discussed in Section VI-4.

The opinions stated below are all within a reasonable degree of scientific certainty.

² Geisinger, K. F., Bracken, B. A., Carlson, J. F., Hansen, J.-I. C., Kuncel, N. R., Reise, S. P., & Rodriguez, M. C. (Eds.). (2013). *APA handbooks in psychology. APA handbook of testing and assessment in psychology, Vol. 1. Test theory and testing and assessment in industrial and organizational psychology*. Washington, DC, US: American Psychological Association.

³ NIDA website, *The Science of Drug Use and Addiction: the Basics*. Last updated July 2018. (Accessed June 27, 2019) <https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics>

⁴ Cotinine is the major metabolite of nicotine that has a longer half-life than nicotine and takes 72-hours to clear from the body, making it a useful objective measure of recent tobacco use and heaviness of use.

VI. General Opinions

1) Conventional cigarettes are defective, unreasonably dangerous, and unsafe when used in a foreseeable manner because they are highly addictive. Nicotine is the addictive drug in tobacco; and cigarettes are designed to create and sustain addiction.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports: e.g., Surgeon General Reports; National Institute on Drug Abuse; FDA; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health
3. Internal industry documents available via Truth Library⁵

Findings: All commercially available cigarettes in the US contain the drug nicotine. On average, a person who smokes absorbs 1 to 1.5 mg of nicotine from each cigarette.⁶ Nicotine is the drug in tobacco that causes addiction. Nicotine establishes and maintains tobacco addiction by complex actions that affect the neurochemistry of the brain.⁷ Prolonged tobacco use results in physiologic dependence and a neuro-behavioral compulsion to use tobacco.

Nicotine from cigarette smoke is rapidly absorbed in the lungs, and then quickly passes into the brain, within 15 to 20 seconds.⁸ The rapidity of absorption is an important determinant of the addictiveness of a drug, and cigarette smoking is the most rapid method of nicotine delivery. Nicotine diffuses readily into brain tissue, where it binds to nicotinic acetylcholine receptors (nAChRs), which are ligand-gated ion channels. The nAChR complex is composed of 5 subunits. In the mammalian brain, there are as many as 9 alpha subunits ($\alpha 2$ – $\alpha 10$) and 3 beta subunits ($\beta 2$ – $\beta 4$); $\alpha 4\beta 2$, $\alpha 3\beta 4$, and $\alpha 7$ (homomeric) are the most abundant receptor subtypes in the brains of humans. The $\alpha 4\beta 2$ receptor subtypes predominate and are believed to be the main receptor mediating nicotine dependence. Stimulation of central nAChRs by nicotine results in the release of a variety of neurotransmitters in the brain, most importantly, dopamine, which is critical in signaling pleasure. Nicotine results in positive, though transient, psychological effects of pleasure, arousal, and mood modulation.

Nicotine has an average half-life of 2 hours, but the half-life can be affected by genetic and environmental factors. With regular smoking, nicotine levels rise in the blood over 4 to 6 hours, plateau throughout the day, then decline overnight. Thus, even though each cigarette produces a spike of arterial nicotine with a rapid decline between cigarettes, the brain is exposed to nicotine for 24 hours each day.⁹ This duration of exposure of nicotine in the brain throughout the day and night changes the structure and function of nicotinic receptors, stimulating intracellular processes of neuroadaptation, and has implications for the development of tolerance and withdrawal symptoms.

With chronic nicotine exposure, as is the case with people who become addicted to nicotine in cigarettes, neuroadaptation occurs, such that more nicotine is required to deliver the same neurochemical effect. As the brain becomes tolerant, nicotine is needed to maintain normal brain functioning. Tolerance is defined as a need for markedly increased amounts of nicotine to achieve the desired effect or a markedly diminished effect with continued use of the same amount of nicotine. In someone who has recently started smoking, tolerance to nicotine is exemplified by the disappearance of nausea and dizziness after repeated

⁵ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

⁶ Benowitz NL, Jacob P III 1984. Daily intake of nicotine during cigarette smoking. *Clin Pharmacol Ther* 35:499–504.

⁷ Benowitz NL. 2010 Nicotine addiction. *N Engl J Med* 362(24):2295–2303.

⁸ Benowitz NL. *Clinical pharmacology of nicotine: Implications for understanding, preventing, and treating tobacco addiction*. *Clin Pharmacol Ther*, 2008. 83(4): p. 531–41.

⁹ Benowitz NL. 2010 Nicotine addiction. *N Engl J Med* 362(24):2295–2303.

intake. Tolerance in someone who smokes regularly also occurs throughout the day.¹⁰ After smoking the first cigarette of the day, the person experiences marked pharmacologic effects, particularly arousal. No other cigarette throughout the day produces the same degree of pleasure/arousal. For this reason, many people who smoke describe the first cigarette as the most important one of the day. Shortly after the initial cigarette, tolerance begins to develop. Accordingly, the threshold levels for both pleasure/arousal and abstinence rise progressively throughout the day as the person becomes tolerant to the effects of nicotine. With continued smoking, nicotine accumulates, leading to an even greater degree of tolerance. As a result, the individual experiences greater withdrawal symptoms between successive cigarettes. Tolerance develops to nicotine's effects, thereby reducing the drug's primary reinforcing effects and inducing physical dependence to the drug, exhibited in the form of withdrawal symptoms in the absence of nicotine. Late in the day, each individual cigarette produces only limited pleasure/arousal and instead, primarily serves to alleviate nicotine withdrawal symptoms. Cessation of smoking overnight allows resensitization of drug responses (i.e., loss of tolerance). Most people dependent on nicotine tend to smoke a certain number of cigarettes per day (usually > 10) and tend to consume 10–40 mg of nicotine per day to achieve the desired effects of cigarette smoking and minimize withdrawal.¹¹

Nicotine in tobacco causes physical alterations to a person's brain structure and functioning. The changes to the central nervous system involved in nicotine addiction are similar to those involved in cocaine and heroin.^{12,13} The presence of nicotine causes the central nervous system to upregulate, or increase, the number of nAChRs in brain cells, which creates a physical need for nicotine. In this context, stopping smoking is associated with deficient neuro-transmitter release and withdrawal symptoms of irritability, anxiety, agitation, depressed mood, difficulty concentrating, insomnia, hunger, and weight gain as well as headache and constipation. Thus, nicotine addiction is sustained both by positive effects of pleasure and arousal (i.e., positive reinforcement) combined with continued use to avoid unpleasant effects of nicotine withdrawal (i.e., negative reinforcement).

In addition to the pharmacological aspects of nicotine addiction, conditioning plays an important role in sustaining tobacco use. Smoking becomes associated with specific behaviors, such as drinking coffee, consuming alcohol, talking on the phone, driving a car, and/or smoking after meals. Via conditioning to the drug nicotine, these behaviors become cues for smoking and contribute to maintained use. Smoking also facilitates nicotine addiction through sensorimotor factors associated with the act of smoking, e.g., the smell, taste, and feel of the cigarette smoke and handling of the cigarette.

Nicotine addiction is a chronic brain disorder, which makes quitting smoking extremely difficult.¹⁴ Most attempts to quit smoking fail. About 7 in 10 US adults who smoke want to stop smoking, and over half make a 24-hr quit attempt in a given year (many more people attempt to quit smoking but are unable to make it a full day).¹⁵ Sixty percent of those who quit for a day, relapse by 1 week.¹⁶ Today, with many more evidence-based treatments available than in the past, about 7 in 100 quit attempts (7%) are sustained for 6-months or more; and about 45% of those attempts will still result in relapse.¹⁷ Over 90% of adults who smoke have tried to quit and most people make multiple quit attempts, averaging about one per year.¹⁸ Only half of those who attempt are ultimately successful in achieving long-term abstinence, and

¹⁰ Benowitz NL. 2010 Nicotine addiction. *N Engl J Med* 362(24):2295–2303.

¹¹ Benowitz NL. 1992 Cigarette smoking and nicotine addiction. *Med Clin N Am* 76:415–437.

¹² US Department of Health & Human Services. 1988 *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*, <https://profiles.nlm.nih.gov/NN/B/B/Z/D/>

¹³ NIDA 2017 [Drug facts: cigarettes and other tobacco products](#)

¹⁴ Prochaska JJ, Benowitz NL. 2016. The past, present, and future of nicotine addiction therapy. *Ann Review Med*, 67: 467–86.

¹⁵ Centers for Disease Control. 2017. [Quitting Smoking Among Adults—United States, 2000–2015](#). *MMWR*, 65:1457–64.

¹⁶ American Psychiatric Association. 2013. *Diagnostic Statistical Manual Fifth Edition (DSM 5)*. Arlington, VA: APA

¹⁷ Centers for Disease Control. 2017. [Quitting Smoking Among Adults—United States, 2000–2015](#). *MMWR*, 65:1457–64.

¹⁸ Borland R, Partos TR, Yong HH, et al. 2012 How much unsuccessful quitting activity is going on among adult smokers? Data from the International Tobacco Control Four Country cohort survey. *Addiction* 107:673–82

most people who smoke do not achieve long-term abstinence until after age 30.¹⁹ In my clinical experience, patients often hide their attempts to quit smoking from family and friends because of past failures to quit, and poor recall of brief unsuccessful attempts is common.

In litigation, tobacco industry lawyers emphasize that 60 million Americans have quit smoking²⁰; typically, this is stated in reference in time to the 1964 Surgeon General's report. It has been more than 55 years since the 1964 report was published. Sixty million successful quits divided by 55 years equates to 1.09 million people quitting smoking each year, with more quits occurring in more recent decades due to developments in tobacco cessation resources and methods, including medications. Over those 55 years, while the smoking prevalence has declined, due to population growth, the absolute number of people smoking in the US has held relatively steady at about 40 million.²¹ With 1.09 million people successfully quitting smoking from a population of about 40 million people smoking, the quit rate averages 2.7%; this is hardly a statistic worth championing. Untold is how "smoker" is defined in this 60-million statistic, although it is likely defined as one who smokes 100 or more cigarettes in one's lifetime. That is, someone who smoked a total of 5 packs of cigarettes in their lifetime and then stopped would be included in this "60 million former smokers" statistic; the statistic does not distinguish between "smokers" who were likely addicted to cigarettes and those who were not, making it invalid and unreliable as to this aspect.

Success with quitting smoking is greater for people who do not smoke daily or who smoke fewer cigarettes per day (i.e., < 5 cigarettes per day) relative to daily, pack or more, heavier, addicted smoking. Further, becoming a former smoker does not equate with being free from harm. Many former smokers, who are counted among this "60 million former smokers" statistic, developed a tobacco-related disease. Many also died from their tobacco use. While the numbers have increased over time, each year, about 400,000 individuals die from smoking each year, a rate which over this 55-year period totals to 22 million Americans with smoking-related deaths. Additionally, for every person who dies from smoking, at least 30 people live with a serious smoking-related illness;²² thus, in the past 55 years, 660 million Americans experiencing the detrimental and costly medical consequences of smoking-related diseases. Smoking-related illness in the US costs greater than \$300 billion each year with nearly \$170 billion in direct medical costs and greater than \$156 billion in lost productivity.^{23,24}

With attrition due to quitting and dying, how has the industry maintained its profitability over time? The 2014 Surgeon General's Report quantified that each day 2300 young people under the age of 18 try smoking, and an additional 2,100 youth and young adults start smoking daily,²⁵ which amounts to 766,500 "replacement smokers"²⁶ annually (based on 2014 statistics). The 2012 Surgeon General's Report indicated that, for the more than 1,000 people in the U.S. who die due to smoking each day, at least two youth or young adults become regular smokers.²⁷ Cigarette use grew rapidly between the 1910s and mid-1960s, first in men and then in women.²⁸ Epidemiologic data for white women in the U.S. born

¹⁹ American Psychiatric Association. 2013. *Diagnostic Statistical Manual Fifth Edition (DSM 5)*. Arlington, VA: APA

²⁰ In several depositions and most trials in which I have testified, I have been asked by defense counsel during cross examination to affirm that there are 60 million former US smokers. Prior to my expert witness work in litigation, I had never heard this statistic, and no attorney has presented the source to me. Notably, the 2014 Surgeon General's Report does not contain this statistic. The CDC estimates that in 2015 there were 52.8 million former US smokers (CDC 2017 MMWR 65:1457-64).

²¹ US Department of Health & Human Services (USDHHS). 2014. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>

²² See 19 USDHHS 2014 SGR

²³ See 19 USDHHS 2014 SGR

²⁴ Xu X, et al. 2014. Annual Healthcare Spending Attributable to Cigarette Smoking: An Update. *Am J Prev Med*;48(3):326–33.

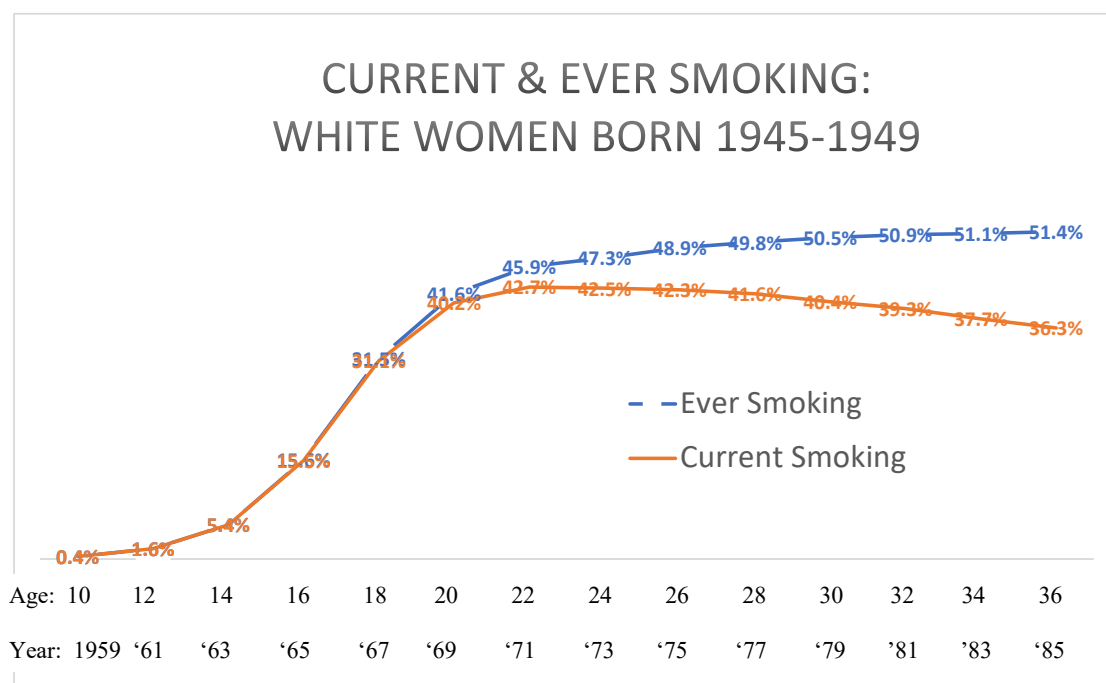
²⁵ See 19 USDHHS 2014 SGR

²⁶ February 29, 1984 RJR report, "Young Adult Smokers: Strategies and Opportunities". Bates No. 501928462-8550, "Younger adult smokers are the only source of replacement smokers... If younger adults turn away from smoking, the industry must decline, just as a population which does not give birth will eventually dwindle."

²⁷ USDHHS. 2012. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta: CDC

²⁸ USDHHS. 2000. *Reducing Tobacco Use. A Report of the Surgeon General*. Atlanta: CDC

when Sandra Camacho was born (1945-49) indicate that nearly 1 in 3 women (31.54%) in her gender- and race-matched birth cohort had ever smoked by age 18 and similarly nearly 1 in 3 (31.08%) were current smokers at age 18.²⁹ The figure below shows the prevalence over time of ever and current smoking among white women born between 1945-1949 by year and age, in 2 year increments. At all years from this NCI Monograph, there were more current than former smokers (quit ratio < 50%).



The next section focuses on nicotine exposure effects on the developing adolescent brain. The adult smoking prevalence began a steady but hardly precipitate decline equaling 0.5% per year in 1965 (the year following the 1964 US Surgeon General's first report on smoking).³⁰ Cigarette sales kept increasing and would not peak until the late 1970s. Although per capita cigarette consumption reached its highest level in 1963, the year before publication of the Surgeon General's report, it did not begin a steady year-to-year decline until 1973.³¹ That the 1964 Surgeon General's report did not change smoking patterns overnight is indicative of the major role of nicotine and the challenges of disseminating and transmitting new information, particularly so in the face of a massive denial and misinformation campaign fueled by the tobacco industry.³² The figure below shows the annual smoking cessation rates, by calendar year, for 5-year birth cohorts of white females born between 1925 and 1969.³³ While cessation rates increased with age and time, for none of the birth cohorts does the annual cessation rate reach even 4%. The trend line with the upside-down white triangle represents Sandra Camacho's birth cohort.

²⁹ Burns DM, Lee L, Shen LZ, et al. 1997. Cigarette Smoking Behavior in the United States. In *Changes in Cigarette-Related Disease Risks and Their Implications for Prevention and Control, Smoking and Tobacco Control Monograph No. 8*. NCI

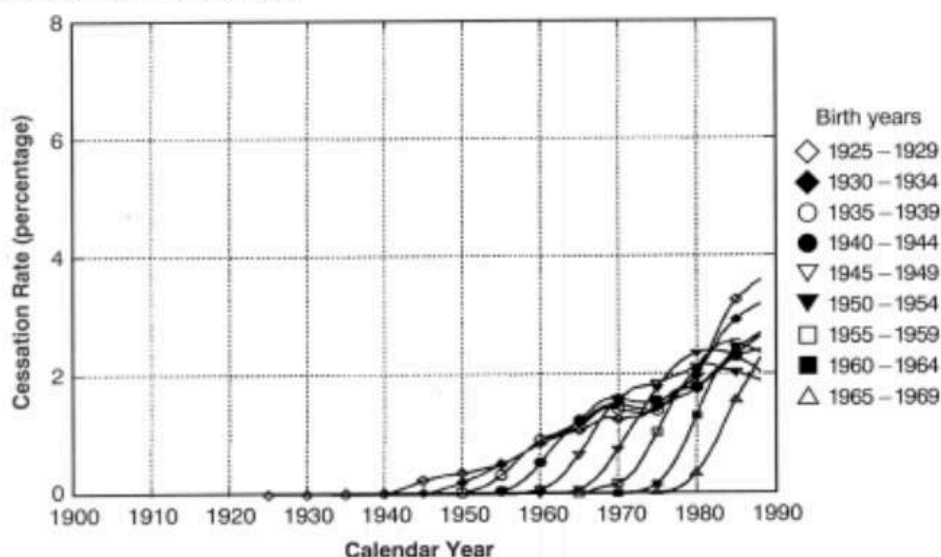
³⁰ USDHHS. 1989 *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General*.

³¹ USDHHS. 1994. *Preventing Tobacco Use Among Young People. A Report of the Surgeon General*. Atlanta (GA): CDC.

³² Kessler G. 2006. United States of America v. Philip Morris USA, Inc., et al., Civil Action no. 99-2496, Final Opinion.

³³ Burns DM, Lee L, Shen LZ, et al. 1997. Cigarette Smoking Behavior in the United States. In *Changes in Cigarette-Related Disease Risks and Their Implications for Prevention and Control, Smoking and Tobacco Control Monograph No. 8*. NCI

Annual smoking cessation rates, by calendar year, for 5-year birth cohorts of white females born between 1925 and 1969



2) Nearly all individuals who smoke started by the age of 18, making smoking a pediatric disease. Nicotine exposure in adolescence adversely affects brain development with lasting changes. Nicotine exposure disrupts the reward system and is associated with the loss of interest in normal, non-drug rewards. This effect is observed in even light smoking teens, suggesting occurrence early in smoking acquisition. With a lower threshold of drug effects relative to adults, adolescents experience symptoms of dependence at lower levels of nicotine exposure. Nicotine exposure during adolescence is associated with more intensive use, a greater risk of addiction, more chronic use, and a lower likelihood of quitting relative to initiation at older ages.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports: e.g., Surgeon General Reports; National Institute on Drug Abuse; FDA; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health
3. Internal industry documents available via Truth Library³⁴

Nearly all (9 in 10) individuals who smoke started by the age of 18. Adolescence is a critical window for brain development, with the brain not reaching full maturity until the mid-20s.³⁵ Adolescence is a period of enhanced neuroplasticity during which the underdeveloped neural networks necessary for adult-level judgment (the prefrontal cortical regions) cannot yet properly regulate impulses and emotion.³⁶ As a consequence, adolescents are highly vulnerable to drug experimentation and addiction.³⁷ The younger one starts smoking cigarettes, for example, the greater the risk of stronger physiological addiction to nicotine.

³⁴ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

³⁵ Giedd, JN. 2004. Structural magnetic resonance imaging of the adolescent brain. *Ann. N. Y. Acad. Sci.* 1021, 77–85.

³⁶ Giedd JN. et al 1999 Brain development during childhood and adolescence: a longitudinal MRI study. *Nat Neurosci* 2: 861–63.

³⁷ USDHHS. 2012. *Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General.* Atlanta, GA

Earlier onset of daily smoking is significantly associated with higher nicotine dependence scores³⁸ and with heavier and longer smoking careers compared to late onset smoking.^{39,40,41}

Further, nicotine exposure during adolescence, may have lasting adverse consequences for brain development. Adolescence is a period during which the brain undergoes important developmental changes.⁴² Adolescent synapses are more numerous and more “plastic” or moldable by experience.^{43,44} Hence, adolescents have superior learning and memory skills compared to adults, with synaptic formation and learning highly strengthened by stimulation from environmental experience.⁴⁵ Beginning in preadolescence and continuing into the mid-20s, cortical grey matter volumes reduce, which reflects a normal pruning process; and white matter volume increases over the course of adolescence, reflecting increases in connectivity, including axonal extension and myelination.⁴⁶ The adolescent brain’s special vulnerability extends to areas involved in higher cognitive function, such as the prefrontal cortex where circuit formation continues into the mid-20s. During the extended maturational period of adolescence, substantial neural remodeling occurs in a variety of pathways, including those governed by dopamine or acetylcholine. Dopamine is critical to reward function, and acetylcholine plays a central role in cognitive maturation, including executive function mediated by the prefrontal cortex.⁴⁷ Normal adolescent-specific behaviors (e.g., risk-taking, novelty seeking, peer pressure sensitivity) increase the propensity to experiment with legal and illegal drugs, which may reflect the incomplete development of brain regions (e.g., myelination of frontal lobe regions) involved in the processes of executive control and motivation.

These features of adolescent brain development can have detrimental consequences when inappropriate stimulation is evoked by exposure to neuroactive chemicals. Addictive stimuli or drugs can activate and strengthen reward circuits to create an addicted state.⁴⁸ Adolescents experience symptoms of dependence at lower levels of nicotine exposure than adults.^{49,50,51} Initial symptoms of nicotine dependence occur, in some teens, within days to weeks of onset of use.⁵² Parent education materials published by Philip Morris in 2004 acknowledge that, “The younger people are when they start smoking, the more likely they are to become strongly addicted to nicotine. Symptoms of addiction (having strong urges to smoke, feeling anxious or irritable, or having unsuccessfully tried not to smoke) can appear in teens and preteens within weeks or only days after they become ‘occasional smokers’” (5095388219-234).

³⁸ Robinson ML, Berlin I, Moolchan ET. 2004 Tobacco smoking trajectory and associated ethnic differences among adolescent smokers seeking cessation treatment. *Journal of Adolescent Health* 35(3):217–24

³⁹ Grant BF. 1998. Age at smoking onset and its association with alcohol consumption and DSM-IV alcohol abuse and dependence: results from the National Longitudinal Alcohol Epidemiologic Survey. *J Subst Abuse* 10(1):59–73.

⁴⁰ Taioli E, Wynder EL. 1991. Effect of the age at which smoking begins on frequency of smoking in adulthood. *N Engl J Med*. 325(13):968–9.

⁴¹ Chen J and Millar W. 1998. Age of smoking initiation: Implications for quitting. *Health Reports*; 9(4):39–46.

⁴² Spear LP. 2013. Adolescent neurodevelopment. *J Adolesc Health* (suppl 2): S7–13.

⁴³ Giedd JN. 2004. Structural magnetic resonance imaging of the adolescent brain. *Ann NY Acad Sci* 1021, 77–85.

⁴⁴ Sowell E, Peterson B, Thompson P, et al. 2003. Mapping cortical change across the human life span. *Nat. Neurosci* 6, 309–315

⁴⁵ Burgaleta M, Johnson W, Waber DP, et al. 2014. Cognitive ability changes and dynamics of cortical thickness development in healthy children and adolescents. *Neuroimage* 84, 810–819.

⁴⁶ Giedd JN, et al. *Nat Neurosci* 1999; 2: 861–63.

⁴⁷ Wallace TL, Bertrand D. 2013. Importance of the nicotinic acetylcholine receptor system in the prefrontal cortex. *Biochem Pharmacol* 85, 1713–1720.

⁴⁸ Russo SJ, Dietz DM, Dumitriu D, et al. 2010. The addicted synapse: mechanisms of synaptic and structural plasticity in nucleus accumbens. *Trends Neurosci* 33, 267–276.

⁴⁹ O’Loughlin J, DiFranza J, Tyndale RF, et al. 2003. Nicotine-dependence symptoms are associated with smoking frequency in adolescents. *Am J Prev Med* 25, 219–225.

⁵⁰ Kandel DB, Chen K. 2000. Extent of smoking and nicotine dependence in the US: 1991–1993. *Nicotine Tob Res* 2, 263–274.

⁵¹ DiFranza J, Rigotti N, McNeill A, et al. 2000. Initial symptoms of nicotine dependence in adolescents. *Tob Control* 9, 313–19

⁵² USDHHS. 2012. Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA

Hence, adolescents and young adults are thus more vulnerable to addiction than adults.⁵³ Animal studies confirm the heightened response of adolescents to nicotine exposure.⁵⁴ Adolescent rodents self-administer nicotine more than adults, and adolescent exposure leads to increased self-administration of nicotine⁵⁵ and other drugs in adulthood.⁵⁶

Functional magnetic resonance imaging (fMRI) examining the neural circuitry involved in nicotine craving and addiction in adolescent smokers has documented smaller neural responses in the ventral striatum and mid-brain in anticipation of financial reward in adolescent smokers (age 14 years) compared to matched non-smoking controls.⁵⁷ The reduced response showed a clear-cut relationship with smoking frequency. Findings support that adolescent smokers display a hypo-responsivity to the anticipation of non-drug reward (i.e., financial reward) relative to non-smokers, and this hypo-responsivity becomes more severe with increased smoking. There also is evidence that adolescents who smoke ≤ 5 cigarettes per day display attenuated responses to other non-drug rewards, including pleasurable food images, relative to non-smokers, in areas including the insula and inferior frontal region.⁵⁸ The implication of both these studies is that the use of extremely rewarding drugs, such as nicotine, decreases the perception of the pleasure obtained from non-drug rewards. Furthermore, that this was demonstrated in young and light smoking teens indicates that such changes in the brain occur in the early phases of smoking.

Nicotine also has been found to have secondary reinforcing effects making other, non-drug activities more enjoyable, enhancing the pleasure of visual (movies) and auditory (music) stimuli, and reducing the speed at which people become bored with a visual reinforcer.^{59,60,61} This secondary reinforcing effect is believed to contribute to the difficulty people have when trying to quit and the resulting feelings of dysphoria and amotivation.⁶² For the teen addicted to e-cigarettes, activities are not as pleasurable or motivating in the absence of nicotine.

The *2016 Surgeon General Report: E-cigarette Use in Youth and Young Adults* concluded that, “Compared with older adults, the brain of youth and young adults is more vulnerable to the negative consequences of nicotine exposure. The effects include nicotine addiction, priming for use of other addictive substances, reduced impulse control, deficits in attention and cognition, and mood disorders.”⁶³ Nicotine changes the way synapses are formed, harming the parts of the brain that control attention and learning. Youth and young adults are uniquely at risk for long-term, long-lasting effects of exposing their

⁵³ USDHHS. 2012. Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA

⁵⁴ Belluzzi JD, Lee AG, Oliff HS, Leslie FM. 2004. Age-dependent effects of nicotine on locomotor activity and conditioned place preference in rats. *Psychopharmacology (Berl.)* 174, 389–395.

⁵⁵ Adriani W, Spijker S, Deroche-Gamonet V, et al. 2003. Evidence for enhanced neurobehavioral vulnerability to nicotine during periadolescence in rats. *J Neurosci* 23, 4712–4716.

⁵⁶ Klein, LC. 2001. Effects of adolescent nicotine exposure on opioid consumption and neuroendocrine responses in adult male and female rats. *Exp Clin Psychopharmacol* 9, 251–261.

⁵⁷ Peters J, Bromberg U, Schneider S, et al. 2011. Lower ventral striatal activation during reward anticipation in adolescent smokers. *Am J Psychiatry* 168, 540–549.

⁵⁸ Rubinstein ML, Luks TL, Dryden WY, Rait MA, Simpson GV. 2011 Adolescent smokers show decreased brain responses to pleasurable food images compared with nonsmokers. *Nicotine Tob Res* 13, 751–755.

⁵⁹ Perkins KA, Karelitz JL, Boldry MC. Nicotine Acutely Enhances Reinforcement from Non-Drug Rewards in Humans. *Front Psychiatry*. 2017;8:65

⁶⁰ Karelitz JL, Perkins KA. Tobacco smoking may delay habituation of reinforcer effectiveness in humans. *Psychopharmacology (Berl)*. 2018 Aug;235(8):2315-2321

⁶¹ Perkins KA, Karelitz JL, Michael VC. Reinforcement enhancing effects of acute nicotine via electronic cigarettes. *Drug Alcohol Depend*. 2015;153:104-108.

⁶² NIDA. 2018, September 28. Recent Research Sheds New Light on Why Nicotine is So Addictive.

⁶³ USDHHS. 2016. *2016 Surgeon General’s Report: E-cigarette Use in Youth and Young Adults*. Atlanta, GA

developing brains to nicotine, including nicotine addiction, mood disorders, and permanent lowering of impulse control. Nicotine also can prime the teen brain for addiction to other drugs such as cocaine.⁶⁴

Young people have been and remain a key target market of the tobacco industry, referred to as “replacement smokers” to make up for the adult smokers who quit and/or die (Bates No. 501928462-8550). Tobacco use in adolescence that starts primarily for psychosocial reasons can transition into a serious drug addiction.⁶⁵ Describing the process from youth experimentation to nicotine addiction, a Philip Morris 1969 draft report titled *Why One Smokes* noted, “Smoking a cigarette for the beginner is a symbolic act... ‘I am no longer my mother’s child, I’m tough, I am an adventurer, I’m not square.’ ...As the force from the psychological symbolism subsides, the pharmacological effect takes over to sustain the habit” (1003287836). A 1969 presentation to the Philip Morris Board of Directors titled *Smoker Psychology Research* similarly noted, “Long after adolescent preoccupation with self-image has subsided, the cigarette will even preempt food in times of scarcity on the smoker's priority list” (Bates No. 1000273741). A 1970 memo from a Lorillard executive stated, “While this cigarette is geared to the youth market, no attempt (obvious) can be made to encourage persons under twenty-one to smoke. The package design should be geared to attract the youthful eye... not the ever-watchful eye of the Federal Government” (Bates No. 92352889). A 1978 memo from a Lorillard executive noted, “The base of our business is the high-school student” (Bates No. TINY0003062). A 1974 R.J. Reynolds’s marketing plan document noted, “They represent tomorrow's cigarette business. . . As this 14-24 age group matures, they will account for a key share of the total cigarette volume -- for at least the next 25 years” (Bates No. 501421310-1335).

With a focus on the “21 and under” group, a 1973 document Claude Teague, an executive with R.J. Reynolds, wrote a memorandum titled, “Some Thoughts about New Brands of Cigarettes for the Youth Market” with an analysis of “perhaps exploitable” “factors influencing pre-smokers to try smoking, learn to smoke and become confirmed smokers.”⁶⁶ Teague wrote that:

“For the pre-smoker and ‘learner’ the physical effects of smoking are largely unknown, unneeded, or actually quite unpleasant or awkward. The expected or derived psychological effects are largely responsible for influencing the pre-smoker to try smoking, and provide sufficient motivation during the ‘learning’ period to keep the ‘learner’ going, despite the physical unpleasantness and awkwardness of the period. In contrast, once the ‘learning’ period is over, the physical effects become of overriding importance and desirability to the confirmed smoker, and the psychological effects, except the tension-relieving effect, largely wane in importance or disappear.”

Factors that Teague identified as driving experimentation include group identification, self-image enhancement, and the desire for new experiences; whereas, the strongest factor driving confirmed smoking is the nicotine response. That is, youth start to use nicotine because they are curious and are seeking membership in a peer group; youth continue to use nicotine products, because they cannot stop. Teague goes on in his memo to provide specifications for nicotine’s effects: “Nicotine should be delivered at about 1.0-1.3 mg/cigarette, the minimum for confirmed smokers. The rate of absorption of nicotine should be kept low by holding pH down, probably below 6.”

Drug exposure in adolescence is associated with more chronic and intensive use and greater risk of a substance use disorder than is initiation at older ages.⁶⁷ Epidemiologic studies document that individuals

⁶⁴ Levine A et al. Molecular mechanism for a gateway drug: Epigenetic changes initiated by nicotine prime gene expression by cocaine, *Science Translational Medicine* 3(107):107ra109

⁶⁵ Rubinstein ML, Prochaska JJ. 2016. Tobacco. In L Neinstein, DK Katzman, T Callahan, et al. (Eds.), *Neinstein’s Adolescent and Young Adult Health Care: A Practical Guide* (6th edition). Lippincott Williams & Wilkins (pp. 536-546).

⁶⁶ Teague CE 1973. Research planning memorandum on some thoughts about new brands of cigarettes for the youth market. 2 Feb. R.J. Reynolds. 502987357/7368.

⁶⁷ Volkow ND. Altered pathways: drug abuse and age of onset. *Addict Professional* 2006; 26: 29.

who begin smoking as teens are more likely to become life-long smokers than those who start smoking in their 20's or later.^{68,69,70} Furthermore, adolescents experience symptoms of dependence at lower levels of nicotine exposure than adults.^{71,72,73} Adults who smoke and initiated as adolescents are less likely to quit smoking than those who initiated as adults. In an interview study of 1,200 individuals, those who initiated smoking at age 13 years or younger had the lowest likelihood of quitting, followed by those who initiated between ages 14 and 17, while adult initiators (18+) had the highest likelihood of quitting.⁷⁴ A number of studies have yielded similar results.^{75,76,77} In a prospective study, initiation of smoking after age 20 predicted a greater likelihood of successfully quitting.⁷⁸ It is generally accepted among experts in the field that initiation of smoking younger in age makes it harder to quit. The importance of prevention cannot be overstated. If youth and young adults, through age 26, remain tobacco-free, very few people will begin to use tobacco products.⁷⁹

Smoking cessation efforts have been particularly challenging in adolescents. The tobacco treatment literature with adolescents largely consists of failed smoking cessation trials.⁸⁰ In my own research, I have collaborated on three tobacco cessation randomized controlled clinical trials with adolescents and younger adults that showed no significant difference by treatment condition at long-term follow-up.^{81,82,83}

3) Addiction to nicotine is characteristically similar to addiction to other drugs of abuse such as cocaine and heroin. Clinically, in research, and in forensic settings, nicotine addiction can be reliably determined.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports: e.g., Surgeon General Reports; National Institute on Drug Abuse; FDA; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health
3. American Psychiatric Association's *Diagnostic Statistical Manual Fifth Edition (DSM 5)*
4. Internal industry documents available via Truth Library

⁶⁸ Dierker L, Swendsen J, Rose J, et al. 2012. Transitions to regular smoking and nicotine dependence in the adolescent national comorbidity survey. *Ann Behav Med* 43, 394–401.

⁶⁹ Hu MC, Griesler PC, Schaffran C, et al. 2012. Trajectories of criteria of nicotine dependence from adolescence to early adulthood. *Drug Alcohol Depend* 125, 283–289.

⁷⁰ Volkow N. 2006. Altered pathways: drug abuse and age of onset. *Addict Prof* 2,6–29.

⁷¹ O'Loughlin J, DiFranza J, Tyndale RF, et al. 2003. Nicotine-dependence symptoms are associated with smoking frequency in adolescents. *Am J Prev Med* 25, 219–225.

⁷² Kandel DB, Chen K. 2000. Extent of smoking and nicotine dependence in the US: 1991–1993. *Nicotine Tob Res* 2, 263–274.

⁷³ DiFranza J, Rigotti N, McNeill A, et al. 2000. Initial symptoms of nicotine dependence in adolescents. *Tob Control* 9, 313–319

⁷⁴ Breslau N, Peterson EL. 1996. Smoking cessation in young adults: age at initiation of cigarette smoking and other suspected influences. *Am J Public Health* 86(2):214–20.

⁷⁵ Khuder SA, Dayal HH, Mutgi AB. 1999. Age at smoking onset and its effect on smoking cessation. *Addict Behav* 24(5):673–7.

⁷⁶ Chassin L, Presson CC, Rose JS, Sherman SJ 1996. The natural history of cigarette smoking from adolescence to adulthood: demographic predictors of continuity and change. *Health Psychol* 15(6):478–84.

⁷⁷ Chen J and Millar W. 1998. Age of smoking initiation: Implications for quitting. *Health Reports*; 9(4):39–46.

⁷⁸ Hymowitz N, Cummings KM, Hyland A. 1997. Predictors of smoking cessation in a cohort of adult smokers followed for five years. *Tob Control*. 6 Suppl 2:S57–62.

⁷⁹ USDHHS. 2012. Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA

⁸⁰ Fanshawe TR, Halliwell W, Lindson N, et al., *Tobacco cessation interventions for young people.* Cochrane Database of Systematic Reviews, 2017(11).

⁸¹ Prochaska JJ, Fromont SC, Ramo DE, et al. (2015). Gender differences in a randomized controlled trial treating tobacco use in adolescents and young adults with mental health concerns. *Nicotine & Tobacco Research*, 17, 479–485.

⁸² Ramo DE, Thrul J, Delucchi KL, Hall SM, Ling, PM, Belohlavek A, Prochaska JJ. (2018). A randomized controlled evaluation of the tobacco status project, a Facebook intervention for young adults. *Addiction*, 113, 1683–1695.

⁸³ Gray KM, Rubinstein ML, Prochaska JJ, Dubrava SJ, Holstein A, Samuels L, McRae TD. (2020). A randomized controlled trial of high- and low-dose varenicline for adolescent smoking cessation. *The Lancet Child & Adolescent Health*, 4, 837–845

Findings: In 1988, the Surgeon General's Report⁸⁴ identified 7 criteria for drug dependence:

Three primary criteria:	Four additional criteria:
1) highly controlled or compulsive use;	1) stereotypic patterns of use;
2) psychoactive (mood-altering) effects;	2) use despite harmful effects;
3) drug-reinforced behavior.	3) relapse following abstinence;
	4) recurrent drug cravings.

Notably, drug effects that are considered useful (e.g., improve mood, reduce tension) can promote drug initiation, strengthen the addiction, and contribute to relapse following cessation. Three common effects of dependence-producing drugs also were identified: (1) tolerance (i.e., adaptation of the brain to the drug with the need for more of the drug over time to achieve similar effects); (2) withdrawal following abstinence, which motivates further drug intake; and (3) creation of pleasant or euphoric effects.

Dependence to nicotine delivered via a combusted cigarette was found to meet all criteria. Today, leading national and international organizations recognize nicotine in cigarettes as addictive including: the office of the US Surgeon General⁸⁵, World Health Organization,⁸⁶ National Institute on Drug Abuse,⁸⁷ American Medical Association, American Psychiatric Association⁸⁸, American Psychological Association, American Society of Addiction Medicine⁸⁹, and the Society for Research on Nicotine and Tobacco.⁹⁰

Whereas nicotine does not yield intoxicating effects like substances such as alcohol, nicotine is highly dependence-producing and addicting and, in turn, extremely difficult to quit and stay quit for good. The table below provides a relative comparison of nicotine to other substances of abuse on five key aspects with rankings from 1 = high potential to 6 = low potential. While nicotine is among the lowest on the potential for intoxication and reinforcement, it is among the highest on dependence-producing and tolerance (i.e., need for more drug to sustain its effects) and in the middle on severity of withdrawal. Nicotine dependence is synonymous with addiction and refers to the chronic, maladaptive and relapsing pattern of chronic tobacco use. Nicotine withdrawal is characterized by mood and sleep disturbance, poor concentration, agitation, and weight gain. Although not life-threatening in their own right, nicotine dependence, tolerance, and withdrawal contribute to morbidity and mortality because they promote continuous and prolonged daily and often heavy tobacco use that leads to disease and death.

Substance	Withdrawal	Reinforcement	Tolerance	Dependence	Intoxication
Nicotine	3	4	2	1	5
Heroin	2	2	1	2	2
Cocaine	4	1	4	3	3
Alcohol	1	3	3	4	1
Caffeine	5	6	5	5	6
Marijuana	6	5	6	6	4

Henningfield Ratings⁹¹ (scale 1-6 / 1=high potential; 6=low potential)

⁸⁴ USDHHS. 1988. *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*

⁸⁵ See 19 USDHHS 2014 SGR

⁸⁶ <http://www.who.int/topics/tobacco/en/>

⁸⁷ NIDA. 2017 *Drug facts: cigarettes and other tobacco products* <https://www.drugabuse.gov/publications/drugfacts/cigarettes-other-tobacco-products>

⁸⁸ American Psychiatric Association. 2015. Position Statement on Tobacco Use Disorder. <https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-2015-Tobacco-Use-Disorder.pdf>

⁸⁹ American Society of Addiction Medicine. 2008. Public Policy Statement on Nicotine Addiction and Tobacco https://www.asam.org/docs/default-source/public-policy-statements/1nicotine-addiction-and-tobacco-rev-10-081.pdf?sfvrsn=7b5b2c23_0

⁹⁰ SRNT Resource on treating tobacco dependence: <http://www.treattobacco.net/en/index.php>

⁹¹ Hilts PJ 1994 "Is Nicotine Addictive? Depends on Whose Criteria You Use," *NY Times* August 2, 1994, C3. At the time these ratings were provided, Jack Henningfield, PhD was NIDA where he led and conducted tobacco and other drug use research.

In clinical practice and in research, there are many tools that have demonstrated validity and reliability in diagnosing nicotine and tobacco addiction. There are, however, tools with demonstrated reliability and validity that are widely accepted and used in practice. Clinically, in my research, and forensically, when I diagnose nicotine and tobacco addiction, I use three resources accepted in the field as valid and reliable. Each have their strengths, and to confirm a reasonable degree of scientific certainty in my methods, I examine patterns and (in)consistencies between the 3 tools. Below, I describe the tools and their relative validity and reliability.

The first, and most reliable and broadly used tool in research and tobacco treatment settings, is the **Heaviness of Smoking Index (HSI)**,⁹² consisting of two reliable and well-validated items⁹³: (1) the usual number of cigarettes smoked per day and (2) the time to first cigarette upon waking.

Assessing quantity of use and compulsion to smoke upon waking, the HSI has high face validity and good content validity. Number of cigarettes smoked per day is a measure both of daily nicotine intake and the frequency of nicotine self-administration. Time to first cigarette is a measure of physical dependence and the intensity of withdrawal symptoms after overnight abstinence. Figure 1 shows the items and scoring. Sum scores of 0-2 are rated as low dependence, 3-4 as moderate dependence, and 5-6 as high dependence.

FIG 1. HEAVINESS OF SMOKING INDEX			
How soon after you wake up do you smoke your first cigarette?			
Within 5 minutes (3)	31-60 minutes (1)		
6-30 minutes (2)	After 60 minutes (0)		
How many cigarettes/day do you smoke?			
10 or less (0)	21-30 (2)	11-20 (1)	31 or more (3)

In terms of criterion validity, the HSI items significantly correlate with biomarkers of tobacco exposure, accounting for 20-30% of the variance in measures of alveolar carbon monoxide, nicotine, and urinary cotinine, which is the major metabolite of nicotine.⁹⁴ The HSI is associated with smoking-induced deprivation, measured as prioritization of spending on cigarettes instead of household essentials such as food.⁹⁵ Both items (time to first cigarette [TTFC] and number of cigarettes smoked per day [CPD]) are used for dosing nicotine replacement medications. The recommendation is use of the highest dose of nicotine gum and lozenge (i.e., 4 mg) with individuals who smoke within 30 minutes of waking. For dosing of the nicotine patch, it is recommended to start at the highest patch dose (i.e., 21 mg) or to double up on patches for those who smoke a pack or more daily.⁹⁶ HSI scores predict difficulty with quitting smoking⁹⁷ and the likelihood of developing tobacco-related diseases, such as heart and lung disease and lung cancer.^{98,99,100} In a prospective study, time to first cigarette and cigarettes per day were the most robust predictors of smoking cessation.¹⁰¹ Research conducted by investigators from Altria Client Services with grant funding from Philip Morris USA Inc. concluded the

⁹² Heatherton TF, Kozlowski LT, Frecker RC, et al. 1989. Measuring the Heaviness of Smoking: Using self-reported time to the first cigarette of the day and number of cigarettes smoked per day. *British Journal of Addiction*; 84:791-799.

⁹³ Borland R, Yong HH, O'Connor RJ, et al 2010 The reliability and predictive validity of the Heaviness of Smoking Index and its two components: Findings from International Tobacco Control Four Country study. *Nicotine Tobacco Research*, 12, S45-S50

⁹⁴ Heatherton TF, Kozlowski LT, Frecker RC, et al. 1989. *British Journal of Addiction*; 84:791-799

⁹⁵ Siahpush M, Borland R, Yong H. 2007. Sociodemographic and psychosocial correlates of smoking-induced deprivation and its effect on quitting: findings from the International Tobacco Control Policy Evaluation Survey. *Tobacco Control*;16:e2.

⁹⁶ Prochaska JJ, Benowitz NL. 2016. The past, present, and future of nicotine addiction therapy. *Ann Review Med*, 67: 467-86.

⁹⁷ Baker TB, Piper ME, McCarthy DE, et al. 2007. Time to first cigarette in the morning as an index of ability to quit smoking: Implications for nicotine dependence. *Nicotine Tob Res* 9 (Suppl 4):S555-570.

⁹⁸ Schnoll RA, Gorin A, Annunziata A, Suaya JA. 2013. The prevalence, predictors and associated health outcomes of high nicotine dependence using three measures among US smokers. *Addiction*, 108, 1989-2000

⁹⁹ Baker TB, Breslau N, Covey L, Shiffman S. 2012. DSM criteria for tobacco use disorder and tobacco withdrawal: a critique and proposed revision for DSM 5. *Addiction*, 107, 263-275

¹⁰⁰ Gu F, Cheung LC, Freedman ND, Katki HA, Caporaso NE. 2017. Potential impact of including time to first cigarette in risk models for selecting ever-smokers for lung cancer screening. *J Thoracic Oncology*, 12, 1646-1653

¹⁰¹ Hymowitz N, Cummings KM, Hyland A. 1997. Predictors of smoking cessation in a cohort of adult smokers followed for five years. *Tob Control*. 6 Suppl 2:S57-62.

two items of the HSI were the most important factors correlating with biomarkers of exposure.¹⁰² Smoking affects gene expression,¹⁰³ and in genomic research, number of cigarettes smoked per day and time to first cigarette, the two HSI items, have shown an association with candidate genes that include those previously associated with cocaine addiction, alcohol dependence, and heroin addiction.¹⁰⁴ The rate of nicotine metabolism, which reflects cytochrome P450 2A6 (CYP2A6) activity and has genetic and environmental influences, also correlates significantly with HSI.¹⁰⁵ The HSI items have demonstrated very good test-retest reliability among adolescents and adults.^{106,107}

The second tool is the American Psychiatric Association's **Diagnostic Statistical Manual Fifth Edition (DSM 5)**¹⁰⁸, which defines Tobacco Use Disorder as "a problematic pattern of tobacco use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period": 1) craving, 2) great deal of time spent using, 3) using larger amounts or for longer periods than was intended, 4) tolerance, 5) continued use despite physical/ psychological problems, 6) repeated attempts to quit or control use, 7) withdrawal or use of a similar substance to avoid withdrawal, 8) hazardous use, 9) social/interpersonal problems related to use, 10) activities given up to use, and 11) neglecting major roles to use. Tolerance is defined as a need for markedly increased amounts of tobacco to achieve the desired effect or a markedly diminished effect with continued use of the same amount of tobacco, and with tobacco is "exemplified by the disappearance of nausea and dizziness after repeated intake." Withdrawal is manifested by either the characteristic withdrawal syndrome for tobacco or tobacco (or a closely related substance, such as nicotine) is taken to relieve or avoid withdrawal symptoms. The characteristic withdrawal syndrome for tobacco is defined as four (or more) of the following signs or symptoms: irritability/frustration/anger, anxiety, difficulty concentrating, restlessness, increased appetite or weight gain, dysphoric or depressed mood, insomnia. Recognizing the chronic nature of Tobacco Use Disorder, with high risk for relapse, specifiers include in "early remission" (i.e., symptom free for 3 months to less than a year after meeting a diagnosis of Tobacco Use Disorder); in "sustained remission" (i.e., symptom free for 12 months or longer); "on maintenance therapy" (i.e., on a long-term maintenance medication such as nicotine replacement therapy); and "in a controlled environment" (i.e., with restricted access to tobacco, such as a locked hospital unit or smoke-free incarceration). Current severity is coded as mild (2-3 symptoms), moderate (4-5 symptoms), or severe (6 or more symptoms).

The American Psychiatric Association has repeatedly revised the official Diagnostic and Statistical Manual of Mental Disorders (DSM) with volume I published in 1952, DSM-II in 1968, DSM-III in 1980, DSM-IV in 1994, and DSM 5 in 2013.¹⁰⁹ The first two editions of the DSM were not comprehensive listings of all psychiatric diagnoses, and neither included tobacco related disorders. With the goal of including "as many conditions as are commonly seen by practicing clinicians,"¹¹⁰ DSM-III added over 100 psychiatric diagnoses, including tobacco dependence and tobacco withdrawal. Each DSM revision entails an extensive multi-year process of review and revision, and an analysis of previously secret

¹⁰² Muhammad-Kah RS et al. 2011. The relationship between nicotine dependence scores and biomarkers of exposure in adult cigarette smokers. *Regulatory Toxicology and Pharmacology* 60, 79-83. BATES: 537266616-537266620

¹⁰³ Kopa PN, Pawliczak R. 2018. Effect of smoking on gene expression profile - overall mechanism, impact on respiratory system function, and reference to electronic cigarettes. *Toxicol Mech Methods* 28(6):397-409.

¹⁰⁴ Chen J, et al. 2020. Genome-Wide Meta-Analyses of FTND and TTFC Phenotypes, *Nicotine & Tob Res*, 22: 900-909

¹⁰⁵ Schnoll RA, George TP, Hawk L, et al. 2014. The relationship between the nicotine metabolite ratio and three self-report measures of nicotine dependence across sex and race. *Psychopharm* 231, 2515-2523.

¹⁰⁶ DiFranza JR, et al. (2012) The retest reliability of nicotine dependence measures, *Addiction Res Theory*, 20:1, 55-63.

¹⁰⁷ Borland R, Yong HH, O'Connor RJ, et al. 2010. The reliability and predictive validity of the Heaviness of Smoking Index and its two components: findings from the International Tobacco Control Four Country study. *Nicotine Tob Res* 12 Suppl:S45-50. Note: over a 3-year gap, test-retest reliability on the HSI items was 0.72, where 1.00 would be perfect.

¹⁰⁸ American Psychiatric Association. 2013. *Diagnostic Statistical Manual Fifth Edition (DSM 5)*

¹⁰⁹ <https://www.psychiatry.org/psychiatrists/practice/dsm/history-of-the-dsm>

¹¹⁰ Kirk SA, Kutchins H. *The selling of DSM*. New York: Aldine de Gruyter, 1992

tobacco industry documents yielded evidence that “the tobacco industry and its allies lobbied to narrow the definition of tobacco dependence in serial revisions of DSM-III,” and worked “to mitigate its impact following publication.”¹¹¹ The authors acknowledge that their study did “not definitively demonstrate that the industry’s efforts resulted in a change in the content of DSM-III.”

DSM-IV had a goal of addressing poor inter-rater reliability (i.e., variability due to clinician effects) in DSM-III due to inconsistencies and instances where diagnostic criteria were unclearly specified.¹¹² While DSM-IV nicotine dependence was regarded as having good face validity, the criteria were criticized for being ambiguous, for underdiagnosing nicotine addiction, and having low predictive validity relative to other measures of tobacco dependence, including frequency of smoking and latency to smoke soon after waking (the HSI items).^{113,114} Test-retest reliability for a DSM-IV nicotine dependence diagnosis was deemed moderate ($\kappa=0.63$), with repeat administration within 2 to 3 months.¹¹⁵

In my own research, in prospective analysis of treatment outcomes with $N=1132$ adults smoking daily, we found that DSM-IV symptoms accounted for a nominal amount of the variance in baseline smoking-related characteristics and were unrelated to smoking abstinence at week 12; whereas, cigarettes smoked per day was the only significant predictor of abstinence at week 12.¹¹⁶ Further, we found internal consistency (reliability) of the DSM-IV criteria to be poor (α of about 0.50, where ideal is 1.00). A 3-year longitudinal study found the number of cigarettes smoked per day and the time to first cigarette were far superior to DSM-IV criteria in predicting smoking status.¹¹⁷

In revising its criteria for DSM 5, the American Psychiatric Association unified its approach to have the same diagnostic framework for all substance use disorders. Criteria for dependence and abuse were combined into a substance use disorder; legal problems were dropped as a criterion; and craving was added. These changes expanded the number of criteria to 11, with 2 or more in a 12-month period meeting diagnosis of a substance use disorder. A study comparing DSM 5 lifetime Tobacco Use Disorder diagnosis using two different structured interviews reported moderate agreement ($\kappa=.70$).¹¹⁸ Test-retest reliability for a past year DSM 5 Tobacco Use Disorder diagnosis obtained by structured interview was strong ($\kappa=0.87$)¹¹⁹, with repeat administration 1 to 10 weeks (average 2.86 weeks).¹²⁰

In terms of face and content validity, DSM 5 Tobacco Use Disorder criteria are identical to the criteria for

¹¹¹ Neuman MD, Bitton A, Glantz SA. 2005 Tobacco industry influence on the definition of tobacco related disorders by the American Psychiatric Association. *Tob Control* 14(5):328–337

¹¹² For example: Spitzer RL, Endicott J, Robins E 1975 *Am J Psychiatr* 132, 1187; Drake RE, Vaillant GE 1985 *Am J Psychiatr* 142, 553; P. Lieberman P, Baker F 1985 *Hosp Commun Psychiatr* 36, 291; Mellsop G, Varghese F, Joshua S, et al. 1982 *Am J Psychiatr* 139, 1360.

¹¹³ Baker TB, Breslau N, Covey L, Shiffman S. 2012. DSM criteria for tobacco use disorder and tobacco withdrawal: a critique and proposed revisions for DSM 5. *Addiction* 107, 263–275

¹¹⁴ DiFranza J, Ursprung W, Lauzon B, et al. 2010 A systematic review of the Diagnostic and Statistical Manual Diagnostic criteria for nicotine dependence. *Addict Behav* 35:373–82.

¹¹⁵ Grant BF, Dawson DA, Stinson FS, et al. 2003. The Alcohol Use Disorder and Associated Disabilities Interview Schedule-IV (AUDADIS-IV): reliability of alcohol consumption, tobacco use, family history of depression and psychiatric diagnostic modules in a general population sample. *Drug Alcohol Depend* 71:7–16

¹¹⁶ Hendricks PS, Prochaska JJ, Humfleet GL, Hall SM. 2008. Evaluating the validities of different DSM-IV-based conceptual constructs of tobacco dependence. *Addiction* 103: 1215–23

¹¹⁷ Breslau N, Johnson EO. 2000. Predicting smoking cessation and major depression in nicotine-dependent smokers. *Am J Public Health* 90: 1122–7. Note: The Area under the curve (AUC) = 76% for TTFC and CPD compared to 56% for DSM, where AUC ranges from 0 to 100%, with 100% being perfect prediction.

¹¹⁸ Hasin DS, et al. 2015 The Alcohol Use Disorder and Associated Disabilities Interview Schedule-5: procedural validity of substance use disorders modules through clinical re-appraisal in a general population sample. *Drug Alcohol Depend* 148:40–46.

¹¹⁹ Note that this reliability statistic was obtained via administration of a fully structured interview. Reliability of DSM 5 Tobacco Use Disorder is anticipated to be far lower when the criteria are applied post-mortem in a forensic evaluation.

¹²⁰ Grant BF, Goldstein RB, Smith SM, et al. 2015 The Alcohol Use Disorder and Associated Disabilities Interview Schedule-5: reliability of substance use and psychiatric disorder modules in a general population sample. *Drug Alcohol Depend* 148:27–33.

diagnosing other substance use disorders in the DSM 5, such as stimulant use and opioid use disorders. A benefit of this common framework approach is clinicians need to learn only a single set of criteria to apply across different substances of abuse. A recognized drawback is that not all DSM 5 criteria are as relevant for Tobacco Use Disorder as they are for other substances.¹²¹ For example, unlike illicit substances, tobacco products are readily accessible for open sale in retail outlets throughout the US and globally. In the US, there are an estimated 375,000 tobacco retailers;¹²² this equates to 27 tobacco retail locations for every McDonald's restaurant.¹²³ Research indicates that retail availability of tobacco, which includes the number of retailers per area or population (i.e., density) and the distance to the nearest retailer (i.e., proximity) from one's home or school, is associated with earlier smoking initiation, increased current smoking and cigarette purchases, and reduced smoking cessation over time.¹²⁴ A recent meta-analysis of 27 studies concluded that lower levels of tobacco retailer density and decreased proximity are associated with lower tobacco use.¹²⁵ Local policy efforts have taken aim at reducing tobacco supply and tobacco use by limiting retailer density and proximity. Tobacco products are mass marketed and promoted in store with constant triggers and reminders to use. In 2017, the tobacco industry spent \$9 billion of its \$9.4 billion a year marketing budget (96%) on marketing/promotions at retailers including outdoor ads, point-of-sale materials, price discounts, and promotional discounts.¹²⁶

Another distinction, as noted earlier, is that nicotine is not intoxicating; cigarette smoking does not impair judgment or create perceptual disturbances (e.g., hallucinations). Hence, unlike heroin or cocaine, one can be addicted to nicotine without giving up activities or neglecting major roles to use. This is particularly true thinking back decades to when smoking was permitted in most public places, including on airplanes, in restaurants, in workplaces, and even in hospitals.

Another drawback to a common diagnostic framework is that addiction criteria that are meaningful for Tobacco Use Disorder, but perhaps less relevant to other substances, are not included. To address this limitation, the DSM 5 lists six associated features supporting diagnosis of Tobacco Use Disorder: (1) smoking within 30 minutes of waking; (2) smoking daily; (3) smoking more cigarettes per day; (4) waking at night to smoke; (5) craving and experiencing withdrawal in the presence of environmental cues; and (6) developing serious medical conditions such as lung and other cancers, cardiac and pulmonary disease, perinatal problems, cough, shortness of breath, and accelerated skin aging.

DSM 5 diagnoses are largely used for billing and insurance reimbursement in mental health treatment settings.¹²⁷ The DSM 5 indicates it is not intended to be used for forensic purposes, and the nomenclature explicitly does not include addiction. In developing the DSM 5 substance use disorders criteria, at least two psychiatrists receiving consulting or expert witness fees from the tobacco industry served in advisory

¹²¹ Baker TB, Breslau N, Covey L, Shiffman S. 2012. DSM criteria for tobacco use disorder and tobacco withdrawal: a critique and proposed revisions for DSM 5. *Addiction* 107, 263–275

¹²² Center for Public Health Systems Science 2014 Point-of-Sale Report to the Nation: The Tobacco Retail and Policy Landscape. St. Louis, MO: Center for Public Health Systems Science at the Brown School at Washington University in St. Louis and NCI.

¹²³ McDonald's states that 75% of Americans are within 3 miles of a McDonald's and 85% are within 5 miles of a McDonald's. <https://www.cnbc.com/2017/03/01/4-ways-mcdonalds-is-about-to-change.html>

¹²⁴ Young-Wolff KC, Henriksen L, Delucchi K, Prochaska JJ. Tobacco retailer proximity and density and nicotine dependence among smokers with serious mental illness. *Am J Public Health*. 2014;104(8):1454-1463

¹²⁵ Lee JGL, Kong AY, Sewell KB, et al. Associations of tobacco retailer density and proximity with adult tobacco use behaviours and health outcomes: a meta-analysis. *Tobacco Control*. Published Online First: 03 September 2021

¹²⁶ Federal Trade Commission Cigarette Report for 2017, published 2019

¹²⁷ <https://www.psychiatry.org/psychiatrists/practice/dsm/about-dsm>

to the DSM 5 Substance-Related Disorders Work Group, one with a focus on forensic applications.^{128,129}

As stated above, the DSM 5 defines Tobacco Use Disorder as “a problematic pattern of tobacco use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period.” The DSM 5 does not separately define “clinically significant impairment” or “problematic pattern of tobacco use.” Rather, meeting 2 or more of the 11 criteria of Tobacco Use Disorder is the manifestation of clinically significant impairment or distress.

Addiction experts testifying for the tobacco industry, however, in their forensic use of the DSM 5, describe first determining whether the individual has experienced clinically significant impairment before proceeding in assessment of the specified 11 criteria.^{130,131,132,133} That is, addiction experts testifying for the tobacco industry have asserted that to proceed in assessing symptoms of having a Tobacco Use Disorder, one must first exceed the threshold of demonstrating clinically significant impairment or distress, asserting “clinical significant impairment is, first and foremost, what you have to prove or find if the patient satisfies, and then you proceed.”¹³⁴ Notably, the DSM 5 does not specify this two-step process nor define clinically significant impairment separately from the manifestation of the 11 detailed criteria. Creation of this two-step process, of separating out the determination of clinically significant impairment from assessment of the DSM 5 criteria, provides ripe opportunity for a clinician to bring in his or her own judgement in determining what meets “clinically significant impairment.” In expert witness testimony on addiction for the tobacco companies, the focus of determining clinically significant impairment often turns to cognitive function, work performance, family relations, and other forms of functioning. Again, because tobacco use is licit and nonintoxicating, as discussed above, impaired cognition and performance at work and socially are not relevant criteria. The DSM 5 clearly states that the significant impairment or distress is manifested by having at least two or more of the specified diagnostic criteria.

The DSM 5 introductory chapter on substance use disorders states that: “Some clinicians will choose to

¹²⁸ Psychiatrist John Hughes, MD is 1 of 10 people listed on the DSM 5 Review Committee on Substance-Related Disorders (APA, 2013). On 5/30/19, Dr. Hughes disclosed taking consulting money from Swedish Match, Altria and Philip Morris International. This followed an email from Dr. Hughes on 5/29/19, without financial disclosures, that was sent to the membership listserv of the Society for Research on Nicotine and Tobacco (SRNT), co-authored with five senior colleagues in the field, calling for SRNT members to reject exclusion of tobacco industry representatives from participation in the annual SRNT meetings. Three of the six authors of the email (including Dr. Hughes) later disclosed active paid consulting with the tobacco industry.

¹²⁹ Psychiatrist Steven K. Hoge, MD, MBA Deposition testimony in Engle Progeny Case of Yvonne Banks, Case #08-025824, in the circuit court of the 17th Judicial Circuit, Broward County, Florida. Bates No. hoges20131105A, hoges20140107B. Dr. Hoge testified on behalf of the defense R.J. Reynolds Tobacco Company, Philip Morris USA Inc., Lorillard Tobacco Co., Liggett Group and Vector Ltd. In Volumes I (11/5/13) and II (1/7/14) of his deposition, Dr. Hoge disclosed earning money from tobacco companies during the time he was an advisor to the DSM 5 substance use disorder work group. He states the work group was tasked with evaluating the DSM-4 TR version of the DSM with respect to substance use disorders, recommending revisions, overseeing discussions about the revision process, and drafting the text that would go along with the criteria. A member of the DSM 5 Forensic Review Group (APA, 2013), Dr. Hoge stated he was assigned to the substance use disorder work group and his role was to “review the work and participate in the conference calls and any other meetings related and to offer input related to the forensic uses, implications of changes.” He estimated his time involvement as an advisor for DSM 5 at “a hundred hours.” Dr. Hoge reports that since 2009 he has been retained by law firms working for the tobacco companies in litigation to evaluate cases for the presence of tobacco use disorders and addictions and the ability of individual plaintiffs to quit smoking. Dr. Hoge states he did not disclose his conflict of interest with the other members of the DSM 5 substance use disorder work group.

¹³⁰ E.g., trial testimony by psychiatrist Daphne Dorce, MD in the Engle Progeny Case of Tognoli, in the circuit court of the Seventeenth Judicial Circuit, Broward County, Florida, case #08-80000(19), Nov 16, 2015. Bates No. dorced20151116

¹³¹ E.g., trial testimony by psychiatrist Charles Ticknor, MD in the Engle Progeny Case of Chacon, in the circuit court of the Eleventh Judicial Circuit, Miami-Dade County, Florida, case #08-00102-CA-09, Sept 20, 2016. Bates No. ticknorc20160920

¹³² E.g., trial testimony by psychiatrist Israel Jack Abramson, MD in the Engle Progeny Case of Mathis, in the circuit court of the Eleventh Judicial Circuit, Miami-Dade County, Florida, case #07-47118-CA-22, Aug 11, 2016. Bates No. abramsonj20160811

¹³³ E.g., trial testimony by psychiatrist Steven K. Hoge, MD, MBA in the Engle Progeny Case of Lustig, Case #2008-80000(19), in the circuit court of the 17th Judicial Circuit, Broward County, Florida, April 30, 2014. Bates No. hoges20140430

¹³⁴ Trial testimony of psychiatrist Daphne Dorce, MD in Engle Progeny Case of Tognoli, 2008-CV-045898 in the circuit court of the Seventeenth Judicial Circuit, Broward County, Florida, case no. 08-80000(19), Nov 16, 2015. Bates No. dorced20151116

use the word addiction to describe more extreme presentations....” The DSM 5 does not define what is intended by extreme presentations. In my clinical practice, extreme presentations can be apparent within individual symptoms. For example, an individual smoking 2 packs of cigarettes a day would be spending over 5 hours a day smoking,¹³⁵ which for the DSM 5 criterion on time spent using the drug is extreme. Extreme presentations also could be reflected by waking regularly at night and smoking or smoking first thing in the morning due to intense craving for nicotine or smoking in extremely dangerous situations.

In litigation, tobacco industry lawyers and tobacco industry addiction experts have sought to limit addiction to severe Tobacco Use Disorder, defined as 6 or more criteria.^{136,137,138,139} The National Institute on Drug Abuse’s (NIDA) website indicates, “NIDA’s use of the term addiction corresponds roughly to the DSM definition of substance use disorder. The DSM does not use the term addiction.”¹⁴⁰ This definition of addiction on NIDA’s website does not restrict the term to those with a DSM 5 severe use disorder (i.e., 6 or more criteria).

The third tool I use is an overarching definition of addiction from the **National Institute on Drug Abuse**, e.g.: “a chronic, relapsing disorder characterized by compulsive drug seeking, continued use despite harmful consequences, and long-lasting changes in the brain.”¹⁴¹ I examine the extent to which the case evidence does or does not support meeting of the measurable elements central to this definition: a) chronic use, b) drug relapse, c) compulsive drug seeking, and d) continued use despite known harms.

4) The tobacco industry has a long history of publicly denying that cigarettes are addictive. As a consequence, the American public has not been well informed of the addictive nature of cigarettes.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; National Institute on Drug Abuse; FDA; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health)
3. Internal industry documents available via Truth Library¹⁴²

Findings: At least since the 1950s, and decades before becoming generally recognized in the scientific community, the tobacco industry internally and/or privately researched and recognized, decades before it became generally recognized in the scientific community, that nicotine was, and is, an addictive drug, that cigarette manufacturers are in the drug business, and that cigarettes are drug delivery devices.¹⁴³

- A June 1959 British American Tobacco Company (BAT Co.) internal document cautioned that to: “Reduce the nicotine per cigarette as much as possible... might end in destroying the nicotine habit in

¹³⁵ It takes about 8 minutes for an individual to smoke a cigarette; 2 packs = 40 cigarettes x 8 minutes = 320 minutes = 5 1/3 hrs

¹³⁶ E.g., Steven K. Hoge, MD, Volume 1 (dated 11/5/13) of Deposition testimony in the Engle Progeny Case of Yvonne Banks, Case #08-025824, in the circuit court of the 17th Judicial Circuit and for Broward County, Florida.

¹³⁷ E.g., trial testimony by psychiatrist Israel Jack Abramson, MD in the Engle Progeny Case of Mathis, in the circuit court of the Eleventh Judicial Circuit, Miami-Dade County, Florida, case #07-47118-CA-22, Aug 11, 2016. Bates No. abramsonj20160811

¹³⁸ E.g., trial testimony by psychiatrist Charles Ticknor, MD in the Engle Progeny Case of Chacon, in the circuit court of the Eleventh Judicial Circuit, Miami-Dade County, Florida, case #08-00102-CA-09, Sept 20, 2016. Bates No. ticknorc20160920

¹³⁹ E.g., trial testimony by psychiatrist Daphne Dorce, MD in the Engle Progeny Case of Tognoli, in the circuit court of the Seventeenth Judicial Circuit in and for Broward County, Florida, case #08-80000(19), Nov 16, 2015. Bates No. dorc20151116

¹⁴⁰ NIDA website, The Science of Drug Use and Addiction: the Basics. Last updated July 2018. (Accessed June 27, 2019)

<https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics>

¹⁴¹ NIDA. 2018. [The Science of Drug Use and Addiction](#).

¹⁴² <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

¹⁴³ Paragraph 829 of Kessler G. 2006. USA v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99-2496, Final Opinion.

a large number of consumers and prevent it from ever being acquired by new smokers” (Bates No. 100099115-9117).

- An August 26, 1959 letter summarizing Psychological Research from J.W. Geiger to Dr. R.W. DuPuis, Vice President of Research at Philip Morris, lists “Addiction” under “Physiological Reasons” why people smoke (Bates No. 1003075169-171).
- A September 22, 1959 memo authored by Hugh Wakeman, Philip Morris’ Vice President for Research and Development, states: “One of the main reasons people smoke is to experience the physiological effects of nicotine on the human system” (Bates No. 10005039423-9424).
- A November 15, 1961 internal memo authored by BAT Chief Scientist Charles Ellis’ stated, “Smoking demonstrably is a habit based on a combination of psychological and physiological pleasure, and it also has strong indications of being an addiction. It differs in important features from addiction to other alkaloid drugs, but yet there are sufficient similarities to justify stating that smokers are nicotine addicts” (Bates No. TIOK0034667-4670).
- A February 13, 1962 memo by Sir Charles Ellis, scientific director to the British American Tobacco Board of Directors, indicates: “As a result of these various researches we now possess a knowledge of the effects of nicotine far more extensive than exists in published scientific literature” (Bates No. 301083820-3835).
- Addison Yeaman, Brown & Williamson (B&W) Counsel, wrote in 1963: “Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms” (Bates No. 1802.05).
- B&W RB Griffith scientist wrote in 1963: “Nicotine is by far the most characteristic single constituent in tobacco and the known physiological effects are positively correlated with smoker response;” “Certainly the nicotine level of B&W cigarettes... was not obtained by accident;” and “we can regulate, fairly precisely, the nicotine and sugar levels to almost any desired level management might require. Of this I am confident” (Bates No. ksvk0198).
- Thomas Osden, in a 1969 Philip Morris draft report, wrote: “We have, then, as our first premise, that the primary motivation for smoking is to obtain the pharmacological effect of nicotine” (Bates No. 2046754810/4822).
- A 1969 document by Philip Morris scientist William Dunn (a.k.a. “the Nicotine Kid”) stated: “I would be more cautious in using the pharmlc-medical model - do we really want to tout cigarette smoke as a drug? It is, of course, but there are dangerous FDA implications to having such conceptualizations go beyond these walls” (Bates No. krvf0021).
- In his 1972 paper titled *Motives and Incentives in Cigarette Smoking*, William Dunn, JR of the Philip Morris Research Center identified the physiological effect of cigarettes as the “primary incentive; all other incentives are secondary”; “no one has ever become a cigarette smoker by smoking cigarettes without nicotine”; “nicotine is the active constituent of cigarette smoke” and “Without nicotine ... there would be no smoking.” This report adds that, “The cigarette should be conceived not as a product but as a package. The product is nicotine. ...Think of a cigarette pack as a storage container for a day’s supply of nicotine...Think of a cigarette as a dispenser for a dose unit of nicotine...Think of a puff of smoke as the vehicle of nicotine...” (Bates No. 1003291922/1939).
- Claude Teague wrote in his 1972 memo titled *RJR Confidential Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*: “In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects” (Bates No. 2072555994/5997). This same document noted, “I believe that for the typical smoker nicotine satisfaction is the dominant desire, as opposed to flavor and other satisfactions” and, “If, as proposed above, nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business.”

- In a 1972 inter-office memo from Al Udow to Chris Bolton at Philip Morris, it was acknowledged: “Although more people talk about ‘taste,’ it is likely that greater numbers smoke for the narcotic value that comes from the nicotine” (Bates No. 2022244800).
- In 1977, HJ Minnemeyer of Lorillard wrote in his report titled *Present Status of the Nicotine Enrichment Project*: “Tobacco scientists know that physiological satisfaction is almost totally related to nicotine intake” (Bates No. 83896672-83896685).
- A 1977 document by BAT Co research executive LCFB Blackman considered the hypothesis that “high profits... associated with the tobacco industry are directly related to the fact that the consumer is dependent upon the product” (Bates No. 109872505, p. 508).
- A 1980 BAT Co document stated that “BAT should learn to look at itself as a drug company rather than as a tobacco company” (Bates No. 109884190, p. 190).
- A 1980 document by Philip Morris scientist Osdene stated, “the thing we sell most is nicotine” (Bates No. 1000125871, p. 871).
- A 1980 Lorillard memo from Ricard E. Smith to Alexander Spears stated: “Goal—Determine the minimum level of nicotine that will allow continued smoking. We hypothesize satisfaction cannot be compensated for by psychological satisfaction. At this point smokers will quit, or return to higher T&N brands” (Bates No. 01394380).
- A 1980 Lorillard memo from ST Jones stated: “Undoubtedly, nicotine serves a primary role in cigarette smoking. Nelsen reports that nicotine has been described as a psychoactive agent with tranquilizing, antianxiety, stimulant, depressant, anti-aggression, mood-stabilizing and stress-attenuating properties. The features common to the categories are they all can be related to an organism’s state of arousal and stimulation” (Bates No. 01105000/5021).
- In 1983, AJ Mellman from Brown & Williamson wrote in an internal memo on Project Recommendations: “Nicotine is the addicting agent in cigarettes” (Bates No. 514110007). This same document proposed adding free nicotine to filter elements as a product enhancement.
- A 1983 document by R.J.R. scientist Teague stated that: “in essence, a cigarette is a system for the delivery of nicotine to the smoker in an attractive, useful form. At ‘normal’ smoke pH, at or below about 6.0, essentially all of the smoke nicotine is... relatively slowly absorbed by the smoker. As the smoke pH increases above about 6.0, an increasing proportion of the total smoke nicotine occurs in ‘free’ form, which is volatile, rapidly absorbed by the smoker, and believed to be instantly perceived as nicotine ‘kick’” (Bates No. sxcg0092).
- A 1989 R.J.R. document noted that the company had a “nicotine optimization” program from 1979 to 1984 (Bates No. 507028876).
- A 1990 R.J.R. document stated: “We are basically in the nicotine business. It is in the best long term interest for R.J.R. to be able to control and effectively utilize every pound of nicotine we purchase. Effective control of nicotine in our products should equate to a significant product performance and cost advantage” (Bates No. rylf0079).

In summary, the tobacco companies have sought to exploit the addictive quality of smoking and nicotine for decades to acquire and retain smokers and to develop new products and increase sales.¹⁴⁴

Despite extensive knowledge of the pharmacologic effects of nicotine in cigarettes, tobacco industry executives have, for many decades, publicly denied and distorted the truth as to the addictive nature of cigarettes.¹⁴⁵ In a draft press release responding to the 1988 U.S. Surgeon General’s report, which concluded that nicotine is addictive, the Tobacco Institute characterized the report as “irresponsible” and using “scare tactics.”¹⁴⁶ Most notably, and with uniform consistency, in 1994, the seven tobacco chief

¹⁴⁴ Paragraph 829 of Kessler G. 2006. *USA v. Philip Morris USA, Inc., et al.*, Civil Action no. 99–2496, Final Opinion.

¹⁴⁵ Paragraph 830 of Kessler G. 2006. *USA v. Philip Morris USA, Inc., et al.*, Civil Action no. 99–2496, Final Opinion.

¹⁴⁶ Tobacco Institute Press Release (draft), “Claims that Cigarettes are Addictive Irresponsible and Scare Tactics,” May 16, 1988, <http://legacy.library.ucsf.edu/tid/pwa12f00>.

executives, including those for Lorillard and R.J. Reynolds, testified before the U.S. House of Representatives' Committee on Energy and Commerce, Subcommittee on Health and the Environment and denied that nicotine in cigarettes was addictive.¹⁴⁷

- James W. Johnston of R.J. Reynolds claimed: "Cigarette smoking is no more addictive than coffee, tea or Twinkies."
- The Chairmen and CEOs of Lorillard, Liggett Group, and Brown & Williamson each stated, "I believe that nicotine is not addictive."
- William I. Campbell of Philip Morris asserted: "Philip Morris does not manipulate nor independently control the level of nicotine in our products"; "Cigarette smoking is not addictive"; and "Philip Morris research does not establish that smoking is addictive."
- The President of US Tobacco stated: "I don't believe that nicotine or our products are addictive."
- The President and CEO of the American Tobacco Company ended: "And I, too, believe that nicotine is not addictive."

Two years later, in 1996, none of the results or conclusions from the Philip Morris Nicotine Program or Behavioral Research Program were made public or were included in Philip Morris' and the industry's collective submission to the FDA (Bates No. 2505597781-7998G).

The tobacco industry failed to inform the public about the addictive nature of nicotine in their cigarette products, and the tobacco industry was well aware of the public's lack of understanding. Market research conducted by Reynolds in the mid-1970s indicated that most people who smoke (73%) were unaware that cigarettes contained nicotine (Bates No. 503560233-0257). HD Steele from Brown & Williamson wrote in a 1978 memo, "Very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison" (Bates No. 3990187048). To this day still, none of the cigarette pack warnings in the US warn of addiction; efforts by the FDA to update pack labeling with inclusion of a warning of the addictive nature of cigarettes were thwarted by the tobacco industry through litigation in 2012.¹⁴⁸ The corrective statements, finally released at the end of 2017, which include truthful statements on the addictiveness of nicotine and the design of cigarettes to create and sustain addiction, were held up in litigation by the tobacco industry for over a decade.¹⁴⁹

Judge Kessler's Final Opinion in *United States of America v. Philip Morris USA, Inc.* stated that for over 50 years, the tobacco industry "publicly, vehemently, and repeatedly denied the addictiveness of smoking and nicotine's central role in smoking. They made these denials out of fear... of... governmental (i.e., FDA) regulation, adverse liability judgments from addicted smokers suffering the adverse health effects of smoking, loss of social acceptability of smoking, and the ultimate loss of corporate profits."¹⁵⁰ Further, Judge Kessler's conclusions stated that the tobacco industry's denial "misled the public about why quitting smoking is so difficult, exactly how difficult it is, and about why failure to quit is not simply a function of personal weakness or lack of willpower."¹⁵¹ The next section addresses the tobacco industry's "smoking is free choice" contention.

¹⁴⁷ <http://www.nytimes.com/1994/04/15/us/tobacco-chiefs-say-cigarettes-aren-t-addictive.html?pagewanted=all>

¹⁴⁸ <https://www.reuters.com/article/us-usa-cigarettes-labels/u-s-court-strikes-down-graphic-warnings-on-cigarettes-idUSBRE87N0NL20120824>

¹⁴⁹ <https://www.nbcnews.com/health/health-news/big-tobacco-finally-tells-truth-court-ordered-ad-campaign-n823136>

¹⁵⁰ Paragraph 1359 of Kessler G. 2006. *USA v. Philip Morris USA, Inc., et al.*, Civil Action no. 99-2496, Final Opinion.

¹⁵¹ Paragraph 1362 of Kessler G. 2006. *USA v. Philip Morris USA, Inc., et al.*, Civil Action no. 99-2496, Final Opinion.

5) The tobacco industry contends that smoking is a free choice, and failure to quit is the result of personal weakness or lack of willpower. In contrast, medical evidence indicates that addiction constrains free choice and ultimately erodes a person's ability to control the impulse to take addictive drugs. Constraints on free will are seen in compulsive drives and preoccupations to dose the drug, smoking soon upon waking and waking at night to use the drug, prioritization of the drug (e.g., with time and money) over other basic survival needs (e.g., food, water, relationships), and continued drug use despite threats to the well-being of self and others.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; National Institute on Drug Abuse; FDA; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health)
3. Internal industry documents available via Truth Library¹⁵²

A September 9, 1980 Tobacco Institute internal memo revealed recognition by the member companies that public admission that nicotine was addictive would undermine their position that a person's decision to smoke is a "free choice" (Bates No. TIMN0107822-7823). Hence, the tobacco industry has sought to discredit evidence of addiction to preserve their "smoking is a free choice" argument¹⁵³ and has sought to shift responsibility away from the tobacco companies and onto their customers.

Addiction to nicotine in cigarettes results in a loss of freedom. A person addicted to nicotine does not freely make choices regarding his or her smoking. Addiction constrains free choice. As discussed earlier in Section 3 addressing sensitization of brain mesolimbic systems, with repeated drug exposure, psychological and physical "wanting" of a drug increases over time as an individual becomes addicted.¹⁵⁴ With repeated nicotine exposure, the brain adapts and becomes hypersensitive ("sensitized") to nicotine and, through associative learning to smoking-associated stimuli in the environment. That is, repeated exposure to nicotine changes the reward, motivation/drive, memory, and control circuits of the brain. These changes are permanent and result in an enhanced saliency value for the drug, in the loss of inhibitory control, and in the drive for compulsive drug administration.¹⁵⁵

This loss of free choice with nicotine addiction is exhibited in preoccupation with maintaining a steady supply of cigarettes and regular, frequent opportunities to smoke and in prioritizing spending on cigarettes over other basic needs.¹⁵⁶ The mindshare dedicated to managing dosing of nicotine can impair attention and performance. In the workplace, smoking is associated with significant worker productivity loss due to distraction and preoccupation, termed "presenteeism."¹⁵⁷ Interrupted sleep to smoke at night is an observable indicator of the physiological need to use the drug, which overrides the body's need for sleep. The body waking itself to smoke is hardly the result of "free will." In addition to sleep, use of the drug becomes more important than other survival functions such as eating, hydrating, and connecting socially. Behaviors that naturally stimulate the dopamine reward pathway include eating to relieve hunger, drinking to alleviate thirst, or engaging in sexual activity. On a primitive, neurochemical level, stimulation of the dopamine reward pathway reinforces the behavior so that it will be repeated.¹⁵⁸ Eating,

¹⁵² <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

¹⁵³ Paragraph 831 of Kessler G. 2006. USA v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99-2496, Final Opinion.

¹⁵⁴ Berridge KC, Robinson TE. 2016. Liking, wanting, and the incentive-sensitization theory of addiction. *Am Psychol*, 71, 670-9

¹⁵⁵ Volkow ND, Fowler J, Wang G 2003. The addicted human brain: insights from imaging studies. *J Clin Invest* 111, 1444-1451

¹⁵⁶ Prochaska, JJ, Michalek, AK, Brown-Johnson, C, et al. 2016. Likelihood of smokers attaining re-employment: results from a one-year observational study. *JAMA Internal Medicine*, 176(1):662-670.

¹⁵⁷ Baker CL, Flores NM, Zou KH, et al. 2017. Benefits of quitting smoking on work productivity and activity impairment in the United States, the European Union and China. *Int J Clin Pract* 71:e12900.

¹⁵⁸ Koob GF, Volkow ND. 2010 Neurocircuitry of addiction. *Neuropsychopharmacology* 35(1):217-238 and 35(4):1051.

hydrating, and procreating are behaviors necessary for continued survival of the organism. The reward pathway, however, also can be stimulated by drugs of abuse, such as cocaine, amphetamine, opiates, and nicotine. When these unnatural stimuli trigger the reward pathway, the same pleasurable feelings are elicited, although at a more rapid and intense degree. Immediately following inhalation of smoke from a cigarette, a bolus of nicotine enters the brain, stimulating the release of dopamine, which induces nearly immediate feelings of pleasure and relief of symptoms of nicotine withdrawal.¹⁵⁹ This rapid dose-response reinforces and perpetuates the smoking behavior.

With chronic drug use, the brain becomes chemically altered—transforming a drug user into a drug addict.¹⁶⁰ In what appears to be irrational decision making to the non-user, people addicted to nicotine in cigarettes deprioritize money, time, and physical well-being, and those he or she smokes around to maintain a steady dosing of cigarette smoke to deliver nicotine to the brain.¹⁶¹ In our research with over 1,000 adults who smoke daily, 97% reported difficulty controlling use and 77% reported a pattern of using more than intended.¹⁶² A medical disorder, nicotine addiction can be a lifelong struggle that affects emotional balance, decision-making, behavioral control, and family functioning. A major conclusion of the 2012 Surgeon General Report was: “Cigarette smoking by youth and young adults has immediate adverse health consequences, including addiction, and accelerates the development of chronic diseases across the full life course.”¹⁶³

The tobacco industry has been well aware of the difficulties young people encounter when trying to quit their nicotine products. Conducted in 1977, Project 16, was market research conducted for the Imperial Tobacco Corp., a Canadian affiliate of a U.S. cigarette firm. Four discussion groups were held with teens aged 16 and 17 who were smoking to “learn everything there was to learn about how smoking begins, how high school students feel about being smokers, and how they foresee their use of tobacco in the future.” A summary prepared for tobacco industry lawyers on the Project 16 findings follows¹⁶⁴:

“The study finds that most teenage smokers began ‘serious’ smoking at the age of 12 or 13. While defiance of parental authority did not, according to the study, constitute a significant factor in starting, the subsequent conflicts were found to create familial hostilities that might not otherwise exist. The study also indicates that some teens ‘regret’ the fact that they began smoking. This regret stems from the fact that smoking has now become a habit; that their early belief that ‘they could experiment with cigarettes’ and not, as they put it, ‘get hooked;’ that ‘they are in a distant sense concerned with smoking and health;’ and that social pressures made them feel ‘second class’ as smokers. The study indicates that over half of the participants wanted to quit ‘someday’ and that some had attempted to quit and found it difficult.... Smoking seems to feed on itself. The adolescent treats it as a thrill, a part of breaking away. The teen is ‘hooked,’ admits the risks, but smokes anyway. Barring a drastic shift in adolescent attitude, or drastic governmental action, smoking will be around for a long time to come. The cycle seems extremely difficult to break” (Bates No. 566628841-566628854).

¹⁵⁹ Benowitz NL 2010 Nicotine addiction. *N Engl J Med* 362(24):2295–2303.

¹⁶⁰ Leshner A. 1997. Drug abuse and addiction are biomedical problems. *Hosp Pract* (special report) April: 2–4.

¹⁶¹ Siapush M, Borland R, Yong H. 2007. Sociodemographic and psychosocial correlates of smoking-induced deprivation and its effect on quitting: findings from the International Tobacco Control Policy Evaluation Survey. *Tobacco Control*;16:e2.

¹⁶² Hendricks PS, Prochaska JJ, Humfleet GL, Hall SM. 2008. Evaluating the validities of different DSM-IV-based conceptual constructs of tobacco dependence. *Addiction* 103: 1215–23

¹⁶³ USDHHS. 2012. Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA

¹⁶⁴ <https://www.industrydocuments.ucsf.edu/docs/#id=ffml0041>

6) Tobacco advertising has targeted the psychological needs of adolescents (e.g., popularity, peer acceptance, positive self-image) and created the perception that smoking will satisfy these needs. Even brief exposure to tobacco advertising influences adolescents' attitudes, perceptions about smoking, intentions to smoke, and progression to regular tobacco use. Product sampling (i.e., providing free packs of cigarettes) was identified by the tobacco industry as one of the most effective methods of creating new customers and is a promotional strategy for cigarettes that dates to at least as early as the 1940s. A focus was on reaching young people with sampling to allow the young starters to try one's brand. Lorillard even handed out free samples to children in the housing projects of urban Boston, until a city ordinance was passed in 1984 prohibiting the practice. The tobacco industry has publicized its Cigarette Advertising and Promotion Code since the 1960s, which specifically stated restrictions on advertising and sampling to individuals under age 21. Yet, the Code was voluntary, lacked an enforcement mechanism, and, while updated over time (in 1991), in practice, it was ignored.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; NCI Monograph 19; U.S. vs. Philip Morris [DOJ Lawsuit]) on tobacco and health
3. Internal industry documents via the Truth Library¹⁶⁵
4. The Stanford Research into the Impact of Tobacco Advertising (SRITA) collection¹⁶⁶

Findings: The tobacco industry has been keenly aware that a successful tobacco brand must attract young people to smoking through a series of stages, starting with experimentation and progressing to loyalty for a particular brand followed by increased consumption as the young person ages into a mature smoker.^{167,168} Tobacco companies understand the importance of adolescents' self-image: The tobacco companies, including Lorillard and R.J. Reynolds, have targeted adolescents' psychological needs (e.g., popularity, peer acceptance, positive self-image) and created the perception that smoking will satisfy these needs. In a 1973 document, Claude Teague, an R.J. Reynolds executive, wrote: "The fragile, developing self-image of the young person needs all the support and enhancement it can get. Smoking may appear to enhance that self-image in a variety of ways. If one values ... an adventurous, sophisticated adult image, smoking may enhance one's self-image."¹⁶⁹

Advertising works and particularly so among young people (Bates No. 322057235). Strong empirical evidence indicates that tobacco companies' advertising and promotions affect awareness of smoking and particular brands, recognition and recall of cigarette advertising, attitudes about smoking, intentions to smoke, and actual smoking behavior.¹⁷⁰ Further, responsiveness to cigarette advertising was found to be three times greater for adolescents than adults.¹⁷¹ Numerous studies find a strong connection among

¹⁶⁵ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

¹⁶⁶ Ads included here are examples from the 50,000 online ad collection http://tobacco.stanford.edu/tobacco_main/index.php

¹⁶⁷ Ling PM, Glantz SA 2002. Why and how the tobacco industry sells cigarettes to young adults: Evidence from industry documents. *Am J Public Health* 92 (6): 908–16.

¹⁶⁸ Wayne GF, Connolly GN. 2002. How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983–93. *Tobacco Control* 11 Suppl. 1: I32–I39.

¹⁶⁹ Teague CE 1973. Research planning memorandum on some thoughts about new brands of cigarettes for the youth market. 2 Feb. R.J. Reynolds. Bates No. 502987357/7368.

¹⁷⁰ National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda, MD: USDHHS, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242, June 2008.

¹⁷¹ Pollay RW, Siddarth S, Siegel M et al. 1996. The last straw: cigarette advertising and realized market shares among youths and adults. *Journal of Marketing* 60(2):1–16.

advertising exposure, adolescent initiation to tobacco use, and progression to regular tobacco use.¹⁷² Experimental studies show that even brief exposure to tobacco advertising influences adolescents' attitudes and perceptions about smoking and intentions to smoke. Strong and consistent evidence from longitudinal studies indicates that exposure to cigarette advertising influences nonsmoking adolescents to initiate smoking and to move toward regular smoking. Cross-sectional econometric studies also show a correlation between tobacco advertising and increased cigarette consumption. A 2003 systematic review of the published longitudinal studies on the impact of advertising concluded that "tobacco advertising and promotion increases the likelihood that adolescents will start to smoke."¹⁷³ Both the industry's own internal documents and its testimony in court proceedings, as well as widely accepted principles of advertising and marketing, also support the conclusion that tobacco advertising recruits new users during their youth.¹⁷⁴ Hence, the weight of the evidence demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use, as manifested by increased smoking initiation and continued consumption.¹⁷⁵

In April 1964, due to rising public pressure and to avoid FTC regulation, the tobacco companies, through the Tobacco Institute, voluntarily adopted the Cigarette Advertising and Promotion Code, with many restrictions attentive to targeting of youth.¹⁷⁶ The textbox shown here lists the restrictions on cigarette advertising and promotional activity. While the tobacco companies claim to continue to operate under the 1964 Code, and as revised in 1991, into present time,¹⁷⁷ by 1970, all the companies had abandoned the office of the Code Administrator, which had been designated to enforce the code. As a result, the Advertising Code had no enforcement mechanism.¹⁷⁸ In a 1975 report prepared for B&W by the Ted Bates Agency, in the section titled "How Can We Introduce Starters and Switchers to our Brands," it was recommended that "an attempt to reach young smokers, starters should be

Cigarette Advertising and Promotion Code in April 1964

- a) Cigarette advertising shall not appear (i) On TV and radio programs, or in publications, directed primarily to persons < 21 years of age; (ii) In spot announcements during any program break in, or during the program break immediately preceding or following a TV or radio program directed primarily to persons < 21 years of age; (iii) In school, college, or university media (including athletic, theatrical and other programs); (iv) In comic books, or comic supplements to newspapers.
- b) Sample cigarettes shall not be distributed to persons < 21 years of age.
- c) No sample cigarettes shall be distributed or promotional efforts conducted on school, college, or university campuses, or in their facilities, or in fraternity or sorority houses.
- d) Cigarette advertising shall not represent that cigarette smoking is essential to social prominence, distinction, success, or sexual attraction.
- e) Persons depicted as smokers in cigarette advertising shall be at least 25 years of age and not dressed or otherwise made to appear < 25 years old.
- f) Cigarette advertising may use attractive, healthy looking models, or illustrations or drawings of persons who appear to be attractive and healthy, provided that there is no suggestion that their attractive appearance or good health is due to cigarette smoking.
- g) No cigarette advertising shall contain a picture or an illustration of a person smoking in an exaggerated manner.
- h) Cigarette advertising shall not depict as a smoker any person well known as being, or having been, an athlete.
- i) Cigarette advertising shall not depict as a smoker any person participating in, or obviously having just participated in, physical activity requiring stamina or athletic conditioning beyond that of normal recreation.
- j) Testimonials from athletes or celebrities in the entertainment world, or other persons who have special appeal to persons < 21 years of age, shall not be used in cigarette advertising.

¹⁷² NCI. 2008 *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda, MD: USDHHS, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242

¹⁷³ Lovato C, Linn G, Stead LF, Best A. 2003 Impact of tobacco advertising and promotion on increasing adolescent smoking behaviours. *Cochrane Database of Systematic Reviews*. (3):CD003439

¹⁷⁴ Perry CL 1999 The tobacco industry and underage youth smoking: tobacco industry documents from the Minnesota litigation. *Archives of Pediatrics & Adolescent Medicine* 153(9):935-41

¹⁷⁵ NCI. 2008 *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda

¹⁷⁶ Cigarette Industry's New Code April 28, 1964 <https://www.nytimes.com/1964/04/28/archives/text-of-cigarette-industrys-new-code.html>

¹⁷⁷ Krugman WD, 163:1-182:23; Bates no. 2025345360-5362; 2070557699-7702; MNAT00608606-8614; TIMN0102493-2494; TIMN0015615-5617; 2022976326-6335; ATX040294056-4056. 3189. Defendants widely publicized their adoption of the Code. 2025345360-5362; 2070557699-7702; MNAT00608606-8614; TIMN0102493-2494; TIMN0015615-5617; 2022976326-6335; ATX040294056-4056.

¹⁷⁸ Langenfeld TT, 3/10/05, 15192:12-15193:17.

based... on the following parameters: [p]resent the cigarette as one of a few initiations into the adult world. Present the cigarette as part of the illicit pleasure category of products and activities... In your ads create a situation taken from the day-to-day life of the young smoker but in an elegant manner have this situation touch on the basic symbols of the growing-up, maturity process. To the best of your ability (considering some legal constraints) relate the cigarette to 'pot', wine, beer, sex, etc."¹⁷⁹ Even when the authority of the Code Administrator was recognized, the Code's provisions were not strictly enforced. A 1989 Tobacco Institute report, in referring to the Youth Industry Practices Code, concluded: "The voluntary code for cigarette advertising and sampling has not served as a strong defense of the industry's stance because it is widely perceived as vague, unenforced and largely ignored" (Bates No. TIMN 0171366). Like other tobacco manufacturers, including Lorillard and R.J. Reynolds, Phillip Morris implemented promotion programs and paid retailers to exhibit product displays and grow their inventory. In its 1973 Tobacco Marketing Five Year Plan report relating to such programs, Philip Morris identified its objective to "Emphasize new and varied youth-oriented programs to take advantage of apparent growing strength among younger smokers" (Bates No. 1005159125).

Sampling. According to the tobacco industry, "One of the most effective methods of creating new customers is 'sampling' at the supermarket, the factory gate, on a downtown thoroughfare, wherever people congregate" (Bates No. 00001764). Sampling as a cigarette promotional strategy dates to at least as early as the 1940s on airlines and on "school and college" campuses (Bates No. 406113246/ 295; 502397183/184). A 1948 speech by Joe Cahn at Philip Morris, titled College Plan for 1949, suggested the slogan "Get 'em young, train 'em right." The plan included hiring and training "Student sampling representatives" and targeting of fraternities, sororities, and living groups (Bates No. 2010015275/5280). Regarding the scale of tobacco industry sampling programs, a 1963 Lorillard letter to retailers announced a 6-week campaign to promote Kent and Newport cigarette brands that stated, "During this Campaign the entire Lorillard Sales Organization will conduct a specialized sampling program that will place several million KENT and NEWPORT sample packages in the hands of millions of cigarette smokers - this, in addition to the millions of KENT and NEWPORT sales messages that will blanket the consumer public" (Bates No. 84409774). The following year, a Kent sampling campaign was devised to coincide with the release of the 1964 Surgeon General's Report on smoking and health, aiming to capitalize on public opinion at the time that Kent cigarettes filtered the best (Bates No. 03059702/715). Kent's sampling campaign was designed to be "the heaviest and most concerted sampling campaign on KENT 4's ever undertaken", with the potential of reaching "as many as two thousand consumers per day" (Bates No. 84410112). The rationale was, "It is felt that when confusion is rampant, a word of assurance is the factor that stabilizes the situation and has lasting effect." A 1974 field report recorded 22,200 Winston samples distributed in 4 days in the Greater Boston and Downtown Boston areas (Bates No. 501709025). Lorillard even handed out free samples of cigarettes to children in the housing projects of urban Boston, until a city ordinance was passed in 1984 prohibiting the practice (Bates No. 85704591, 85704594/4597).¹⁸⁰ Signing the ordinance in 1984, Boston's major Flynn emphasized concern for public health and the need to prevent youth from receiving the cigarette samples, stating "The unregulated distribution of tobacco products gives our children and teenagers too much easy and cheap exposure to this health danger" (Bates No. 85704598-4599). The ordinance was opposed by the Tobacco Institute (Bates No. 85704681-4686). Lorillard and Philip Morris documents indicate repeated sampling promotions of Newport 4's and Marlboro 4's in 1966 (Bates No. 50017-0155/0174; 500170174A-500170200). A July 1966 promotional piece for Marlboro Green (menthol line) stated, "Don't be surprised if a lady approaches you on a Boston

¹⁷⁹ Bates 680092632-2668 at 2664-2665 (US 21693); 170043558-3593 at 3581-3582 (US 20293); 679018003-8278 (US 87928)

¹⁸⁰ A five-year effort to end cigarette sampling in Boston (85704602/605) resulted in the Mayor signing an ordinance "to protect the health of the youth of the city of Boston." The Tobacco Institute "engaged in vigorous direct and indirect lobbying activities with the Mayor during the period" leading up to his signature, and in response to the Mayor's ban on sampling, immediately started work to "introduce a new ordinance through a supportive member of the Boston City Council...[taking] some or all of the elements of the industry's "Sampling Code of Ethics" and codify[ing] them in the form of an ordinance. Ideally, this new ordinance would take the place of and supersede the recently passed ordinance" Bates No. 85704591 and 85704594/4597.

street today and offers you a cigarette” and referred to the 4-cigarette Marlboro “guest packs” (Bates No. 2010025958/59). A Lorillard Consumer Sampling Procedure document from 1972, that includes an interview guide for the team handing out the samples, does not assess the age of the sampling recipients (Bates No. 03059705). An internal Lorillard memorandum dated June 5, 1978 identified “sampling” as one of its recommended actions for cigarette marketing “in the ‘inner-city’ Black areas” (Bates No. 84274935-84274944). Listed “PROMOTION IDEAS” were: “More sampling by reps,” “Customized NEWPORT van for sampling,” and “How to Reach Younger Smokers: P.O.S. material, sampling, Black inner-city newspapers, Tee-Shirt give aways.” In *Evans vs. Lorillard* in the Commonwealth of Massachusetts, Suffolk County Superior Court, relevant facts, cited by the court’s decision include:¹⁸¹

- “Defendant sampled its free cigarettes in boxes of 4 cigarettes to persons, including minors, in Boston at various times from 1957–1983, when street sampling of cigarettes became illegal in Boston. Defendant’s free sampling of its cigarettes occurred through either defendant’s employees or its authorized agents. (Ex. 364, 359, 370, 124, 125, 127, 129–134)”

“Even Defendant’s representative Leonard Jones agreed Defendant never had any written policy to not provide children with free samples of its cigarettes in 1957–1964. There is no question but that this defendant over decades pre and post 1979, targeted youths, children under age 18, as sought-after marketing targets of its cigarettes, including Newports.”

The tobacco industry has spent billions of dollars annually on marketing activities to encourage young people to try, and then, continue smoking their cigarettes to generate the replacement smokers that the companies need to survive. Tobacco industry expenditures on cigarette advertising and promotion increased dramatically after the Master Settlement Agreement signing.¹⁸² Over the decades, the tobacco industry has used the following marketing channels: advertising on television, radio, and billboards, and in magazines and newspapers; sponsoring events, such as sporting events, bar promotions, festivals, concerts, and contests; providing coupons, price reductions, and free packs with purchases; providing gifts with purchases (aka “continuity items”), such as t-shirts, mugs, and sporting goods; direct-mail marketing by sending magazines and other materials directly to individuals’ homes; distributing free cigarette samples at retail stores, public events, bars, or other locations; and strategically locating point of sale (POS) advertising and promotions at retail outlets, like convenience stores, that young people are most likely to frequent, such as convenience stores.¹⁸³ Despite evidence to the contrary, the tobacco companies have repeatedly denied that they have marketed to youth.¹⁸⁴

Cigarette ads construct a world in which everyone smokes at social, sporty, and romantic occasions and no one thinks about disease, polluted air, financial costs, or death. The stated or implied pleasures of smoking – “taste,” “relaxation,” “fun,” “status,” and “sex appeal” – in most ads have not significantly changed over the decades. Identified as an industry leader in advertising and marketing, cigarette advertising campaigns have consistently been included in trade lists of leading 20th-Century campaigns. For *Advertising Age*, the Marlboro Man was the top advertising icon of the century and Marlboro was ranked as the third-best advertising campaign of the century. Benson & Hedges, Winston, Camel, and Lucky Strike advertising campaigns also were on the *Advertising Age* top 100 list.¹⁸⁵ Enduring cigarette advertising taglines include: “I’d walk a mile for a Camel;” “Come to Marlboro Country;” Virginia Slims’ “You’ve come a long way, baby;” Benson & Hedges’ “The length you go to for pleasure;” and Newport’s “Alive with Pleasure!” The slogan, “Winston tastes good like a cigarette should,” was named

¹⁸¹ *Evans v. Lorillard*, 465 Mass. 411 (2013) <http://masscases.com/cases/sjc/465/465mass411.html>; *Evans v. Lorillard*, Civil Action No: 2004–2840–B (Mass. Super. Ct., Suffolk Cty. 2011) Findings of Fact, Rulings of Law and Order of Judgment on Plaintiff’s Chapter 93a Claim, reversed on separate grounds, <https://caselaw.findlaw.com/ma-superior-court/1601163.html>

¹⁸² Krugman WD, 23:10-24:4.

¹⁸³ Krugman WD, 43:14-2; Dolan WD, 48:6-3

¹⁸⁴ Kessler G. 2006. United States of America v. Philip Morris USA, Inc., et al., Civil Action no. 99–2496, Final Opinion.

¹⁸⁵ *Advertising Age*. 2005. The advertising century. *Advertising Age*. <http://adage.com/century>

as one of the top 10 jingles of the twentieth century in *Advertising Age*.¹⁸⁶

Young people are drawn to big brands (Bates No. 322057236), and for decades, Marlboro has been the leading cigarette brand among teens.¹⁸⁷ A March 29, 1979 memorandum on Philip Morris letterhead, titled “Marlboro,” stated: “Marlboro dominates in the 17 and younger age category, capturing over 50% of this market” and itemized various special promotions, including “summer sampling” and the Marlboro Cup (Bates No. 20483828174-8176). A March 31, 1981 report conducted by the Philip Morris Research Center, titled “Young Smokers Prevalence, Trends, Implications, and Related Demographic Trends” stated that: “Today’s teenager is tomorrow’s potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens.... [I]t is during the teenage years that the initial brand choice is made” (Bates No. 1000390803-0855).



L&M cigarettes were introduced to the market by the tobacco company Liggett & Myers in 1953. The L&M motto was “American cigarettes of the highest quality with the best filter.” L&M ads from the 1950s featured Hollywood actors and claimed the cigarettes were light and mild and just what the doctor ordered. The ads claimed the L&M filters used a “highly purified alpha cellulose” that was “entirely harmless” and “effectively filtered the smoke” (Bates No. Bates No. 2021368933).¹⁸⁸ In the 1960s, candy cigarettes with L&M branding were sold to children (image at left). Print ads from the early 1960s, when Sandra Camacho started smoking L&M, and into the 1970s, featured attractive couples engaged in playful, romantic, and seductive poses; included children (e.g., building a snowman, youth baseball) and cartoons; and featured nature and national landmarks (examples below). L&M ad messaging emphasized “pure white miracle tip,” “modern filter,” “more flavor,” “fine tobaccos,” “choice tobaccos,” “all white – inside and outside,” “only pure white touches your lips,” “first puff is good,” “fresh smoking pleasure,” “they always treat you right,” “the L&M moment,” “the proud smoke” (examples below). L&M cigarette ads when Sandra started smoking as a teen did not warn of the health harms of smoking. L&M advertisements also ran on television until January 1971 (examples below). L&M television ads featured messaging like “just for the taste of it!” with attractive models and cute dogs and the promise of great taste, and with jingles such as, “Come on Over, You’ll be Glad You Did. Come on Over to the L&M Side.”¹⁸⁹ L&M ads ran during the popular western television and radio show *Gunsmoke*. In the early 1970s, L&M sponsored Carl Haas Racing in motorsports (see image). L&M remained Sandra’s primary brand until 1990. In 1999, Philip Morris acquired the L&M trademark rights. The rebranded Altria Group still produces and sells L&M today.



1970 TV ads



¹⁸⁶ *Advertising Age*. 2005. The advertising century. *Advertising Age*. <http://adage.com/century>

¹⁸⁷ USDHHS. 2012 [Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General](#). Atlanta: CDC,

¹⁸⁸ Gardner MN, Brandt AM. 2006. “The Doctors’ Choice Is America’s Choice” *Am J Public Health* 96, 222-232

¹⁸⁹ https://archive.org/details/tobacco_hpv08h00/tobacco_hpv08h00.VOB



1960



1960



1960



1961



1962



1962



1963



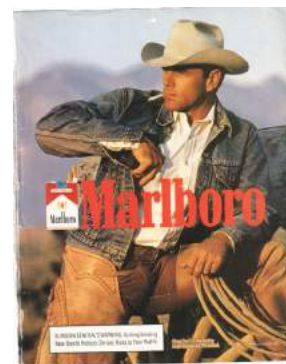
1968



1969



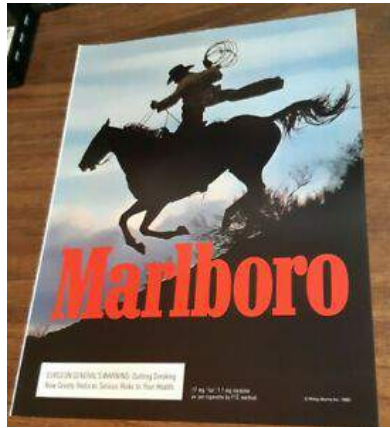
Marlboro is the longstanding, leading cigarette brand in the US and globally. In 1963, the “Marlboro Country” campaign debuted with exclusive use of athletic and heroic, role-model cowboys and images of the American West in national Marlboro advertising. A 1986 analysis for the Smithsonian noted, “The Marlboro Man, ubiquitous in America, is recognized on every continent” and is “a tangible symbol of the rite of passage into adulthood” (Bates No. pnvh0045). The report states, “Marlboro advertising, particularly since the early 1960s, is notable not only for its role in dramatically increasing sales, but for its use of a body of imagery deeply imbedded in American popular culture” (Bates No. pnvh0045). The Smithsonian National Museum of American History’s Archives Center holds > 13 hours of Marlboro television commercials, primarily U.S. commercials aired from 1955 to 1971.



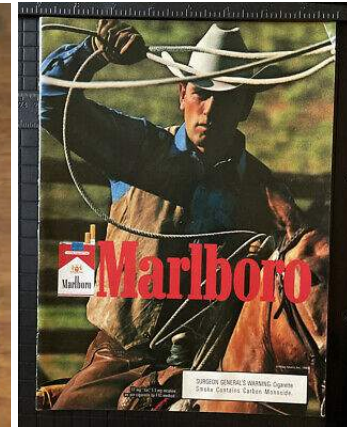
Marlboro ads are aspirational, promote American values of individuality and freedom, and emphasize flavor. The Marlboro Man is viewed as “successful and sophisticated but rugged” (Bates 2045214247-249). The ad examples below ran nationally when Sandra Camacho smoked Marlboro from 1990 to the mid-1990s. They depict athleticism with horse wrangling and riding and feature landscapes with pure water and snow. Colors are bright and light. The iconic Marlboro cowboy is shown as strong, capable, individualized, and vigorous. Marlboro merchandize and sweepstake prizes are featured in magazine ads as well as retail posters and point-of-sale (POS) marketing.



1990



1990



1990



1992 (outdoor signage)



1993



1993 (outdoor signage)



1993 (POS indoor ad)



1994



1994



1994



1995

Basic Cigarettes was launched in the 1970s as a discount brand. In 2005, Basic was the fourth most popular cigarette brand in the U.S. (following Marlboro, Newport, and Camel) and the second most popular among non-Hispanic white smokers aged 26 and older.¹⁹⁰ Basic is manufactured and sold in the U.S. by Philip Morris. With an emphasis on authenticity and trustworthiness, the brand “essence” of Basic is that “It never pretends to be something it is not.”¹⁹¹ Basic’s advertising campaigns track as:

- 1993: “Tastes Good - Costs Less” campaign
- 1994: “All You Need” campaign
- 1995: “Keep It Basic” tagline
- 1996: Evolved to “New Look,” and incorporated “Life’s Simple Pleasures” insight
- 1997: “Basic is an honest, down to earth brand that offers good taste at a low price; it's one of life's simple pleasures”

Basic POS display, direct mail, and ad examples included below ran nationally when Sandra Camacho smoked Basic as a primary brand from 1990 to when she ultimately quit smoking in 2017. Basic ad themes feature cigarettes as art; cigarettes for all seasons with imagery for spring, summer, autumn, and winter; cigarettes paired with health-oriented objects such as flowers and an apple; cigarettes as part of a balanced breakfast; and cigarettes paired with hobbies such as knitting, floral arranging, and gardening. The ad captions read “YOUR BASIC WORK OF ART,” “Tastes Good. Costs Less,” “Keep it Basic,” “THE BEST THINGS IN LIFE ARE BASIC,” and “from your friends at Basic.”



1992 (POS signage)



1996 (POS signage)

¹⁹⁰ Chapter 7. Tobacco Product Brand Preferences". National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration. 2007-01-12.

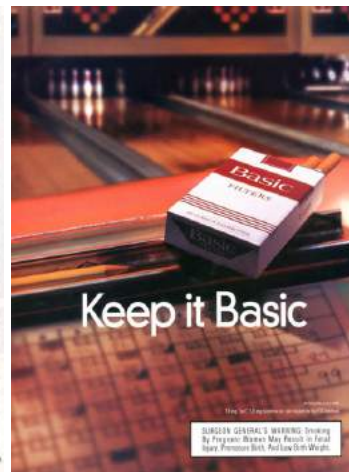
¹⁹¹ <https://tobacco-img.stanford.edu/wp-content/uploads/2019/12/06212608/basic-campaignhx.pdf>



1994 (POS feature)



1995



1998



1997



1997



1999



2000



2000



2001

7) Conventional cigarettes are unreasonably dangerous because the tobacco industry has a long history of employing marketing tactics that allay consumer concerns of smoking-related harms. These practices, which include the illusion of filtration and the production of “light” and “ultralight” cigarettes, have been determined to be deliberately deceptive and to lead smokers to delay quitting smoking. Most cigarette filters are unreasonably dangerous because they do not reduce the risk of harm as they are marketed to do. Light or Ultralight cigarettes are defective and unreasonably dangerous because the respective levels of exposure, as indicated by tobacco toxin biomarkers, are no different when compared to regular cigarettes.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health
3. Internal industry documents via the Truth Library¹⁹²
4. SRITA collection as it relates to low-tar, filtered and light cigarettes¹⁹³

Findings: The tobacco industry’s legacy of health assurance marketing strategies to allay smokers of health concerns and encourage switching instead of quitting includes: using physicians in 1940s ad campaigns; creating the illusion of filtration in the 1950s; using menthols to create the illusion of a safer cigarette in the 1950s, targeting Caucasian smokers, and in the 1960s, when it began to target the African American market; marketing cigarettes as light/mild in the 1970s; and marketing organic, natural, additive-free and environmentally-friendly cigarettes more recently.¹⁹⁴

In the 1940s, R.J. Reynolds ran ads with models dressed as doctors in white coats with stethoscopes, cigarettes in hand; a single campaign running 1940 to 1949 claimed that More Doctors smoke Camels; cigarettes were advertised in medical journals; and Reynolds had a Medical Relations Division to lead their aggressive physician and health claims promotional strategy.¹⁹⁵

In the 1950s, as tobacco’s harms became increasingly apparent, the industry shifted to a focus on filtered cigarettes. This new technology created an illusion that filters removed harmful elements from inhaled smoke.¹⁹⁶ In 1953, R.J. Reynolds invented filter tip materials that underwent color change (a darkening) on contact with tobacco smoke. The color change was noted internally to have little to no effect on the actual efficiency of the filter tip material but would yield “advertising and sales advantages” because it gave the perception of trapping harmful particles in smoke (Bates No. 501650188). Marlboro was reinvented and released anew in a 1954 national campaign stressing “Filter, Flavor, Flip-Top Box” and the keyword “fresher” was used in most ads (Bates No. 542001043/050). Internal tobacco industry documents from the 1970s portray the filters of the 1950s as merely “cosmetic” and noted that “once the consumer had been sufficiently educated on the virtues of filters, a vacuum was created for a filter with



¹⁹² <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

¹⁹³ Ads included here are examples from the 50,000 online ad collection http://tobacco.stanford.edu/tobacco_main/index.php

¹⁹⁴ Epperson AE, Henriksen L, Prochaska JJ. 2017 Natural American Spirit brand marketing casts health halo around smoking. *AJPH* 107(5):668-67.

¹⁹⁵ Gardner MN, Brandt AM 2006 “The Doctors’ Choice is America’s Choice”: The physician in US cigarette advertisements, 1930–1953. *AJPH*, 96:222–232

¹⁹⁶ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=qgqp0034>

taste; this vacuum was filled by Winston and Marlboro.”¹⁹⁷ Providing health reassurance, the aim was to have smokers switch to filtered and low-tar cigarettes, rather than quit smoking altogether, and to engage future generations of smokers. Oxford defines filter (noun) as “a device containing paper, sand, chemicals, etc. that a liquid or gas is passed through in order to remove any materials that are not wanted.”¹⁹⁸ That Sandra Camacho smoked only filtered cigarettes and that she continued smoking filtered cigarettes for more than four decades, rather than quitting, is evidence that weighs heavily toward Sandra being a victim of the tobacco industry’s filter fraud.

Findings from focus groups run in 1987 for Lorillard found that “smoking a lower tar brand makes them ‘feel less guilty’” (Bates No. 93376238-6267). Targeted mailings were done to market low-tar cigarettes to “quitting prone smokers” (Bates No. 970107494; 991378096-8116). Those who switched to low-tar products were more likely to be female, older, and better educated, groups that tend to be more motivated to quit smoking (Bates No. 89566033; 1005122741-2744). Yet, the lower tar versions did not help with quitting smoking. A Philip Morris 1980 memo reported that smokers of low-tar brands quit less than other smokers, “Low-tar smokers (and Ultra-lows) say they’ll quit more than smokers in general, but actually they quit less, especially Ultralows” (Bates No. 1005122741-2744). A 1977 R.J. Reynolds document reported, “There are no differences in quitting rates between ultra low ‘tar’ brands and other low ‘tar’ brands” (Bates No. 501707850-7852).

The figure at right, published by the FDA, shows what goes into making a cigarette. I provide this handout to patients I treat clinically because many are unaware of the design of a cigarette including that most filters are made from plastic (cellulose acetate) and ineffective; that many cigarettes are pumped up with sugar to make the smoke milder; that menthol is added to mask the harshness, making it easier to inhale; and that the difference between regular and light cigarettes is simply an extra row of ventilation holes that can easily be blocked with fingers or lips. We also discuss the dangerous chemicals formed in tobacco and created through combustion via pyrolysis, prosynthesis, and distillation.



¹⁹⁷ Latimer FE. Cigarette advertising history. Brown & Williamson, Nov 29, 1976:5. Bates No. 680086043

¹⁹⁸ Oxford Advanced American Dictionary. 2002. Oxford University Press

Cigarette packs are a central vector for communicating to consumers, viewed 7,300 times a year by people who smoke a pack-a-day, viewed in retail settings, and, with product placements, in TV programming and movies. Language featured on the front of the cigarette packs that Sandra Camacho smoked emphasized the: The Miracle Tip, Filters, Filter, and Class A.



The first pack communication of possible health harm was a cautionary statement added on January 1, 1966, that read: “Caution: Cigarette Smoking May Be Hazardous To Your Health.”¹⁹⁹ On November 1, 1970, the statement was changed to: “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous To Your Health.” On October 12, 1985, the warning was changed to rotating four health warnings, one of which stated that smoking causes lung cancer. To this day, cigarette packs in the U.S. have not included a warning to consumers that smoking is addictive or causes head and neck cancer. The Surgeon General warnings are kept to the side of the packs, in small font, out of direct view, and typically covered by the hand when the pack is held. The FDA has determined the current pack warnings “go unnoticed and are effectively ‘invisible’.”²⁰⁰ Based on the best scientific evidence, for effective consumer communication, the FDA has determined that cigarette pack warnings “must comprise at least the top 50% of the front and rear panels of the cigarette package (i.e., the two largest sides or surfaces of the package)”.²⁰¹

The ads above report “nicotine av. per cigarette by FTC method.” Based upon machine testing applying the Cambridge Method, at the time Sandra Camacho smoked the brands, reported nicotine levels ranged per cigarette between 1.0 mg to 1.5 mg for Marlboro, 1.0 mg to 1.1 mg for L&M, and 1.0 mg to 1.1 mg for Basic, which are levels sufficient to create and sustain addiction.²⁰² Tobacco companies “recognized the need to design cigarettes that would produce low nicotine and tar measurements under the FTC method while also delivering the minimum nicotine levels to create and sustain addiction.”²⁰³ The “light” and “ultralight” cigarettes that appeared in the 1970s in many instances simply added an extra row of ventilation holes to cigarette filters to allow fresh air to dilute and lighten the apparent harshness of the smoke. By the late 1990s, the promotion of light cigarettes constituted half of the tobacco industry’s advertising budget.²⁰⁴ Philip Morris used multiple criteria in defining the low tar and nicotine category, but noted that no matter what the technical specifications, “consumer opinion should be the ultimate criterion for market segmentation.”²⁰⁵

Ultimately, the filters were shown to be ineffective; the ventilation holes, which lowered yield levels in standard machine testing, resulted in compensation (deeper inhalation, more frequent puffs) and blocking of the vents by smokers’ lips or fingers.^{206, 207} Notably, biomarker measurements of exposure to tobacco toxins were no different than regular cigarettes. A Philip Morris document, dated March 1, 1974, stated

¹⁹⁹ R.J. Reynolds Tobacco “Public Health Information” <https://rjrt.com/tobacco-use-health/public-health-information/>

²⁰⁰ <https://www.federalregister.gov/documents/2020/03/18/2020-05223/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements>

²⁰¹ <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements>

²⁰² Benowitz NL, Henningfield JE. 2013. Reducing the Nicotine Content to Make Cigarettes Less Addictive. *Tobacco Control*, 22(Suppl 1):i14-i17.

²⁰³ Kessler G. 2006. United States of America v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99–2496, Final Opinion.

²⁰⁴ <http://bit.ly/2kHoxNa>

²⁰⁵ Tindall JE. A new low delivery segment. Philip Morris USA Research Center. 22 May 1973:16. Bates No. 1002473802

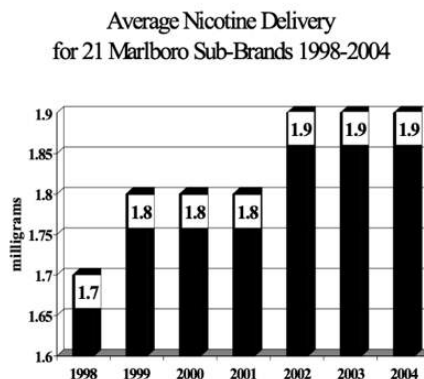
²⁰⁶ Kozlowski LT, O’Connor RJ. 2002. Cigarette filter ventilation is a defective design because of misleading taste, bigger puffs, and blocked vents. *Tobacco Control*, 11:i40-50

²⁰⁷ <https://www.govinfo.gov/content/pkg/CHRG-110shrg73848/html/CHRG-110shrg73848.htm>

“People do not smoke like the machine... generally people smoke in such a way that they get much more than predicted by machine. This is especially true for dilution cigarettes [sic].”²⁰⁸ Further, the document stated in the “CONCLUSION” section: “The FTC standardized test should be retained: 1) It gives low numbers.” Another Philip Morris document, dated September 17, 1975, from Barbro Goodman to Leo Meyer, then Philip Morris Director of Research, demonstrates that, specifically, Philip Morris was aware that people got as much tar and nicotine from Marlboro Lights as from full-flavor Marlboros and that “Marlboro Lights cigarettes were not smoked like regular Marlboros.”²⁰⁹

James Morgan, who later became CEO of Philip Morris, and served as Brand Manager of Marlboro from 1969-1972, and was Director of Brand Management at Philip Morris at the time of Marlboro Lights’ introduction, has admitted that the “light” descriptor as invented by Philip Morris was intended to convey a health message. He testified that “Philip Morris made a calculated decision to use the phrase ‘lowered tar and nicotine,’ even though its own marketing research indicated that consumers interpreted that phrase as meaning that the cigarettes not only contained comparatively less tar and nicotine, but also that they were a healthier option.”²¹⁰ In 2006, *United States vs. Philip Morris (D.O.J. Lawsuit)* determined that selling and advertising of low tar and light cigarettes as less harmful than regular cigarettes was deliberate deception by the US tobacco companies of the American public, leading many people to switch rather than to quit smoking.²¹¹ In 2009, the US FDA banned the misleading “light” and “mild” product labels in the advertising and on the packs, although the tobacco industry uses color coding to perpetuate the idea that some cigarettes are healthier: typically, it is gold for light, blue for mild, and silver for ultralight.

Massachusetts is one of three states to receive information about nicotine levels in tobacco products. The Massachusetts Department of Public Health examined changes in nicotine yields reported by the three major tobacco companies from 1998 to 2004. Total nicotine content of the sub-brands tested increased 16.6%, from 12.9 milligrams in 1998 to 14.3 milligrams in 2004 ($p < .0001$).²¹² The increases were comparable for each type of cigarette tested (full flavor, mild/medium, light, ultra-light), for menthol and non-menthol cigarettes, for filtered cigarettes, and for all companies (Philip Morris, R.J. Reynolds, Lorillard). The chart at right shows the measured nicotine delivery for 21 Marlboro sub-brands from 1998-2004. The Massachusetts testing protocols were set to simulate actual smoking behavior more closely with deeper and more frequent puffs and with partial blockage of the small vents on smoking filters.



²⁰⁸ Wakeham HD. Some unexpected observations on tar and nicotine and smoker behavior. 1974. Bates No. 1003293476-3493

²⁰⁹ <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=mpgv0184>

²¹⁰ Kessler G. 2006. United States of America v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99-2496, Final Opinion.

²¹¹ Kessler G. 2006. United States of America v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99-2496, Final Opinion.

²¹² <https://www.mass.gov/doc/report-changes-in-nicotine-yield-1998-2004/download>

9) Cigarettes are defective because the tobacco industry has intentionally designed cigarettes with enough nicotine to create and sustain addiction and has controlled the impact and delivery of nicotine in many ways. Safer cigarette design alternatives include those that reduce the nicotine level in the cigarette rod to substantially minimize the addictiveness; raise the smoke pH level to 8 or more (back to its level prior to 20th century methods of cigarette manufacturing); and exclude the use of additives, such as menthol, ammonia and sugars, and cigarette filters, all of which mask the harshness of cigarettes and facilitate exposure to nicotine. Safer design alternatives can substantially reduce the addictiveness of cigarettes in adults and adolescents who smoke and in nicotine naïve individuals. The safer design would be a “choice” cigarette rather than a “need” cigarette – a cigarette that does not compel repeated dosing within a day and chronic use over time, a product that does not carry a quit failure rate exceeding 90%. Minimizing the addictiveness of cigarettes thereby reduces the compulsion, the need and drive to smoke, and ultimately the harm that results from repeated toxin exposure with heavy, sustained cigarette smoking.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health, NCI Monographs)
3. Internal industry documents available via Truth Library²¹³

Findings: Cigarettes are dangerous by design, and there are safer design alternatives. Smoke is harmful, but smoke laced with the highly addictive drug nicotine which compels compulsive use and therefore repeated exposures to the carcinogens in tobacco smoke is unreasonably dangerous. Smoke is harmful, but smoke that is altered to be less harsh so that it can be inhaled into the vulnerable large surface area of the lungs, which results in the spike of nicotine to the brain is unreasonably dangerous. There are safer (less deadly) alternatives that can be easily produced, and consumer research has demonstrated that there is a market for them.

Corrective statements concerning cigarette design ordered by Judge Kessler²¹⁴ for disclosure to the American public are that cigarette companies Altria, R.J. Reynolds Tobacco, Lorillard, and Philip Morris:

- intentionally designed cigarettes with enough nicotine to create and sustain addiction;
- intentionally designed cigarettes to make them more addictive;
- control the impact and delivery of nicotine in many ways, including by designing filters and selecting cigarette paper to maximize the ingestion of nicotine, by adding ammonia to make the cigarette taste less harsh, and by controlling the physical and chemical make-up of the tobacco blend.

As early as the 1950s, the tobacco industry was aware that to lower nicotine too much “might end in destroying the nicotine habit in a large number of consumers and prevent it ever being acquired by new smokers.”²¹⁵ A 1967 British American Tobacco (BAT) proceedings report²¹⁶ from a Research & Development (R&D) conference summarized (and edited as shown) “assumptions made by R&D scientists” including: “There is a minimum level of nicotine. Smoking is an addictive habit attributable to nicotine and the form of nicotine affects the rate of absorption by the smoker.” A 1971 BAT document identified as a primary assumption: “Nicotine is the predominant reason for smoking” (Bates No.

²¹³ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

²¹⁴ Kessler G. 2006. United States of America v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99–2496, Final Opinion.

²¹⁵ British American Tobacco Company. RDW. Complexity of the PA 5A machine and variables pool. Minnesota Trial Exhibit 10,392. State of Minnesota et al v. Philip Morris, Inc., et al., 1959.

²¹⁶ BAT: R & D Conference – Montreal. 1967 October 24. Bates No. 500014079-500014085

100061274-1279; also 101472699-2715). A 1974 private and confidential BAT R&D conference proceedings report²¹⁷ acknowledged a German study that “suggests that whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg per cigarette).” In 1994, Benowitz and Henningfield proposed the idea of federal regulation of the nicotine content of cigarettes to reduce levels over time, resulting in lower intake of nicotine and a lower level of nicotine dependence.²¹⁸ When nicotine levels get very low, cigarettes would be much less addictive.

Very low nicotine content cigarettes (VLNCs) are engineered to have reduced yields of nicotine in the tobacco contained in the cigarette rod. For decades, Philip Morris and other tobacco companies were experimenting with various means to reduce the nicotine level of tobacco.²¹⁹ Plant breeding was the first method, and in the 20th century, solvents, steam, microbes, and gases have all been used to extract nicotine. Supercritical extraction was an adaptation of a patented process to decaffeinate coffee beans that Philip Morris acquired in 1985, when they purchased General Foods.^{220,221} Most recently, researchers have experimented with ways to genetically modify tobacco to block nicotine biosynthesis. In 1986, Philip Morris researchers identified over 100 patents for the denicotinisation of tobacco.²²² The methods did not completely eliminate nicotine, but reductions were substantial, in the range of 80–98%.

A 1972 R.J. Reynolds document acknowledged “a small market for a quality cigarette delivering essentially no nicotine” (Bates No. 500915642-5650). A 1973 Philip Morris document titled “Index to New Smoking Product Concepts” included: “Full Flavor/Zero Tar and Nicotine” (Bates No. 2023162212-2220). A 1983 Philip Morris document titled “New Product Ideas”²²³ included:

- “Zero or very low nicotine with high tar and acceptable taste – maybe 10-20% of the market doesn’t smoke for nicotine” and
- “Kit of cigs. with decreasing levels of nicotine for smokers who want to quit.”

Classified as “Secret” 1976 and 1977 RJR “Planning Assumptions and Forecast” reports for the next decade identified with interest: “A cigarette (85 and/or 100 mm) at or just above the Carlton (“tar” 4 mg, nicotine 0.4 mg) with good smoking quality should offer excellent long-term growth potential for RJR-T, i.e., a cigarette at a 5- to 7-mg “tar,” 0.5-mg nicotine, and 5-mg or less carbon monoxide level.”²²⁴

An October 1987 internal market analysis for Philip Morris identified the low nicotine market as having the highest potential for growth, though a chief concern was creating a “less enjoyable product which will be easier to give up, and finally quit”.²²⁵ A 1988 marketing memo estimated the potential market share of a free standing de-nicotinised cigarette brand at 1.5% to 2%, or “9–12 billion units.”²²⁶ Perceived benefits of a reduced nicotine cigarette identified in focus group research in 1989 included, “The cigarette would

²¹⁷ BAT. Notes on the Group Research & Development Conference at Duck Key, Florida. 12th – 18th January 1974. Bates No. 680048892-680048897

²¹⁸ Benowitz NL, Henningfield JE, *Establishing a nicotine threshold for addiction. The implications for tobacco regulation*. NEJM, 1994. 331(2): p. 123-5.

²¹⁹ Philip Morris USA. Alkaloid Reduced Tobacco (ART) Program. September 1, 1994. Bates No. 2057908259-8291.

²²⁰ Philip Morris. Philip Morris developments: The denicotinized tobacco story, 1999. Bates No. 2078425524/5540

²²¹ Philip Morris USA. Alkaloid Reduced Tobacco (ART) Program. September 1, 1994. Bates No. 2057908259-8291.

²²² J Dunsby, L Bero A nicotine delivery device without the nicotine? Tobacco industry development of low nicotine cigarettes. Tobacco Control 2004;13:362–369.

²²³ Philip Morris. New Product Ideas. April 13, 1983. Bates No. 1003656948-6956

²²⁴ Planning Assumptions and Forecast for the Period 1977-1986 (and 1978-1987) for R.J. Reynolds Tobacco Company. April 15, 1976 and May 6, 1977. Bates No. 500774773-500774792 and 502964953-502964976

²²⁵ Alter S. Philip Morris USA. ART marketing overview. October 9, 1987. Philip Morris Collection. Bates No 2023086633/6651

²²⁶ Project ART: Q & A - Marketing, February 22, 1988. Philip Morris Collection. Bates No. 2023086626/6629.

be healthier (43%) and it would not be addictive (24%). Also cited by 14% of the smokers was that it might be easier to quit smoking.”^{227,228}

Philip Morris released cigarette brands with reduced nicotine content in 1989 (Next, Merit De-Nic) and the early 1990s (Benson & Hedges De-Nic).²²⁹ These cigarette brands do not have the addiction defect, yet Philip Morris failed to promote their advantage in the marketplace as a safer cigarette. To promote them as safer would require admitting the brand leaders’ greater harms. Test marketing of Next lasted less than 6 months before the brand was discontinued. The De-Nic versions of Merit and Benson & Hedges also were short-lived. R.J. Reynolds had a “Nicotine Reduction Program” or “Project LN,” which it never commercialized, which used genetically low nicotine tobacco developed in conjunction with extraction processes. The industry’s claim that reduced nicotine content cigarettes will be less successful in the marketplace among addicted smokers is a reckless and unreasonable argument for failing to provide a safer design alternative. Returning the pH to the original levels and reducing nicotine will not change the appeal of cigarettes among the nicotine naïve and early initiates, for whom nicotine is aversive (a negative). People do not start smoking to become addicted, and 7 in 10 adults who smoke want to quit.

VLNCs actually deliver much lower levels of nicotine than earlier cigarettes that were marketed as “light” or “ultralight” but which in practice allowed smokers to obtain levels of nicotine similar to regular “full-flavor” cigarettes through compensation behaviors, such as blocking ventilation holes or inhaling more deeply.²³⁰ The nicotine in cigarettes can be reduced to a level that is minimally addictive and lead to lower levels of consumption, making it easier for smokers to quit. Randomized trials examining the effects of VLNCs have shown reductions in smoking and dependence and increases in quit attempts for VLNCs in comparison with standard nicotine cigarettes. A 6-week trial found decreases in nicotine exposure and dependence on nicotine for VLNCs, decreases in craving during abstinence from smoking, and decreases in the number of cigarettes smoked without significantly increasing levels of expired carbon monoxide or total puff volume, which suggests minimal compensation behavior.²³¹ In a randomized, parallel-arm, semi-blinded study of adults smoking daily, participants receiving 0.05-mg/g cigarettes showed greater relief of withdrawal from usual-brand cigarettes than the nicotine lozenge; significantly higher abstinence at the 6-week follow-up than the 0.3-mg/g cigarette; and a similar rate of cessation as the nicotine lozenge.²³² At 12-months follow-up, however, findings were not sustained.²³³

In clinical trials, problems with nonadherence to VLNCs is at least in part a function of the easy availability of conventional cigarettes in the current environment.^{234,235} Combining VLNCs with nicotine patches may aid with the transition to VLNCs and increase compliance but doing so was not found to improve long-term quit rates. If the nicotine content in all cigarettes was reduced to make them less addictive, either through federal regulation or by the tobacco industry’s own initiative, then problems with adherence and attrition could be less of an issue and the ability of smokers to successfully sustain abstinence from smoking long-term could be higher.

²²⁷ Philip Morris. Nicotine free concept test (discussion draft). 1989/E. Philip Morris Collection. Bates No. 2045737946/8012

²²⁸ Nicotine Concept Test. February, 1988. Philip Morris Collection. Bates No. 2045723380/3427.

²²⁹ Philip Morris USA. Alkaloid Reduced Tobacco (ART) Program. September 1, 1994. Bates No. 2057908259-2057908291.

²³⁰ See Benowitz NL, Henningfield JE NEJM 1994

²³¹ Donny EC, Denlinger RL et al. *Randomized trial of reduced-nicotine standards for cigarettes*. NEJM, 2015. 373(14): 1340-49

²³² Hatsukami DK, Kotlyar M, Hertsgaard LA, et al. *Reduced nicotine content cigarettes: Effects on toxicant exposure, dependence and cessation*. Addiction, 2010. 105(2): 343-55.

²³³ Benowitz NL, Nardone N, Dains KM, et al. *Effect of reducing the nicotine content of cigarettes on cigarette smoking behavior and tobacco smoke toxicant exposure: 2-year follow up*. Addiction, 2015. 110(10): 1667-75.

²³⁴ Nardone N, Donny EC, Hatsukami DK, et al. *Estimations and predictors of non-compliance in switchers to reduced nicotine content cigarettes*. Addiction, 2016. 111(12): 2208-2216.

²³⁵ Mercincavage M, Wileyto EP, Saddleson ML, et al. *Attrition during a randomized controlled trial of reduced nicotine content cigarettes as a proxy for understanding acceptability of nicotine product standards*. Addiction, 2017. 112(6): 1095-1103.

While research on VLNCs has been conducted with current smokers (due to ethical concerns with research that would have nicotine-naïve individuals start smoking), useful and relevant animal models have been developed. Tested in adult rats, nicotine naïve animals (acquirers) responded at a lower rate and earned less infusions than nicotine experienced rats (currents), suggesting that the prior experience of self-administering a higher nicotine dose may have increased sensitivity to low nicotine doses.²³⁶ These data suggest that never users who try smoking with VLNCs are likely to find them less reinforcing (i.e., addicting) than current smokers. A second study compared male and female adolescent and adult rats and nicotine self-administration initiation of three nicotine doses (3, 10, 30 ug/kg/infusion).²³⁷ At the highest dose, both adolescent and adult rats acquired self-administration; at the lowest dose, neither adolescent or adult rats acquired self-administration; and at the middle dose, adult but not adolescent rats acquired self-administration. An earlier study found that adolescent rats were less likely than adult rats to acquire self-administration of nicotine at a dose of 15 ug/kg/infusion.²³⁸ The findings suggests that adolescents (based on animal model studies) are likely to be less sensitive to reinforcement from very low levels of nicotine compared with adults, and that nicotine doses below the threshold for reinforcement in current adult smokers are also likely to be below threshold for adolescents initiating smoking for the first time.

Research with adolescent humans complement the preclinical findings. In a within subject double-blinded design, adolescent (age 15-19) daily smokers rated research cigarettes with the lowest nicotine content (0.4 mg/g) less reinforcing than cigarettes with the highest nicotine content (15.8 mg/g).²³⁹ That is, the lower nicotine content cigarettes appeared to have a reduced abuse liability. The study found no effect of cigarette nicotine content on compensatory smoking.

Based on rigorous review of the scientific evidence, the FDA determined that authorizing reduced nicotine products for sale in the US is appropriate for the protection of the public health.²⁴⁰ The tobacco company 22nd Century Limited LLC received FDA approval for its' Moonlight cigarettes, which were identified by the FDA as helpful in reducing nicotine dependence among adults addicted to smoking. The Moonlight cigarettes have nicotine content between 0.2 to 0.7 mg per cigarette, compared to conventional cigarettes which have between 10 to 14 mg of nicotine per cigarette. People who smoked reduced nicotine cigarettes were less dependent on cigarettes. As a result, they smoked fewer cigarettes, exposing themselves to fewer carcinogens, and they made more attempts to quit, compared to people who smoked conventional cigarettes. Young adults also reported that reduced nicotine cigarettes were less satisfying and also ended up smoking fewer cigarettes per day. The agency determined that young people and those naïve to nicotine who experiment with reduced nicotine products are less likely to become addicted than people who experiment with conventional cigarettes.

Last month, the FDA approved 22nd Century Limited LLC's application to market its VLNC cigarette as a modified risk tobacco product (MRTP).²⁴¹ This alternative cigarette has 0.5 mg nicotine/g of tobacco filler (dry weight), which is 95% less nicotine compared to the top 100 brands representing over 80% of all cigarettes sold in the U.S. 22nd Century has made cigarettes at this level under the SPECTRUM brand name for NIDA, which have been extensively researched (see above). 22nd Century must see the market viability of such a product in the U.S. to invest time and resources in seeking FDA approval. Consumer

²³⁶ Smith TT, Schassburger RL, et al. 2014. Low-Dose Nicotine Self-Administration Is Reduced in Adult Male Rats Naïve to High Doses of Nicotine: Implications for Nicotine Product Standards. *Exper Clin Psychopharmacol* 22 (5): 453–459

²³⁷ Schassburger RL, Pitzer EM, Smith TT, et al. 2016. Adolescent Rats Self-Administer Less Nicotine Than Adults at Low Doses. *Nicotine & Tobacco Research* 18 (9): 1861–68.

²³⁸ Shram MJ, Li Z, Lê AD. Age differences in the spontaneous acquisition of nicotine self-administration in male Wistar and Long-Evans rats. *Psychopharmacology*. 2008;197(1):45–58.

²³⁹ Cassidy RN, Colby SM, Tidey JW, et al. 2018. Adolescent Smokers' Response to Reducing the Nicotine Content of Cigarettes: Acute Effects on Withdrawal Symptoms and Subjective Evaluations. *Drug Alcohol Dependence* 188 (July): 153–60.

²⁴⁰ <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application>

²⁴¹ <https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications>

interest in a low nicotine cigarette product has been known by the tobacco industry since at least as early as the 1980s.²⁴² The interest was based on the perception that such a product would be healthier; “a way to quit smoking;” “that the product would allow smokers to cut down or quit”.^{243,244} More recent opinion poll surveys show support among U.S. adults for a federally regulated nicotine reduction product standard: measured at 47% in 2010²⁴⁵ and 76% in 2011 (not a nationally representative sample).²⁴⁶ In research funded by the FDA, a simulation model was run to quantify the potential public health effects of enacting a regulation in the US that makes cigarettes minimally addictive by setting a maximum level of nicotine in cigarettes.²⁴⁷ Model inputs were derived from empirical evidence and expert opinion; outputs included the prevalence of tobacco use, tobacco-related mortality, and life-years gained. The statistical model found that cutting nicotine levels to “minimally addictive levels” could slash smoking rates from 15% to as low as 1.4% and lead to a substantial reduction in tobacco-related deaths. The researchers estimated that such an initiative “could save millions of lives and tens of millions of life-years over the next several decades.”

With modeling looking back in time and with review of previously internal tobacco industry documents and public patents to determine what was known and what was capable, Levy et al. estimated that “millions of premature deaths could have been averted if companies had only sold VLNCs decades ago.”²⁴⁸ Their review found that tobacco companies recognized cigarettes were deadly and addictive at least by the 1950s and early 1960s and had the technical capability to lower cigarette nicotine content for decades. Patents and internal company documents from at least the 1920s and 1930s describe methods to extract nicotine from tobacco.^{249,250,251} Had the tobacco industry chosen to implement a VLNC standard in 1965, 21 million smoking attributable deaths (SADs, a 54% reduction) and 272 million life years lost (LYLs, a 64% reduction) could have been averted from 1965 to 2064; a standard implemented in 1975 could have averted 18.9 million SADs and 245.4 million LYLs from 1975 to 2074; and a standard implemented in 1985 could have averted 16.3 million SADs and 211.5 million LYLs from 1985 to 2084.

Manipulation of the pH level of cigarette smoke also affects the addictiveness and resulting harm of cigarettes. As early as the 1970s, researchers noted that the irritation and harshness of smoke at higher pH made it harder for smokers to inhale the smoke into the lungs.²⁵² Commercial US cigarettes today have an acidic pH of about 5.5 to 6.²⁵³ When cigarette smoke is inhaled, nicotine moves quickly to the lungs,

²⁴² Dunsby J, Bero L. A nicotine delivery device without the nicotine? Tobacco industry development of low nicotine cigarettes. *Tobacco Control* 2004;13:362–369.

²⁴³ Bamundo Qualitative Research. A qualitative exploration designed to gain insights into the appeal of a 97% nicotine-free cigarette. December 1987. Philip Morris Collection. Bates 2023087252/2023087283. <http://legacy.library.ucsf.edu/tid/dmt71f00>

²⁴⁴ Bonhomme J, Lalley C, Levy C, Stamel N. Leo Burnett Agency. Marketing research department report: Qualitative research on ART, Oct 17, 1988. Philip Morris Collection. Bates No. 2023088868/2023088871. <http://legacy.library.ucsf.edu/tid/opc68e00>

²⁴⁵ Pearson JL, Abrams DB, Niaura RS, Richardson A, Vallone DM. Public support for mandated nicotine reduction in cigarettes. *AJPH*. 2013;103(3):562–567.

²⁴⁶ Bolcic-Jankovic D, Biener L. Public opinion about FDA regulation of menthol and nicotine. *Tob Control*. 2015;24:e241–e245

²⁴⁷ Apelberg BJ, Feirman SP, Salazar E et al. Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States. *N Engl J Med* 2018; 378:1725-1733.

²⁴⁸ Levy DT, Cummings KM, Heckman BW, et al. 2021. The public health gains had cigarette companies chosen to sell very low nicotine cigarettes. *Nicotine & Tobacco Research*, 23, 438–446 <https://doi.org/10.1093/ntr/ntaa128>

²⁴⁹ Federman H. Removing nicotine from tobacco. US Patent 1,719,291. July 2, 1929.

<https://pdfpiw.uspto.gov/piw?Docid=1719291&idkey=NONE&homeurl=http%3A%252F%252Fpatft.uspto.gov%252Fnetathtml%252FPTO%252Fpatimg.htm>

²⁵⁰ Lippmann LM, Faitelowitz A. *Method of denicotinizing tobacco*. US Patent 2,000,855. May 7, 1935.

<https://pdfpiw.uspto.gov/piw?Docid=2000855&idkey=NONE&homeurl=http%3A%252F%252Fpatft.uspto.gov%252Fnetathtml%252FPTO%252Fpatimg.htm>

²⁵¹ American Tobacco Company. *Improving the Taste and Character of Cigarette Tobacco With a View to Removing Irritants and Producing a Light Smoke*. December 9, 1935. American Tobacco Company Records. <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/sxwv0024>.

²⁵² Brunnemann KD, Hoffmann D. The pH of tobacco smoke. *Food and Cosmetic Toxicology*. 1974;12(1):115–24.

²⁵³ Prochaska JJ, Benowitz NL. (2019). Current advances in research in treatment and recovery: nicotine addiction. *Science Advances*, 5 (10), eaay9763.

arterial blood, and to the brain in only 15-20 seconds,²⁵⁴ where it exerts its addiction-related effects. Rapidity of delivery to the brain is thought to be an important factor in the abuse liability of inhaled nicotine compared to other routes of nicotine administration. The importance of rapid delivery relates to higher arterial concentrations, nearly immediate psychological effects, and the ability to titrate doses to desired effects. Higher arterial levels also allow the smoker to overcome effects of tolerance to the desired psychological effects of nicotine. In contrast, dependence on nicotine from medications (e.g., nicotine patches, gum, lozenge) that deliver nicotine slowly, appears to be low. Raising the pH of cigarettes to 8 or more (its level prior to 20th century methods of cigarette manufacturing) would make cigarettes harder to inhale.²⁵⁵ A more acrid smoke that cannot easily be drawn deep into the lungs, could reduce both smoking uptake and the risk of lung cancer and other lung diseases, resulting in a safer way to smoke.²⁵⁶

A series of documents show R.J. Reynolds's interest in developing a non-inhalable cigarette. In 1964, R.J. Reynolds received a consumer proposal to develop a cigarette designed for "smoking without allowing the smoke to enter the lungs... a non-inhalable cigarette" (Bates No. 501889844-9845). In a confidential research planning memorandum dated November 1971, R.J. Reynolds executive Claude Teague considered the health advantages of pipe smoking over cigarette smoking "due to the fact that the pipe smoke is not inhaled" and proposed developing a product that "would consist physically of a tobacco rod, encased in paper or other suitable material" with "tobacco in the rod... more like that in pipe tobacco" and "smoke... designed to be non-inhalable, which would require, most probably, an alkaline smoke of rather high nicotine content" (Bates No. 511242019-2024). In 1972, R.J. Reynolds scientist Frank Colby similarly highlighted the perceived health value of a non-inhalable cigarette achievable with an "alkaline pH" with appeal for those who "are very health-conscious on the one hand and unwilling or unable to give up smoking on the other hand" (Bates No. 502987369-7371 and 511242099-2104; also 500286252-6286). A 1973 R.J. Reynolds Teague document included as targets for further consideration (Bates No. 504476859-6868):

- "Prepare and evaluate prototype non-inhalable cigarette system"
- "Prepare and evaluate prototype cigarette system with draft, flavor, satisfaction, non-inhalability, etc., of pipe smoking system, i.e., convenience of a cigarette with the qualities of a pipe."

A 1973 R.J. Reynolds document, "Summary of Ideas Discussed by the Profitability Date Idea Group," included on a short-list of new products: "A non-inhalable cigarette" (Bates No. 504010538-0539 and 502987325-7327 also see 504652411-2414 and 500915642-5650). A 1975 R.J. Reynolds document on "Research Department Missions and Technical Objectives" included "non-inhalable cigarette" in its list of "new product prototypes" (Bates No. 508292827-2836). A classified as "Secret" 1976 RJR "Planning Assumptions and Forecast" report for the next decade included "A cigarette designed and labeled as being non-inhalable, i.e., high alkaline, high nicotine smoke, may appeal to a limited market."²⁵⁷

A 1967 BAT proceedings report²⁵⁸ from an R&D conference summarized "assumptions made by R&D scientists" including: "If there is no inhaling, there is no lung cancer or respiratory disease." A 1971 BAT report extolled the value of a non-inhalable cigarette (Bates No. 100061274-1279; 101472699-2715). A 1974 private and confidential BAT R&D conference proceedings report²⁵⁹ noted "Carbon monoxide will become increasingly regarded as a serious health hazard for smokers" and provided an update that

²⁵⁴ Benowitz NL, *Clinical pharmacology of nicotine: Implications for understanding, preventing, and treating tobacco addiction*. Clin Pharmacol Ther, 2008. 83(4): p. 531-41.

²⁵⁵ Proctor RN. *Golden Holocaust: origins of the cigarette catastrophe and the case for abolition*. Berkeley: UC Press, 2011.

²⁵⁶ Chang, C.M., Corey, C.G., Rostron, B.L. et al. Systematic review of cigar smoking and all cause and smoking related mortality. *BMC Public Health* 15, 390 (2015)

²⁵⁷ Planning Assumptions and Forecast for the Period 1977-1986 for R.J. Reynolds Tobacco Company. April 15, 1976. Bates No. 500774773-500774792

²⁵⁸ BAT: R & D Conference – Montreal. 1967 October 24. Bates No. 500014079-500014085

²⁵⁹ BAT. Notes on the Group Research & Development Conference at Duck Key, Florida. 12th – 18th January 1974. Bates No. 680048892-680048897

“Although the Conference had concluded in the past that the non-inhalable cigarette was a worthwhile concept, no work had been done in this field and the operating companies represented did not feel that it presented a realistic approach. It was agreed to record a difference of view on this subject.”

Philip Morris internal documents also indicate interest in development of non-inhalable cigarettes in the 1970s and 1980s and understanding of the harmful effects of inhaling cigarette smoke (e.g., 2023162212-2220, 1005099001-9024, 1000082556, 1003478734-8735, 2001298704-8719, 2021500981, 200516012, 2028871250-1253). An April 1983 Philip Morris document titled “New Product Ideas”²⁶⁰ included:

- Cigt. with high mouth feel/flavor (non-inhalable) - intended to taste like a high impact, full-flavored cigt.,”
- “Non-inhalable smoke cigt.”
- “Cigt. you can enjoy without inhaling.”

Philip Morris board meeting minutes from June 1983 indicated a “Non-inhalable high taste cigarette” made it on the shortlist as worthwhile new product efforts to target (Bates No. 1003656510-6511).

Other design changes to reduce cigarette harms at the population level include a ban on additives, such as menthol, ammonia, and sugars, and on certain cigarette filters, which mask the harshness of cigarettes and facilitate exposure to nicotine.

- **Menthol:** With the explicit intent of protecting youth from smoking initiation, in 2009, the US Congress banned all traditional cigarettes’ characterizing flavors, except menthol.²⁶¹ The 2009 flavored cigarette ban reduced the U.S. youth smoking prevalence; however, menthol cigarette use among adolescent smokers has increased.²⁶² In 2013, the FDA concluded that menthol cigarettes lead to increased smoking initiation among youth and young adults, greater addiction, and decreased success in quitting smoking.²⁶³ In 2017, menthol cigarettes comprised 36% of the U.S. cigarette market.²⁶⁴ In 2018, then-FDA Commissioner Dr. Scott Gottlieb announced the FDA’s intention to initiate rulemaking to ban menthol in cigarettes, stating that menthol cigarettes “represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes” and “exacerbate troubling disparities in health related to race and socioeconomic status.”²⁶⁵
- **Filters:** Banning filters, which provide no health benefit but reduce irritation and may make it easier for those experimenting with smoking to become regular smokers, also could yield harm reduction at the population level.
- **Added Sugars:** While sugars are naturally present in tobacco leaf, tobacco companies also have added sugars to their products in substantial quantities to neutralize tobacco’s harsh taste and make the smoke seem milder and easier to inhale. By making cigarettes more palatable to first time users, sugars ultimately increase the risk for addiction because they encourage initiation.²⁶⁶ For Marlboro, sugar is the main constituent after tobacco. When sugars are burned in cigarettes, they form the addiction-enhancing, cancer-causing chemical acetaldehyde, which is believed to interact with nicotine to enhance nicotine’s addictive effects by making receptors in the brain more receptive to

²⁶⁰ Philip Morris. New Product Ideas. April 13, 1983. Bates No. 1003656948-6956

²⁶¹ H.A. Waxman, *H.R.1256 - Family Smoking Prevention and Tobacco Control Act*, House - Energy and Commerce and Oversight and Government Reform, Editors. 2009, 111th Congress (2009-2010).

²⁶² Courtemanche CJ, et al, Influence of the flavored cigarette ban on adolescent tobacco use. *AJPM*, 2017. 52(5): e139-e146.

²⁶³ FDA 2013, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*

²⁶⁴ US Federal Trade Commission (FTC), *Federal Trade Commission Cigarette Report for 2017*. 2019, U.S. FTC.

²⁶⁵ Press Announcement, Statement from FDA Commissioner Scott Gottlieb, MD, on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes (Nov. 15, 2018).

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

²⁶⁶ Talhout R, et al., “Sugars as tobacco ingredient: effects on mainstream smoke composition,” *Food and Chemical Toxicology* 44(11):1789-1798, 2006. SCENIHR, *Addictiveness & Attractiveness of Tobacco Additives*, 2010.

nicotine.²⁶⁷ Philip Morris animal research demonstrated a synergistic interaction between nicotine and acetaldehyde – rats pressed the lever more for the combination of nicotine and acetaldehyde than for either substance by itself.²⁶⁸ Researchers have concluded that sugars and how they are manipulated in tobacco significantly contribute to the adverse health effects of smoking.²⁶⁹

- **Ammoniation:** With regard to ammonia as a cigarette additive, many tobacco industry documents mention augmentation of nicotine impact, and many of those also reveal a conviction that ammoniation was increasing the rate of nicotine delivery, causing a more immediate and profound “kick” to a smoker’s central nervous system, and driving sales.^{270,271,272,273,274,275,276,277,278,279} Terms used within the tobacco industry to describe this augmented impact include: volatile nicotine, pH effect, amelioration, extractable nicotine, burley impact and increased satisfaction or augmentation.²⁸⁰

Safer design alternatives can substantially reduce the addictiveness of cigarettes in adult and adolescent smokers and in nicotine naïve individuals. The safer design would be a “choice” cigarette rather than a “need” cigarette – a cigarette that does not compel repeated dosing within a day and chronic use over time, a product that does not carry a quit failure rate exceeding 90%. Minimizing the addictiveness of cigarettes thereby reduces the compulsion, the need and drive to smoke and ultimately the harm that results from repeated toxin exposure, with heavy, sustained cigarette smoking. The modeled population health benefits in terms of deaths averted and life years gained is enormous.²⁸¹

10) E-cigarettes are alternative nicotine delivery devices that can create and sustain addiction. Though not approved as a cessation therapeutic by the FDA, e-cigarettes have been marketed as “switching” devices, and many Americans have turned to e-cigarettes in an attempt to switch or quit combustible cigarette use. The evidence for e-cigarettes’ effectiveness as a cessation strategy, however, is weak, and dual use (using both e-cigarettes and combustible tobacco) is common. There is no evidence of a health benefit for dual use relative to continued combustible cigarette use. Dual use may delay quitting smoking.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. Original data from my own published research

²⁶⁷ See Talhout et al. 2006

²⁶⁸ Rabinoff M, et al., “Pharmacological and Chemical Effects of Cigarette Additives,” *AJPH* 97(11):1981-91, 2007

²⁶⁹ See Talhout et al. 2006

²⁷⁰ Stevenson T, Proctor RN. The secret and soul of Marlboro: Phillip Morris and the origins, spread, and denial of nicotine freebasing. *AJPH*. 2008;98(7):1184–1194.

²⁷¹ Seligman RB “The Use of Alkalies to Improve Smoke Flavor,” Philip Morris, 1965, Bates no. 2026351158-1163

²⁷² Gullotta FP et al. to HL Spielberg, “When Nicotine Is Not Nicotine,” Philip Morris, Aug 2, 1989, Bates No 2025986931-6935

²⁷³ Trimmer to Seligman, “Analysis of TPM and Nicotine Delivery of Production DAP,” Philip Morris, Bates No. 2050872548

²⁷⁴ Crayton FH, Spielberg HL. “Flavor Development: Effects of Ammonia - Odor and Smoke,” Philip Morris, Nov 8, 1971, Bates no. 2028660823-0831, <http://legacy.library.ucsf.edu/tid/cuq74e00>

²⁷⁵ Teague Jr CE. “Modification of Tobacco Stem Materials by Treatment with Ammonia and Other Substances,” RJ Reynolds, Aug 3, 1954, Bates No. 504175083-5084, <http://legacy.library.ucsf.edu/tid/gpt58d00>

²⁷⁶ Casey WJ, Perfetti TA. “Method to Improve Quality of Tobacco via Sugar-Ammonia Reactions,” RJ Reynolds, Mar 19, 1980, Bates No. 504168866-8868, <http://legacy.library.ucsf.edu/tid/vrt58d00>

²⁷⁷ Colby FG to Blevins Jr RA. “Cigarette Concept to Assure RJR a Larger Segment of the Youth Market,” Dec 4, 1973, Bates No. 500529772-9773, <http://tobaccodocuments.org/rjr/500529772-9773.html>

²⁷⁸ Kornhurst EE. “PM’s Global Strategy: Marlboro Product Technology,” Brown and Williamson, Oct 26, 1992, Bates No. 569203392-3628, <http://legacy.library.ucsf.edu/tid/hus20f00>

²⁷⁹ Deposition of William Anthony Farone, Ph.D., *Labelle v. Philip Morris Inc*, July 20, 2000, Bates no. faronew072000, <http://tobaccodocuments.org/datta/FARONEW072000.html>

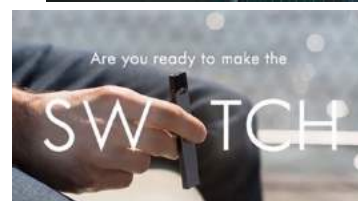
²⁸⁰ Minnemeyer HJ. “Continuation of Nicotine Augmentation Project (Conap),” Lorillard, Feb 9, 1977, Bates No. 00982446-2453, <http://legacy.library.ucsf.edu/tid/aut71e00>

²⁸¹ See Apelberg BJ, Feirman SP, Salazar E et al. *NEJM* 2018; 378:1725-1733.

2. Other published scientific articles and official reports (e.g., Surgeon General Reports; National Academies of Sciences)
3. Internal industry documents available via Truth Library²⁸²
4. The SRITA collection as it relates to e-cigarettes²⁸³

While e-cigarettes are likely less harmful than combustible tobacco, which contribute to the deaths of two in three long-term users, this does not mean e-cigarettes are safe.²⁸⁴ E-cigarette aerosol contains nicotine, which is addictive; ultrafine particles, that can be inhaled deeply into the lungs; flavorings such as diacetyl, a chemical linked to serious lung disease; volatile organic compounds; cancer-causing chemicals; and heavy metals such as nickel, tin, and lead, though all at lower levels than in combusted tobacco smoke.²⁸⁵ This list is limited by the chemicals assayed to date. Other toxicants, yet to be determined, may be created by repeated heating of the plastic and metal devices.

E-cigarettes have been marketed as switching devices, and adults who smoke cigarettes have responded by turning to e-cigarettes in an effort to quit combustible tobacco use. Among U.S. adult smokers making a quit attempt, 1 in 4 (25%) reported trying e-cigarettes to quit, the same percent that tried nicotine replacement therapy (NRT).²⁸⁶ NRT is FDA-approved for quitting smoking, e-cigarettes are not. Dual use of e-cigarettes and combustible cigarettes is common.²⁸⁷ The health benefits of e-cigarette use among continued smokers (i.e., dual users) are unproven, and the long-term health effects of e-cigarette use are unknown.²⁸⁸



The National Academies of Sciences (NAS), in its review of the research on e-cigarettes, identified insufficient evidence on the effectiveness of e-cigarettes as cessation devices. Only three randomized controlled trials have examined e-cigarettes as a cessation device; none were conducted in the US; two had nonsignificant treatment effects; the most recent trial, conducted in the UK, found e-cigarettes when provided with cessation counseling outperformed NRT with quit rates at 6-months of 18% (e-cigarettes) versus 10% (NRT).²⁸⁹ Notably, among participants randomized to the e-cigarette arm who quit smoking, 80% were still using e-cigarettes at 1 year; in comparison, among those randomized to the NRT arm, continued use of NRT was 9% for those who quit smoking. Hence, e-cigarettes may continue addiction to nicotine and themselves be challenging to quit.

Blu e-cigarettes are available in rechargeable and disposable versions with tobacco and other flavored e-liquids. Blu was launched independently in 2009 and acquired by Lorillard Tobacco Co for an estimated \$135 million in 2012.²⁹⁰ With Lorillard's acquisition, retailers selling blu increased (from 10,000 to 136,000), as did advertising, including on television (in 2012, blu accounted for 75% of the e-cigarette

²⁸² <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

²⁸³ Ads included here are examples from the 50,000 online ad collection http://tobacco.stanford.edu/tobacco_main/index.php

²⁸⁴ Prochaska JJ. (2019). The Public Health Consequences of E-cigarettes: A Review by the National Academies of Sciences. A call for more research, a need for regulatory action. *Addiction*, 114, 587-589

²⁸⁵ USDHHS. *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: 2016

²⁸⁶ Caraballo RS, et al. Quit Methods Used by US Adult Cigarette Smokers, 2014–2016. *Prev Chronic Dis* 2017;14:160600

²⁸⁷ Coleman B, Rostron B, Johnson SE, et al. Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015). *Tob Control*. 2019;28(1):50–59

²⁸⁸ National Academies of Sciences, Engineering, & Medicine. 2018. *Public health consequences of e-cigarettes*. Washington DC

²⁸⁹ Hajek P, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *NEJM*, 2019. 380: 629-637.

²⁹⁰ <https://www.wsj.com/articles/SB10001424052702304723304577365723851497152>

advertising expenses and >60% in 2013).²⁹¹ The percent of minors viewing e-cigarette TV commercials increased 250% from 2011 to 2013;²⁹² and in that same period, e-cigarette use among middle and high school students quadrupled.²⁹³ Analysis of e-cigarette market trends for 2012-2013 indicated that e-cigarette sales more than doubled (from \$273.6 million to \$636.2 million), with growth particularly strong in the convenience store channel, and blu quickly emerged as the best-selling brand, constituting 44% of overall sales in 2013.²⁹⁴ In 2014, when Lorillard was purchased by R.J. Reynolds, blu was sold to Imperial Brands to avoid antitrust concerns. In 2015, blu was the second most popular e-cigarette brand in the US with 24% of dollar sales and 17% of unit sales. In 2015, the blu website stated: “our position is that electronic cigarettes are addicting.”²⁹⁵ On September 12, 2018, blu was among those to receive an FDA issued warning letter²⁹⁶ for illegal product sales to minors, along with Vuse (Reynolds), JUUL, MarkTen (Altria), and Logic (Japan Tobacco).



In the U.S., e-cigarette use among youth has been termed an epidemic by the FDA and Surgeon General.^{297,298} From 2017 to 2018, e-cigarette use increased by 78% among high school and 49% among middle school students. US data for 2019 indicated past 30-day e-cigarette use climbed further to 17% of 8th graders, 31% of 10th graders, and 35% of 12th graders; 1 in 9 high school seniors (11.7%) vaped nicotine nearly daily.²⁹⁹ CDC surveillance data indicated a majority of the active youth e-cigarette users identified JUUL as their usual brand. The CDC’s 2020 surveillance data, which was interrupted due to the COVID-19 pandemic, indicate a significant 1-year decline from 2019 with 1.8 million fewer U.S. youth reporting current e-cigarette use.³⁰⁰ Declines in the e-cigarette market observed in 2020 are believed related to CDC³⁰¹ public health alerts and media coverage of e-cigarette or vaping product use-associated lung injury (EVALI) as well as federal and state regulatory actions. In January 2020, to address the youth e-cigarette epidemic, the FDA prioritized enforcement on unauthorized flavored cartridge-based e-cigarettes that appeal to children (i.e., JUUL), including fruit and mint (but not menthol).³⁰² The 2020 youth e-cigarette surveillance data show a return to 2018 prevalence levels, which is 3.6 million US youth currently vaping nicotine, or nearly 1 in 5 high school students, still epidemic levels, with > 80% of users reporting using e-cigarettes with non-tobacco flavors (e.g., mint, fruit, candy flavored). The observed 2019 to 2020 decline in U.S. youth e-cigarette use coincides in time with JUUL’s reduction in child-friendly flavors and parallels declines in JUUL’s closed-system e-cigarette market share (from 75% in

²⁹¹ Giovenco DP, Hammond D, Corey CG, Ambrose BK, Delnevo CD. E-Cigarette Market Trends in Traditional U.S. Retail Channels, 2012-2013. *Nicotine Tob Res.* 2015;17(10):1279-1283.

²⁹² <https://www.consultant360.com/story/e-cig-advertising-seen-us-youth-rise>

²⁹³ Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA & King BA. *E-Cigarette Use Among Middle and High School Students – United States, 2020.* MMWR, 2020;69(37):1310-12.

²⁹⁴ See Giovenco DP, Hammond D, et al. 2015 NTR

²⁹⁵ <https://www.pressconnects.com/story/news/local/2015/08/14/broome-ecigs-ban/31732469/>

²⁹⁶ <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more>

²⁹⁷ FDA, *Trump administration combating epidemic of youth e-cigarette use with plan to clear market of unauthorized, non-tobacco-flavored e-cigarette products.* 2019, FDA

²⁹⁸ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

²⁹⁹ Monitoring the Future Report. 2019

³⁰⁰ Wang TW, et al. MMWR, 2020;69(37):1310-12.

³⁰¹ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

³⁰² FDA. FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint. Jan 2, 2020. <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>

2018/2019 to 58% in 2020),³⁰³ suggestive of the substantial role of youth in JUUL's market success.

JUUL, which came to the market in 2015, contains nicotine salts, which allow for high nicotine levels to be rapidly inhaled and absorbed into the bloodstream, with less irritation, relative to the freebase nicotine that has traditionally been used in other e-cigarettes and tobacco products. This innovation may enhance the efficiency of nicotine delivery and could potentially increase the likelihood that adult smokers are able to transition completely from conventional cigarettes, though clinical trial data are lacking. JUUL's appealing flavors and youthful marketing that went viral via social media, coupled with the speed and efficiency with which it is able to deliver nicotine to the user, appears to have driven initiation and dependence among young people.



My own research, a prospective study, examined the question of whether adolescents are engaging in e-cigarette trial use versus dependent use.³⁰⁴ The sample was adolescent past-month e-cigarette users reporting 10+ uses in their lifetime at baseline. At 12-months follow-up, 80% continued their e-cigarette use, daily use increased from 14.5% to 29.8%, and the adolescents tended to “graduate up” to higher nicotine content pod-type devices such as JUUL. The youths’ top e-cigarette flavor preferences -- fruit, mint/menthol, and candy -- remained stable over time. The adolescents’ self-rated level of e-cigarette addiction correlated significantly with their level of nicotine exposure as measured by the nicotine metabolite biomarker of urinary cotinine.³⁰⁵

Dr. Neal Benowitz and I published a review of studies of JUUL's nicotine pharmacokinetic profile and studies quantifying nicotine in a JUULpod, emitted in the aerosol, and absorbed by users, and with comparison to nicotine delivery via traditional combustible cigarettes.³⁰⁶ The studies tested the 5% nicotine strength JUULpods. JUUL's time to maximum nicotine concentration in plasma (Tmax) was similar to that of cigarettes, indicating rapid delivery and suggesting high abuse potential. The nicotine boost for 5% JUUL pods was 10 ng/mL or higher. Nicotine boost is a measure of the absorbed dose of nicotine. Prior research has found that a nicotine boost of 10 ng/mL per cigarette is suitably rapid for positive reinforcing effects,³⁰⁷ whereas, nicotine patches and gum predominantly provide negative reinforcement via alleviation of withdrawal.³⁰⁸ Though with notable product and user variability, the review indicated that 1 JUULpod appears capable of delivering the nicotine equivalent to smoking about a pack of cigarettes. With close comparability to a combustible cigarette in terms of nicotine delivery yet minimizing harshness with its patented nicotine salt and added flavors, JUUL's design facilitates initiation to a high nicotine, and ultimately, highly addictive vaping product.

Prior to JUUL, a leader in the e-cigarette market was Vuse, produced by R.J. Reynolds Vapor Co., a subsidiary of Reynolds American. Vuse was launched in 2013 with a nicotine content of 4.8%, which was

³⁰³ Maloney J. Reynolds American Gains on Juul by Marketing Vaping as Cool Again. Aug 17, 2020. Wall Street Journal <https://www.wsj.com/articles/reynolds-american-gains-on-juul-by-marketing-vaping-as-cool-again-11597688033>

³⁰⁴ Vogel EA, Prochaska JJ, Ramo DE, Andres J, Rubinstein M. (2019). Adolescents' e-cigarette use: increases in frequency, dependence, and nicotine exposure over 12 months. *Journal of Adolescent Health*, 64, 770-775.

³⁰⁵ Vogel EA, Prochaska JJ et al. (2020). Measuring e-cigarette addiction among adolescents. *Tobacco Control*, 29, 258-262.

³⁰⁶ Prochaska JJ, Vogel EA, Benowitz NL. (in press). Nicotine delivery and cigarette equivalents from vaping a JUULpod. *Tobacco Control*

³⁰⁷ Patterson F, Benowitz N, Shields PG, et al. Individual differences in nicotine intake per cigarette. *Cancer Epidemiol Biomarkers Prev*. 2003;12(5):468-471

³⁰⁸ Hays JT. Chapter 47 - Treatment of tobacco use and dependence. In: Levine GN, ed. *Cardiology Secrets (Third Edition)*. Mosby; 2010:305-310.

high compared to other e-cigarettes available in 2013.³⁰⁹ Vuse is offered in a variety of kid-friendly flavors including nectar, mint, melon, fusion, menthol, and tropical. R.J. Reynolds promoted Vuse with print, direct mail, and TV advertising. By 2015, Vuse was the most popular e-cigarette in the US with 33% market share in Nielsen-tracked channels³¹⁰ and the best-selling e-cigarette device in convenience stores in the US.³¹¹ Vuse lost its top position in 2017 when JUUL overtook it to become the most popular e-cigarette in the US; in August 2018, Vuse held 9.6% of the US e-cigarette market, compared to JUUL's 72% market share.³¹² With JUUL facing greater regulatory action by the FDA, Vuse has regained market share using price promotions (selling at 99 cents apiece), young models, and social media marketing. Four-week unit sales for Vuse in US retail stores rose 83% for July 2020 compared to July 2019.³¹³



Unregulated, heavily marketed, delivering an addictive drug (nicotine) to the lungs, through heated plastic and metal devices, mass produced in China with variable quality control in manufacturing and materials, e-cigarettes are a diverse group of products.³¹⁴ There are hopes, including among FDA leadership, that e-cigarettes may be a tool in transitioning nicotine in combustible cigarettes to minimally addictive levels. Needed, however, is a well-controlled product, rather than what currently exists in the US: a population-level, natural experiment lacking regulatory oversight.

11) Cigarettes are unreasonably dangerous because the tobacco industry has known of the health harms of smoking for decades and yet has repeatedly denied them, creating confusion, uncertainty, and doubt among the American public.

Method: In addition to the general methodology described above, the basis for my opinions is a weighing of the evidence in consideration of the following sources:

1. My own published research
2. Published scientific articles and official reports (e.g., Surgeon General Reports; U.S. vs. Philip Morris (DOJ Lawsuit) on tobacco and health
3. Internal industry documents available via Truth Library³¹⁵

Findings: Cigarette smoke is harmful and inhalable with an estimated 4,800 different chemical compounds of which at least 70 are proven or suspected human carcinogens including: arsenic, benzene, formaldehyde, lead, nitrosamines, and polonium 210. Tobacco smoke also contains poison gasses: carbon monoxide, hydrogen cyanide, butane, toluene, and ammonia. Smoking causes 85% of head and neck cancers³¹⁶ and about half of all bladder cancers; people who smoke are at least 3 times as likely to get bladder cancer as people who do not smoke.³¹⁷ Tobacco causes about half a million US

³⁰⁹ Samara Lynn (27 November 2013). "Vuse Digital Vapor Cigarettes". *PC Magazine*

³¹⁰ Melissa Vonder Haar (18 August 2015). "Nielsen: Electronic Cigarette Sales Growth Declines". *CSPnet*.

³¹¹ Craver, Richard (4 September 2015). "'Vapers,' vendors say they are here to stay". *Winston-Salem Journal*.

³¹² Craver, Richard (25 August 2018). "Juul expands e-cig market share gap with Reynolds' Vuse". *Winston-Salem Journal*.

³¹³ Wall Street Journal Aug 17, 2020, <https://www.wsj.com/articles/reynolds-american-gains-on-juul-by-marketing-vaping-as-cool-again-11597688033>

³¹⁴ Prochaska JJ. (2019). The Public Health Consequences of E-cigarettes: A Review by the National Academies of Sciences. A call for more research, a need for regulatory action. *Addiction*, 114, 587-589

³¹⁵ <https://www.industrydocumentslibrary.ucsf.edu/tobacco/>

³¹⁶ ASCO *Laryngeal and Hypopharyngeal Cancer: Risk Factors and Prevention*, 2020

³¹⁷ <https://www.cancer.org/cancer/bladder-cancer/causes-risks-prevention/risk-factors.html>

deaths each year, of which 50,000 are nonsmokers exposed to secondhand smoke.^{318,319} More than half of people who smoke long-term die from a tobacco-caused disease. Smoking causes 85% of head and neck cancers.³²⁰ In the US, annually, over 12,000 Americans are diagnosed with laryngeal cancer and 3,750 individuals die from these cancers.³²¹ Smoking causes over 87% of lung cancer deaths, 61% of all pulmonary disease deaths (COPD, emphysema), and 1 in 3 cancer deaths.⁶ Among heavy former smokers (defined as greater than 21.3 pack years), while lung cancer risk drops within 5 years since quitting relative to continuing smokers, it remains more than threefold higher than never smokers after 25 years since quitting.³²² From 1964 to 2014, 20 million Americans died due to smoking,⁶ and an estimated 1 billion people will die worldwide this century. For every person who dies because of smoking, at least 30 people live with a serious smoking-related illness.³²³

For more than 60 years, the tobacco industry has known of cigarettes' harms to health. The text in the box is from a 1961 Philip Morris document and it summarizes the health harms and addictive nature of cigarettes (Bates No. 2017027199-201). A Brown & Williamson document on the HIPPO I & II projects from 1963 similarly emphasized the cancer promoting and addictive aspects of tobacco cigarettes (Bates No. 1802-1805). A 1963 memorandum to Philip Morris' President and CEO from the company's Vice President of Research describes components of cigarette smoke as "known carcinogens" and identified a link between smoking and bronchitis and emphysema (Bates No. 3990181423-426).

1. There are biologically active materials present in cigarette tobacco.

These are: a) cancer causing
b) cancer promoting
c) poisonous
d) stimulating, pleasurable, and flavorful.

Yet, the tobacco industry has repeatedly publicly denied the health harms of cigarettes creating confusion among the American public. On January 4, 1954, the tobacco industry published *A Frank Statement to Cigarette Smokers*, appearing in newspapers in nearly all US cities with a population of 50,000 or more (Bates No. 2015002376). In the Frank Statement, the tobacco industry made the claims:

- 1) *That medical research of recent years indicates many possible causes of lung cancer;*
- 2) *That there is no agreement among the authorities regarding what the cause is; and*
- 3) *That there is no proof that cigarette smoking is one of the causes."*

Further, in the Frank Statement, the tobacco industry asserted:

We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business. We believe the products we make are not injurious to health. We always have and always will cooperate closely with those whose task it is to safeguard the public health. For more than 300 years tobacco has given solace, relaxation and enjoyment to mankind. At one time or another during these years critics have held it responsible for practically every disease of the human body. One by one of these charges have been abandoned for lack of evidence."

To address the public concern, the tobacco industry announced:

³¹⁸ USDHHS. 2014. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*.

³¹⁹ USDHHS. 2006. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*.

³²⁰ ASCO *Laryngeal and Hypopharyngeal Cancer: Risk Factors and Prevention*, 2020

³²¹ ASCO statistics for laryngeal cancers in the United States, 2020

³²² Tindle H et al. 2018. Lifetime Smoking History and Risk of Lung Cancer: Results from the Framingham Heart Study JNCI J Natl Cancer Inst (2018) 110(11): djy041

³²³ See USDHHS. 2014. SGR

1. *We are pledging aid and assistance to the research effort into all phases of tobacco use and health. This joint financial aid will of course be in addition to what is already being contributed by individual companies.*
2. *For this purpose we are establishing a joint industry group consisting initially of the undersigned. This group will be known as Tobacco Industry Research Committee [TIRC].*
3. *In charge of the research activities of the Committee will be a scientist of unimpeachable integrity and national repute. In addition, there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities.*

Listed sponsors of the Frank Statement were American Tobacco, Brown & Williamson, Lorillard, Philip Morris, U.S. Tobacco, and Reynolds. In her Final Opinion, US District Judge Gladys Kessler concluded: “The Frank Statement set forth the industry’s ‘open question’ position that it would maintain for more than forty years -- that cigarette smoking was not a proven cause of lung cancer; that cigarettes were not injurious to health; and that more research on smoking and health issues was needed.”³²⁴

For decades, the tobacco industry has repeated the false promises and misleading statements about the health harms of smoking published in their *Frank Statement to Cigarette Smokers*. Many of these statements and public relation campaigns were put out by TIRC, which in January 1964 was renamed the Council for Tobacco Research [CTR], to distinguish it from the public relations and lobbying efforts of the well-funded Tobacco Institute [TI]. In June 1965, the Tobacco Institute's public relations campaign on issues of smoking and health was aptly dubbed in a confidential tobacco industry memorandum by James Bowling, then Vice President of Philip Morris, as the “chronology of confusion” (Bates No. 3990090740-745). A 1970 document by Philip Morris Vice President of Research Helmet Wakeham and titled “*Best Program for CTR*” included the following: “It has been stated that CTR is a program to find out ‘the truth about smoking and health.’ What is truth to one is false to another. CTR and the Industry have publicly and frequently denied what others find as ‘truth.’ Let’s face it. We are interested in evidence which we believe denies the allegation that cigarette smoking ... causes disease” (Bates No. 1000255938-940).

Publicly, however, tobacco industry leaders, TIRC, CTR Scientific Directors, and the Tobacco Institute put out statements denying the health harms of smoking. Examples over time are listed here:

- In March 1954, George Weissman, a Philip Morris Vice President, gave a speech in Chicago and was quoted in the newspaper stating that the cigarette industry would “stop business tomorrow” if it “had any thought or knowledge that in any way we were selling a product harmful to consumers.” He blamed the cancer problem on “medical propaganda” (Bates No. 3990105243-245).
- In April 1954, TIRC published a white paper reaffirming the promises of the Frank Statement and raising question on the evidence of harm titled, *A Scientific Perspective on the Cigarette Controversy*, mailed to 176,800 doctors and deans of medical and dental colleges as well as 15,000 press contacts.
- On June 25, 1964, Bowman Gray, Chairman of the Board of R.J. Reynolds, testified at a hearing of the Committee on Interstate and Foreign Commerce that TIRC was free and independent, and had found nothing injurious, but that if it had, they would bring it out. He also affirmed to Congress that: “If it is proven that cigarettes are harmful, we want to do something about it regardless of what somebody else tells us to do. And we would do our level best.”
- In the 1960s, CTR’s Robert C. Hockett, Ph.D. asserted that “neither tobacco and health research in general, nor that of the Council has established that tobacco use or cigarette smoking in particular is a ‘major health hazard’...” (Bates No. HK1281014-025).
- On February 7, 1965, the Binghampton Press quoted a Tobacco Institute spokesman as saying that the

³²⁴ Kessler G. 2006. *United States of America v. Philip Morris USA, Inc., et al.*, Civil Action no. 99–2496, Final Opinion (pg 24).

link between smoking and disease was still unproven despite the 1964 Surgeon General's Report.

- On December 29, 1965, the Tobacco Institute issued a press release stating that research had not established whether smoking causes disease and that it was still an “open question.” The release went on to state that “[i]f there is something in tobacco that is causally related to cancer or any other disease, the industry wants to find out what it is, and the sooner the better.”
- A 1968 letter from the R.J. Reynold’s Public Relations Department to a 5th grade elementary school teacher reassured, “Despite all the research going on, science has not found any conclusive evidence that an element in tobacco smoke causes any human disease” (Bates No. 500320466).
- In 1970, the Tobacco Institute placed advertisements throughout the US claiming that there was no known link between cigarettes and disease.
- In 1979, Sheldon Sommers (member of CTR’s Scientific Advisory Board) stated, “Cigarette smoking has not been scientifically established to be a cause of chronic disease, such as cancer, cardiovascular disease or emphysema. Nor has it been shown to affect pregnancy outcome adversely. Rapidly accumulating new basic scientific discoveries and reports and the medical literature render the simplistic statements... invalid.”
- Preemptive to the release of the 1979 Surgeon General Report, the Tobacco Institute sent to the media their report titled, “Smoking and Health 1964-1979 the Continuing Controversy” (Bates No. PA/000786). Within it, the tobacco industry sought to blame the rise in lung cancer and other respiratory disorders on things other than cigarettes, such as environmental factors. For example, in New Mexico, the Tobacco Institute sought to blame the rise in lung cancers on mining operations.
- In 1981, an article published in the *British Medical Journal* on the dangers of secondhand smoke was criticized for statistical errors.³²⁵ The Tobacco Institute had articles placed all over the US, including in New Mexico newspapers, calling into question the accuracy of the data and, hence, the dangers of secondhand smoke; the express purpose was perpetuating doubt (Bates No. TI10150674-0798).
- In 1982, Edward A Horrigan, Jr., then the Chairman of the Executive Committee of the Tobacco Institute, publicly stated: “After three decades of investigation and millions of dollars invested by the government, the Tobacco Industry and private organizations, the smoking and health controversy remains unresolved. The net result of all of this effort has been that no causal link between smoking and disease has been established. That is not merely the opinion of tobacco industry executives. That is scientific fact readily available to anyone willing to make an objective, unemotional study of the existing evidence.” (Bates No. TI55230001).
- In January 1990, the R.J. Reynolds Public Relations Department in a letter to an elementary school principal asserted, “Despite all the research going on, the simple and unfortunate fact is that scientists do not know the cause or causes of the chronic diseases reported to be associated with smoking.” And requested, “We would appreciate your passing this information along to your students.” (Bates No. 508466199-200).

In notes from a 1978 tobacco industry meeting in New York, Shook, Hardy & Bacon lawyer Bill Shinn’s description of CTR’s history was summarized:

CTR began as an organization called Tobacco Industry Research Council (TIRC). It was set up as an industry ‘shield’ in 1954. That was the year statistical accusations relating smoking to diseases were leveled at the industry; litigation began; and the Wynder/Graham reports were issued, CTR has helped our legal counsel by giving advice and technical-information, which was needed at court trials. CTR has supplied spokesmen for the industry at Congressional hearings. The monies spent at CTR provides a base for introduction of witnesses. ...Bill Shinn mentioned that the “public relations” value of CTR must be considered and continued. ...It is extremely important that the industry continue to spend their dollars on research to show that we don’t

³²⁵ Hirayama T. (1981). "Non-smoking wives of heavy smokers have a higher risk of lung cancer: A study from Japan". *BMJ*;282 (6259):183-5.

agree that the case against smoking is closed (Bates No. USX0042113-117).

In 1996, CTR established a secretive, lawyer-directed Special Projects division with the primary purpose to develop research data to use to defend the industry in court. Ultimately, in 1999, CTR and the Tobacco Institute were disbanded as part of the Master Settlement Agreement.

In 1999, the US Department of Justice filed a lawsuit against the tobacco companies, and in 2006, US District Judge Gladys Kessler found the tobacco companies to have violated civil racketeering laws (RICO) and to have engaged in a decades-long conspiracy (dating back to the 1950s) to deceive the American public about the health harms of smoking and their marketing to children. Judge Kessler's Final Opinion from 2006 stated, "Over the course of more than 50 years, Defendants lied, misrepresented and deceived the American public, including smokers and young people they avidly sought as 'replacement' smokers about the devastating health effects of smoking and environmental tobacco smoke."³²⁶ To prevent continued deception, Judge Kessler ordered the tobacco companies to publish corrective statements on five topics about which they had deliberately deceived the public: 1) health harms of smoking; 2) addictiveness of smoking and nicotine; 3) lack of significant health benefits from smoking "low tar", "light", "ultra-light", "mild", and "natural" cigarettes; 4) manipulation of cigarette design and composition to optimize nicotine delivery; and 5) health harms of secondhand smoke exposure. After over a decade of legal appeals by the tobacco industry to delay and change the messaging, the corrective statements finally started appearing in US newspapers and television stations at the end of November 2017. The figure above shows the original and final language following the tobacco industry legal appeals (stricken text removed, bolded italicized text added).

A federal court has ruled that ***ordered*** Altria, RJ Reynolds Tobacco, Lorillard, and Philip Morris USA ***deliberately deceived the American public about the health effects of smoking, and has ordered those companies to make this statement ***about the health effects of smoking.******
Here is the truth:

- Smoking kills on average, 1200 Americans. Every day.
- More people die every year from smoking than from murder, AIDS, suicide, drugs, car crashes, and alcohol, ***combined.***

VII. Case Specific Material & Opinions: SANDRA CAMACHO

1) Materials Reviewed

- **Interrogatories**
- **Deposition Testimony:** Sandra Camacho (4 vols, Nov & Dec 2020), Anthony Camacho (husband, 2 vols, Nov & Dec 2020)
- **Education:** River Grove-St. Cyprian (1st-3rd), Santa Maria Del Poplo (4th-5th), St. Celastine (6th-8th), Notre Dame-High School (9th-12th, graduated 1964) all in Chicago, IL; Beauty School in Oak Park, IL
- **Employment:** hairdresser, waitress (IHOP, Denny's), cashier (7-11, Texaco)
- **Cigarette Brands Smoked:** L&M (1964-1990), Marlboro (1990-mid-1990s), Basic (1990-2017)
- **Quit Attempts:** cold turkey, throwing away cigarettes, nicotine and regular gum, Blu e-cigarette
- **Medical Records** (Appendix C)
- **Photos:** 1978 photo with an L&M pack in Sandra's hand
- **Clinical Interview of Sandra Camacho on March 27, 2020** (Appendix D)
- **Medical Examination by Daphne Dorce, MD** (2 vols, Jan 20-21, 2022)

NOTATION: Dates are indicated for medical records.
For deposition testimony, notation indicates initials of the deposed and page #
(e.g., SC100 = SANDRA CAMACHO page 100; I=Interview; E=Examination).

³²⁶Kessler G. 2006. United States of America v. Philip Morris USA, Inc., *et al.*, Civil Action no. 99-2496, Final Opinion.

2) Methodology for Case Specific Opinions

In this case, there is direct testimony from Sandra Camacho obtained in depositions held over 4 days at the end of 2021, two days in a medical examination with defense expert Daphne Dorce, MD in January 2022, and her interview with me on March 27, 2020. During her depositions, Sandra reported some difficulty recalling past events and reported that side effects from her radiation treatment include “memory loss, forgetful” (SC279). Sandra performed well on Mini Mental Status Exam items in her medical examination with Dr. Dorce; however, for many questions focused on the past she stated, “I don’t know” and she expressed “Anything leading up to my cancer I don’t remember anything” (SC-E44).

Sandra Camacho’s medical records include reporting on her age and year of starting smoking (1965; started at age 18³²⁷; a few cigarettes a day at 16³²⁸), amount smoked (5-9 cigarettes³²⁹; daily 10+³³⁰, 11-20 per day³³¹, 1 pack or less³³², 1 pack per day³³³; “at least about one pack per day”³³⁴), years of smoking (44 years in 2010³³⁵, 40 years in 2011³³⁶ and 2013³³⁷, 44 years in 2013³³⁸, 50 years in 2013³³⁹, 2017³⁴⁰, and 2019³⁴¹), pack years of smoking (40 pack years in 2015³⁴²; 49 pack years in 2013³⁴³; 50 pack years charted in 2015³⁴⁴, 2016³⁴⁵, 2017³⁴⁶, 2018³⁴⁷, 2020³⁴⁸ and 2021³⁴⁹; 48 pack years charted in 2019³⁵⁰), being advised and counseled to quit smoking or stay quit,³⁵¹ her readiness to quit smoking (charted as “precontemplative,”³⁵² “Strongly encouraged stopping smoking. Pt not willing to,”³⁵³ and “Advised to dc

³²⁷ Medical Record Bates No. 201600.049.000009 on 1/5/16, 201600.049.000007 on 3/31/16 and 201600.049.000003 on 7/11/16; also 201600.279.000056 on 6/15/15, 201600.279.000117 on 10/13/15, and 201600.279.000238 on 11/18/15

³²⁸ Medical Record Bates No. 201600.078.000024-0027 on 4/4/18

³²⁹ Medical Record Bates No. 201600.035.001018 on 10/20/16

³³⁰ Medical Record Bates No. 201600.035.001018 on 6/9/17 and 6/14/17

³³¹ Medical Record Bates No. 201600.078.000031 on 4/26/13 and 201600.220.000003 on 3/17/17

³³² Medical Record Bates No. 201600.341.000003 on 1/9/09

³³³ Medical Record Bates No. SC.0005.000004 in 2010, 201600.078.000031 on 4/26/13, 201600.225.000106-0108 on 5/21/13, SC.0008.000001-003 in 2013, 201600.229.000028 on 10/13/16; 201600.049.000009, 201600.049.000007, SC.0005.000069, 201600.049.000003, 201600.035.000415, 201600.035.000515 in 2016, 201600.237.000012 and 201600.035.000684 in 2017; 201600.078.000024-0027 on 4/4/18

³³⁴ Medical Record Bates No. 201600.035.000211 on 7/11/11

³³⁵ Medical Record Bates No. SC.0005.000004

³³⁶ Medical Record Bates No. SC.0005.000032 in 2011

³³⁷ Medical Record Bates No. 201600.086.000013 on 4/5/13

³³⁸ Medical Record Bates No. 201600.086.000010 on 7/10/13, 201600.086.000013 on 4/5/13, 201600.086.000016 on 3/29/13, 201600.117.000024 on 7/24/17, and 201600.117.000029 on 4/24/18

³³⁹ Medical Record Bates No. 201600.270.000020 on 5/31/13

³⁴⁰ Medical Record Bates No. SC.0005.000117 on 6/15/17 and SC.0005.000120 on 6/7/17

³⁴¹ Medical Record Bates No. SC.0002.000001

³⁴² Medical Record Bates No. 201600.279.000241 on 11/12/15

³⁴³ Medical Record Bates No. 201600.225.000106-0108 on 5/21/13

³⁴⁴ Medical Record Bates No. 201600.279.000056 on 6/15/15

³⁴⁵ Medical Record Bates No. SC.0001.000005, 201600.084.000111, 201600.084.000118

³⁴⁶ Medical Record Bates No. SC.0001.000018, SC.0001.000031, 201600.035.000684, 201600.084.000090, 201600.084.000104

³⁴⁷ Medical Record Bates No. SC.0001.000064 and 201600.084.000057

³⁴⁸ Medical Record Bates No. 201600.084.000012 on 6/29/20; 201600.084.000007 on 10/26/20

³⁴⁹ Medical Record Bates No. 201600.084.000196 on 7/20/21

³⁵⁰ Medical Record Bates No. SC.0006.000001, 201600.084.000204

³⁵¹ Medical Record Bates No. 201600.035.000034 on 1/5/10, 201600.035.000099 on 8/6/10, 201600.035.000241 on 7/11/11, 201600.270.000035 on 6/18/12, 201600.086.000018 on 3/29/13, 201600.078.000042 on 4/26/13, 201600.225.000106-0108 on 5/21/13, 201600.049.000009 on 1/5/16, 201600.035.000457 on 10/20/16, 201600.084.000106 on 3/30/17, 201600.035.000552 on 6/7/17, 201600.035.000670 on 6/9/17, 201600.035.000846 on 6/15/17, 201600.035.000971 on 1/22/18, 201600.035.001081 on 8/23/19, 201600.035.001211 on 9/17/19

³⁵² Medical Record Bates No. 201600.086.000085 on 12/30/08, 201600.086.000082 on 1/6/09, 201600.086.000079 on 7/9/09, and 201600.086.000055 on 5/24/10 (same language repeated each instance)

³⁵³ Medical Record Bates No. 201600.279.000117 on 10/13/15

smoking, pt not willing at this time”³⁵⁴), smoking despite tobacco-related illnesses like bronchitis³⁵⁵, her cutting back on smoking in May and July 2017³⁵⁶, ultimately quitting smoking (September 2017³⁵⁷), and sustaining her quit.³⁵⁸ More generally, Sandra’s medical record characterizes her as a “heavy smoker,”³⁵⁹ with “a strong smoking history”³⁶⁰ and a “long history of smoking.”³⁶¹

There are a series of medical records from Dignity Health Medical Group that indicate, “Current every day smoker, Cigarettes, 1 per day. 5 year(s). Total pack years: 50. Started age 18 Years.”³⁶² There is an ED assessment dated 7/17/12³⁶³ that indicates she was a former smoker, having quit more than 12 months prior. There also is a record by Ana Tolentino, RN dated 9/17/19 indicating “10 or more cigarettes (1/2 pack or more)/day in last 30 days.”³⁶⁴ These records are notably inconsistent with other records and fact witness reports (SC214, SC354, AC191, A193).

In clinical practice, errors or inconsistencies in medical records are common³⁶⁵ and are anticipated based upon my experience with reviewing medical records, specifically regarding smoking history.^{366,367} Years can be rounded or under-reported and data can be entered inaccurately. With electronic health records, text can be copied and/or auto-populated into future entries thereby carrying errors forward.⁴⁶ Where the medical records differ, inconsistencies are noted. Generally, Sandra Camacho’s medical record indicates she smoked 1 ppd for 50 years starting at age 18 and quit smoking in September 2017 having reduced her smoking in the months prior.

Evidence also is available from Sandra’s husband Anthony Camacho. Overall, the agreement between the reports by the fact witnesses was largely consistent on facts queried and was further substantiated via comparison with evidence in the medical record. The process I undertook in reconciling information in the record was to compare fact witness testimony with the medical records.

3) Timeline of major milestones in Sandra Camacho’s life

1944 June 11 DOB older sister Donna Kinsella
1946 April 28 DOB Sandra in Chicago, IL
1948 Feb 18 DOB younger sister Linda Blake
1952 Aug 11 DOB husband Anthony
1964 First smoked and smoking regularly (age 17 or 18); L&M
1964 Graduated Notre Dame-High School
1966 Smoking 1 ppd (by age 20)
1966 Sept 26 Married Dominic Stramaglia in St Joseph, MI
1967 Nov 28 DOB son John Stramaglia
1969 Mar 6 DOB daughter Laura Purkett

³⁵⁴ Medical Record Bates No. 201600279.000178 on 12/7/15

³⁵⁵ Medical Record Bates No. 201600.086.000118 on 3/25/13

³⁵⁶ Medical Record Bates No. 201600.117.000017 on 5/17/17 and 201600.117.000021 on 7/24/17

³⁵⁷ Medical Record Bates No. SC.0006.000066, SC.0008.000011, 201600.113.000154 on 4/6/18, 201600.078.000024-0027 on 4/4/18; 201600.078.000036 on 4/4/18; 201600.078.000045 on 7/16/18

³⁵⁸ Medical Record Bates No. 201600.035.001018 on 1/22/2018

³⁵⁹ Medical Record Bates No. 201600.045.000002 on 5/24/13 and 201600.279.000177 on 12/7/15.

³⁶⁰ Medical Record Bates No. 201600.237.000013 on 3/19/17

³⁶¹ Medical Record Bates No. 201600.279.000179 on 12/10/15.

³⁶² For example, Medical Record Bates No. 201600.279.000056 on 6/15/15

³⁶³ Medical Record Bates No. 201600.035.001364 and 201600.035.001376 on 7/17/12

³⁶⁴ Medical Record Bates No. 201600.035.001267 on 9/17/19

³⁶⁵ Weis JM, Levy PC. (2014). Copy, Paste, and Cloned Notes in Electronic Health Records. *Chest*, 145, 632-638.

³⁶⁶ Prochaska JJ et al. 2004. Treatment of tobacco use in an inpatient psychiatric setting. *Psychiatric Services*, 55, 1265-1270

³⁶⁷ Prochaska JJ, Fromont SC, Lee D, et al. 2008. Evaluation of an evidence-based tobacco treatment curriculum for psychiatry residency training programs. *Academic Psychiatry*, 32, 484-492.

1970 Divorced Dominic
1980 Oct 16 Married Anthony in Cook County
1990 Moved to Las Vegas
1990 Oct 25 DOD father John Mucci heart attack, stroke, bladder cancer
By 2013 Sandra Dx COPD (per med rec)
2017 Sept Sandra quit smoking; unable to smoke due to blockage/tumor in throat
2018 Mar 16 Total laryngectomy + radical neck dissection at UCLA; squamous cell carcinoma

4) Addiction Formulation: Sandra Camacho

The first cigarette that Sandra Camacho smoked was a filtered L&M that she got from a girlfriend (SC146), stating “I thought the filtered cigarette was safer for me” (SC151, SC332). When Sandra first started smoking around age 17 or 18 in 1964 (SC146, SC332),³⁶⁸ she coughed (SC149, I) and felt “light-headed a little bit” (I). Sandra testified that she inhaled and smoked the entire first cigarette that she tried (SC305). Sandra tried her second cigarette, also L&M and also from her girlfriend, “Right after first one” (SC153). Sandra testified that “after the first cigarette, I wanted another and then another” (SC305). Sandra believes she was addicted after her first cigarette, “because I wanted more” (SC195). Soon thereafter she was smoking daily (I, SC154). By age 20, she was smoking a pack a day (ppd) (I) and at times 2 ppd (SC154, SC332, SCE-53). Sandra testified that she kept smoking because she “Got addicted to having a cigarette” (SC304).

Sandra started smoking because “Everybody was doing it” (I) and “My first cig I did because it was the cool thing to do then” (SC194, SC231, SC324). Smoking was portrayed as “The in thing, with the Marlboro man and Philip Morris – the bell hop Johnny” (I). Sandra saw smoking in the movies “cowboy movies, John Wayne,” in magazines, and on billboards (I, SC144, SC324). When Sandra first started smoking cigarettes, she was unaware of the harms of smoking, and she did not know anything about nicotine addiction. When Sandra started smoking, there were no warnings of smoking’s harms, including addiction, on cigarette packs or within cigarette ads.

As a teen, Sandra received cigarettes from her girlfriend and used her allowance to buy cigarettes (SC155). Sandra started buying her own cigarettes at age 18, and she bought L&M (regular length, nonmenthol, SC159), which she described as “weren’t strong, and they weren’t light” (I). She tried Camels but found them too strong. She did not like menthol cigarettes. Out of curiosity and after smoking regularly (SC301), Sandra tried a friend’s unfiltered cigarette and did not like that the tobacco got into her mouth (SC147). Sandra smoked during her pregnancies in the mid-to-late 1960s (I, SC203, SC337) and was not advised by her physician at that time to quit (I). It was not until 1985 that a small side-of-the-pack warning was added to cigarettes concerning the harms of smoking in pregnancy.

In 1990, Sandra’s father died, she moved to Las Vegas, and she recalls a quit attempt around this time. In Las Vegas, Sandra had a more difficulty time finding L&M cigarettes and, after having smoked L&M for 25 years, she switched to Marlboro, which she found more easily in stores (SC120, SC333, I, AC98). Sandra described Marlboros as “fine, a little stronger.” When smoking Marlboro cigarettes, Sandra used coupons and participated in the Marlboro Miles program receiving “Marlboro duffle bags, camping stuff, flashlights, knives, tools, shoes - mountain climbers” (I). Sandra’s husband Anthony also received Marlboro merchandise from Sandra’s miles (I). Sandra tried Marlboro Lights but found them too light and too difficult to smoke; she “sucked really hard on it – too light” (made a contorted face during our interview showing puckered lips and sucking) (I). For a period of time, Sandra smoked both Marlboro and Basic Full Flavor, depending on what was available, and then she “switched to Basic because

³⁶⁸ Medical Record Bates No. 201600.049.000009 on 1/5/16, 201600.049.000007 on 3/31/16 and 201600.049.000003 on 7/11/16; also 201600.279.000056 on 6/15/15, 201600.279.000117 on 10/13/15, and 201600.279.000238 on 11/18/15

Marlboro getting expensive (I, SC160, SC333, AC98). Eventually switched to Basic full time” (I, SC161).

Sandra’s parents both smoked unfiltered cigarettes - Pall Mall for her mother and Lucky Strike for her father (I, 158). Sandra did not smoke her parents’ cigarettes (SC158). Sandra’s father stopped smoking when he got bladder cancer; he died in 1990 from a heart attack and/or stroke (SC57-58). Sandra’s older sister Donna smoked cigarettes and later quit (I). Sandra’s husband Anthony smoked socially, maybe 4 days in a month (I). He smoked his first cigarette at age 26 with Sandra in 1978, an L&M “her favorite cigarette” (AC91). When he was 15, Anthony (Tony) passed around cigars with kids in the neighborhood (AC93). Tony described himself initially as a “recreational” cigarette smoker that progressed to smoking regularly after they moved to Las Vegas (AC94-95). Tony smoked L&M with Sandra in Chicago and then switched with her to Marlboro in Las Vegas (AC97). Sandra’s daughter Laura smokes Marlboro Light (SC84).

Sandra Camacho made repeated failed efforts to quit smoking, with a cold turkey attempt in her 20s, throwing out her cigarettes, use of the nicotine gum a few times (SC216), and a trial with a Blu e-cigarette (I). Characteristic of people addicted to nicotine in cigarettes who have tried and failed to quit smoking³⁶⁹ and are in the precontemplation stage of change,³⁷⁰ Sandra felt low confidence, hopeless, defeated, and demoralized about her ability to quit for good. Dr. Aaron Adaoag charted Sandra as “precontemplative,” with regard to readiness to quit smoking from 2008 to 2010, though the language is repeated verbatim.³⁷¹ Medical records from 2015 indicate, Sandra was “Strongly encouraged stopping smoking. Pt not willing to,”³⁷² and “Advised to dc smoking, pt not willing at this time.”³⁷³ Asked during our interview whether she used quit smoking support services like the quitline, Sandra stated “wouldn’t help me, I was too far gone” (I). The medical record documents Sandra cutting back on smoking in May and July 2017³⁷⁴ and ultimately quitting smoking in September 2017.³⁷⁵ Sandra reported quitting smoking in 2017 when she was physically unable to smoke due to a blockage in her throat, which was later determined to be laryngeal cancer (I, AC127, AC301).

With respect to other substances, Sandra’s medical record consistently indicates no alcohol or illicit drug use,³⁷⁶ indicates “2-4 glasses of beer (12 oz) on a yearly basis”³⁷⁷, and that “she does not abuse alcohol or drugs.”³⁷⁸ Caffeine use was charted as 24 oz of coffee.³⁷⁹ Tony testified that he and Sandra smoked cannabis together a few times (AC190).

- Sandra’s Heaviness of Smoking Index (HSI) was 4 to 6, indicating moderate to high dependence.
- Sandra met 10 of 11 DSM 5 criteria for many years, with 1 criterion non-applicable, indicating Tobacco Use Disorder, severe in sustained remission. She met 6 of 6 DSM 5 associated features.
- Consistent with NIDA’s definition of addiction, Sandra’s addiction to nicotine was characterized by compulsive, at times uncontrollable, drug craving, seeking, and use that persisted, with relapse

³⁶⁹ Clyde M, Pipe A, Reid R, Els C, Tulloch H. A bidirectional path analysis model of smoking cessation self-efficacy and concurrent smoking status: impact on abstinence outcomes. *Addict Biol.* 2019 Sep;24(5):1034-1043.

³⁷⁰ Das S & Prochaska JJ. (2016). Smoking, nicotine, health, and mental health. In H. Friedman (Ed.), *Encyclopedia of Mental Health (2nd edition)*. Vol. 4, Waltham, MA: Academic Press (pp.300-313).

³⁷¹ Medical Record Bates No. 201600.086.000085 on 12/30/08, 201600.086.000082 on 1/6/09, 201600.086.000079 on 7/9/09, and 201600.086.000055 on 5/24/10 (same language repeated each instance)

³⁷² Medical Record Bates No. 201600.279.000117 on 10/13/15

³⁷³ Medical Record Bates No. 201600279.000178 on 12/7/15

³⁷⁴ Medical Record Bates No. 201600.117.000017 on 5/17/17 and 201600.117.000021 on 7/24/17

³⁷⁵ Medical Record Bates No. SC.0006.000066 and SC.0008.000011 and 201600.113.000154 on 4/6/18

³⁷⁶ Medical Record Bates No. 201600.341.000003 on 1/9/09

³⁷⁷ Medical Record Bates No. 201600.225.000106-0108 on 5/21/13

³⁷⁸ Medical Record Bates No. 201600.035.000211 on 7/11/11

³⁷⁹ Medical Record Bates No. 201600.225.000106-0108 on 5/21/13

following attempts to quit, and resulted in extremely negative consequences.

- Sandra's medical record includes diagnoses of "Non Dependent Tobacco Use Disorder (305.1),"³⁸⁰ "Nicotine Dependence,"³⁸¹ "Tobacco Dependence,"³⁸² "Tobacco Use Disorder"³⁸³ and "Tobacco Abuse."³⁸⁴

FTND items/Heaviness of Smoking Index (HSI): scored 4 to 6 (moderate to high dependence)

How soon after you wake up do you <u>smoke your first cigarette?</u>	How many cigarettes per day do you smoke?
3 - Within 5 minutes	0 - 10 or less
2 - 6-30 minutes	1 - 11-20
1 - 31-60 minutes	2 - 21-30
0 - After 60 minutes	3 - 31 or more

Sandra would smoke first thing in the morning, "Right away, first thing, before brushing my teeth" within "30 seconds" (I). Sandra testified during her deposition to smoking upon wakening within a minute (SC335). She also would wake and smoke in the middle of the night (I, SC338, AC174-175).

Once an established daily smoker, Sandra smoked 1 to 2 packs per day (I, SC154, SC332). During her medical examination with Dr. Dorce, Sandra reported smoking for 50 years or more and most of the time smoking 2 packs per day (SCE-53). The medical records report on Sandra Camacho's amount smoked as 1 pack per day³⁸⁵ and "at least about one pack per day."³⁸⁶

DSM 5 Tobacco Use Disorder: positive for 10 of 11, within a 12-mo period, with 1 N/A

- ✓ **Tolerance** – absence of nausea/dizziness/etc. despite using substantial amounts or diminished effect observed with continued use of the same amount of nicotine-containing products

When Sandra first tried a cigarette at age 17 or 18, she coughed and felt "light-headed a little bit" (I). Within a day or two she was smoking daily (I). Demonstrating tolerance to the drug nicotine, Sandra Camacho increased her smoking to a pack per day by age 20 (I). In the 1990s, she increased to 1.5 packs per day (I). When she tried Marlboro Light cigarettes, she found them to be too light and had to suck too hard to get the nicotine, so she went back to regulars (I). When she tried Blu e-cigarettes, the feeling of the nicotine was not the same as a traditional cigarette (I).

- ✓ **Craving** – continuous desire or intention to use

Demonstrating continuous desire and intention to use, Sandra Camacho would purchase her cigarettes by the carton or a couple of packs at a time (I). Sandra would smoke first thing upon wakening and wake in the middle of the night and smoke (I, AC174-175). Sandra reported cravings which she described as "Terrible – tense, agitated, mean" (I). At times she felt like she could not think of anything other than

³⁸⁰ Medical Record Bates No. 201600.086.000018 on 3/29/13

³⁸¹ Medical Record Bates No. SC.0008.000009 on 4/4/18; 201600.078.000039 on 4/16/18; 201600.078.000003 on 4/30/18; 201600.078.000048 and 201600.078.000002 on 7/24/18

³⁸² Medical Record Bates No. 201600.225.000106-0108 on 5/21/13

³⁸³ Medical Record Bates No. SC.0005.000033 on 7/11/11 and 201600.045.000003 on 5/24/13

³⁸⁴ Medical Record Bates No. 201600.035.000041 on 1/12/10, 201600.035.000108 on 8/6/10, 201600.035.000260 on 7/11/11, 201600.279.000056 on 6/15/15, 201600.27.9.000177 on 12/7/15, SC.0005.000068 on 10/20/16, 201600.035.000537 on 6/7/17, 201600.035.000614 on 6/12/17, 201600.035.000750 on 6/15/17, SC.0005.000099 on 1/22/18, 201600.035.001069 on 8/23/19, SC.0006.000003 on 8/27/19, and 201600.269.000009-010 on 8/29/19; 201600.035.001154 on 9/17/19; also 201600.035.000046

³⁸⁵ Medical Record Bates No. SC.0005.000004 in 2010, SC.0008.000001-003 in 2013, and SC.0005.000069 in 2016

³⁸⁶ Medical Record Bates No. SC.0005.000032 in 2011

smoking (I). When trying to quit, Sandra testified that she was “Always thinking about having cigarettes” (SC210). Sandra had craving and urges to smoke when “driving, seeing other people smoke, [and having] coffee” (I). When in settings unable to smoke, Sandra would feel compelled to leave and “would go outside when I needed one” (I). In discussing Sandra’s failed quit attempts, Tony testified “she needed whatever was in the cigarettes. She needed it. She was hooked on it, and she needed it” (AC198). Tony heard Sandra use the term “nicotine fit” when needing a cigarette (AC227).

- ✓ **Much time spent using** – does person spend a great deal of time in activities to get or use tobacco (e.g., chain-smoking, moving to locations where smoking is permitted, making efforts to buy cigarettes, getting money for cigarettes) or recover from its effects (get over illness)?

Sandra Camacho smoked 1 to 2 packs daily for 50 years. With each cigarette taking about 8 minutes to smoke, this is 2.67 to 5.33 hours a day, which over a period of 50 years is 48,000 to 97,000 hours in Sandra’s lifetime spent smoking, which is a great deal of time. Sandra smoked first thing in the morning, last thing before going to bed at night, and in the middle of the night (SC335, SC338, AC174-175, AC178). Sandra left restaurants to smoke (I), and she took breaks at work to smoke (I). At times, Sandra would chain smoke; she “lit one off butt of another, smoked one right after another” (I, SC338, SC193-194). Asked if she smoked more when stressed, Sandra testified, “I smoked all the time” (SC200). Tony testified that when he met Sandra in 1978 she was “constantly smoking” and increased when they moved to Las Vegas (AC155). Tony did not consider Sandra to be a chain smoker, which he defined as “people who light one up after another” (AC155).

- ✓ **Activities given up to use** –person gives up or changes social, work, or recreational activities because of tobacco use (activities affected by the need to smoke; need to smoke interrupts work)

When Sandra started smoking in the mid-1960s, she “could smoke everywhere” (I). As smoking policies became more restrictive, Sandra changed her behavior. In restaurants, she would smoke at the table. When sections were designated, she would sit in the smoking section. When smoking was no longer permitted, she would go outside to smoke (I). Sandra would go to drive-in movies and smoke in the car (I). At movie theaters, she would smoke in the lobby (I). She could not sit through the movie because she “wanted cigs” (SC202, SC337). When visiting friends, she would smoke in their homes, even if they did not smoke (I). If family or friends did not permit smoking in their homes, Sandra would go outside to smoke (AC69-70), even if it was freezing cold in Chicago (AC163). She would not smoke at church but would smoke walking to the car to go home after church (I). The need to smoke interrupted Sandra’s work. When waitressing, Sandra worked 8-hour shifts. She would smoke during lunch and designated breaks and “go back and smoke again and go out and smoke when I could” (I, AC132-133). She would take puffs on a cigarette that she “pinched” over the course of an hour when serving (SC110-111). When working as a cashier, Sandra would take smoke breaks in the back and reported smoking more than 1 cigarette an hour (I, SC117). Sandra testified during her deposition to taking breaks at work to smoke “Every chance I get. After taking customer order, went back” (337).

- ✓ **Hazardous Use** – failure to abstain in situations where physically hazardous

Sandra Camacho smoked when driving, which is dangerous (SC336).³⁸⁷ She stated, “I couldn’t drive without one” (I). She had cigarette burn marks in her car, on the ceiling and the seat (I, SC337). She also

³⁸⁷Research conducted on cigarette smoking and auto collisions has found that smokers have an increased collision involvement. Studies from 1967 through 2014 indicate a relative risk of about 1.5 among smokers compared to nonsmokers (e.g., Bellew & Winstanley 2011 Review chapter on *Smoking and accidents* in Scollo & Winstanley text *Tobacco in Australia: Facts and Issues*; Lestikow et al. 1998 *Prev Med* meta-analysis of 10 studies; Lestikow, Martin & Samuel 2000 Injury Prevention; Vingilis et al. 2018 *Traffic Inj Prev*). Video analysis of people driving while smoking suggests a mean measured driving distraction time of ~12 seconds, or enough to cover a distance of 524 feet at a speed of 31 mph (Mangiaracina & Palumbo 2007 *Annali di Igiene*).

had cigarette burn marks on her clothing and in her home (I). Sandra did not smoke in bed because her husband forbade it (I, AC159). Sandra did not smoke when pumping gas (I).

✓ **Used larger amounts/longer period than was intended**

Sandra Camacho started smoking as a teenager and continued smoking for 5 decades. Sandra smoked larger amounts and for a longer period than was intended, failing when trying to quit smoking (I). During our interview, Sandra stated, “I tried to quit, I didn’t intend to smoke that long” (I).

✓ **Physical/psychological problems related to use and continues to smoke**

Sandra would continue to smoke when she had a bout of bronchitis (I). Sandra’s medical records in 2013 indicate she was diagnosed with bronchitis,³⁸⁸ hypertension, and COPD and continued to smoke.³⁸⁹ Sandra’s medical record dated 5/24/13 indicates “I believe her leukocytosis is likely tobacco related” and “I believe that her erythrocytosis is a reactive process due to smoking.”³⁹⁰ A medical record dated 11/10/16 indicates “she does have polycythemia due to tobacco use and will need hematology.”³⁹¹ When she had a tumor in her throat, Sandra continued to smoke until she no longer was physically able to get the smoke down (I).

✓ **Repeated attempts to quit/control use** – persistent desire or unsuccessful efforts to cut down, quit or control use

Sandra Camacho tried many times to quit smoking (SC211, SC214, SC340) and during our interview reported at least two times she tried to reduce her smoking (I). Tony testified that “She told me many times, ‘I would like to quit one day’” (AC157).

During her depositions, Sandra reported her first quit attempt was in 1990 after moving to Las Vegas and after her father’s death (SC59-61, SC207, SC339). Factors motivating Sandra to try quitting smoking were the expense, the habit, and the smell (SC63, SC207, SC212). In quit attempts, she threw away her cigarettes (I, SC208, SC340, AC196), crumpled or squashed her cigarettes (AC208), and would put away her lighters and ashtrays (SC209, SC217). Tony testified that with her cigarettes, when trying to quit, “she tried hiding them, breaking them, throwing them away, putting away ashtrays. Nothing worked. She went right back to it” (AC197). Sandra purchased the nicotine gum over the counter, used it a couple of hours for a couple times, and stated it “didn’t work” (I, SC216, AC214). She also tried to quit cold turkey (I). Sandra tried a Blu e-cigarette and stated “I didn’t like it... not the same with the nicotine. I wanted to try it – I thought would be safer than smoking cigarettes – but they’re not” (I). Before quitting for good, the longest Sandra went without smoking was “not even a day, 2 or 3 hours” (I).

Sandra ultimately quit smoking in 2017 when she found smoking was “choking off my airway, I would cough and cough and cough - the tumor was behind the airway – the smoke irritation made it worse. I quit smoking because I couldn’t breathe. The tumor was growing so I couldn’t smoke. I quit before I knew that it was cancer – that’s how I found out – I couldn’t inhale anymore” (I, AC127, AC301). Sandra reported her laryngeal cancer was diagnosed in March 2018 (I). In her depositions, Sandra testified that she quit smoking at the time of her laryngectomy, which would be in 2018 (SC224).

³⁸⁸ Medical Record Bates No. 201600.086.000118 on 3/25/13

³⁸⁹ Medical Record Bates No. SC.0008.000001-003 on 4/26/13

³⁹⁰ Medical Record Bates No. 201600.045.000003 on 5/24/13

³⁹¹ Medical Record Bates No. SC.0001.000009, SC.0001.000012, SC.0001.000018-020

- ✓ **Withdrawal** – irritability/frustration/anger, anxiety, difficulty concentrating, restlessness/agitated, increased appetite or weight gain, dysphoric or depressed mood, insomnia; used nicotine/tobacco products

Asked to describe Sandra's personality, Tony testified, "She has a very good personality. She's friendly, very friendly, and she's just a nice person all around. She's the best wife I ever had for 41 years. No problems. Always the same attitude." (AC223).

When going without cigarettes, Sandra Camacho was irritable, tense, and agitated ("mean"); she had difficulty concentrating; and was restless (I). When trying to quit smoking, she testified to becoming "Miserable, mean, anxious" (SC226, SC340). Tony testified that "when she tried, her attitude changed. She became meaner toward me. She was real hostile about everything. She needed the cigarette, I guess. When she went back on it, she was okay again with her attitude" (AC197). Tony testified "she probably just went that one day or two, and there was no way she could do it. She just turned into a different person" (AC197).

At the time Sandra quit for good, she also experienced depressed mood ("cry everyday"), anxiety (was Rx Ativan), and difficulty sleeping, though these three symptoms likely also related to her health problems at the time (I). Sandra reported weight loss (50 lbs) due to the medical problems with her throat (I).

In quit attempts, Sandra used nicotine gum and e-cigarettes to relieve/avoid nicotine withdrawal and she relapsed to smoking (I). Nicotine withdrawal symptoms interfered with her functioning (I, SC210).

- ✓ **Social/interpersonal problems related to use**

Sandra Camacho's family pressed upon her to quit smoking and they would have arguments over the years, including her daughter Laura, mother, and husband Anthony. Asked why she was trying to reduce her smoking when she was 28 years old, Sandra responded, "Boyfriend, lasted 1 hour, that was the end of him" (I). Sandra reported interpersonal problems related to her smoking stating, "My daughter used to yell all of the time, and my mom quit smoking, and she would get on me about wanting to quit. My husband would get on me to quit. That didn't work – arguments" (I). Tony testified that they never fought about their smoking (AC136-137).

N/A Neglected major roles to use

This criterion does not apply well to smoking given that nicotine is non-intoxicating and that in places where Sandra worked, she was able to freely smoke or take smoke breaks. When she worked as a hairdresser, Sandra smoked inside the salon while cutting clients' hair (I, SC114). Sandra did not get in trouble for smoking when waitressing (SC108). There was a smokeroom for breaks, and she would take puffs on a cigarette that she "pinched" over the course of an hour when serving (SC110-111). Sandra was never not hired because she smoked cigarettes, and she was unaware of clients ever complaining about her smoking (I).

DSM 5 associated features supporting a diagnosis of Tobacco Use Disorder: 6 of 6

(1) smoking within 30 minutes of waking; (2) smoking daily; (3) smoking more cigarettes per day; (4) waking at night to smoke; (5) craving and experiencing withdrawal in the presence of environmental cues; and (6) developing serious medical conditions such as lung and other cancers, cardiac and pulmonary disease, perinatal problems, cough, shortness of breath, and accelerated skin aging.

Summary:

Sandra Camacho started smoking L&M cigarettes at the age of 17 or 18 in 1964. She was smoking 1 ppd by age 20 and at times increased to 1.5 ppd and even 2 ppd. Characteristic of individuals becoming addicted to nicotine as adolescents, Sandra had a difficult time controlling her use and made multiple failed quit attempts, smoking for 50 years. Addiction to cigarettes containing nicotine is the fundamental reason that people continue to smoke. Nicotine addiction contributes substantially to causing an individual to persist in smoking with exposure to the toxins in cigarette smoke. It is the long-term use of tobacco that causes cancer in people who smoke.

Cigarette smoke is harmful and inhalable with over 7,000 different chemical compounds in every puff, of which at least 70 are proven or suspected human carcinogens including: arsenic, benzene, formaldehyde, lead, nitrosamines, and polonium 210. Tobacco smoke also contains poison gasses: carbon monoxide, hydrogen cyanide, butane, toluene, and ammonia. Tobacco causes about half a million US deaths each year, of which 50,000 are among nonsmokers exposed to secondhand smoke.^{392,393}

More than half of all people who smoke long-term die from a tobacco-caused disease. From 1964 to 2014, 20 million Americans died due to smoking,³⁹⁴ and an estimated 1 billion people will die worldwide this century. For every person who dies because of smoking, at least 30 people live with a serious smoking-related illness.³⁹⁵ Smoking causes 85% of head and neck cancers.³⁹⁶ In the US, annually, over 12,000 Americans are diagnosed with laryngeal cancer and 3,750 individuals die from these cancers.³⁹⁷ Smoking causes over 87% of lung cancer deaths, 61% of all pulmonary disease deaths (COPD, emphysema), and 1 in 3 cancer deaths.³⁹⁸ The risk of developing cancer increases with the duration of smoking and the number of cigarettes smoked per day (i.e., pack years of exposure).³⁹⁹ Among heavy former smokers (defined as greater than 21.3 pack years), while lung cancer risk drops within 5 years since quitting relative to continuing smokers, it remains more than threefold higher than never smokers after 25 years since quitting.⁴⁰⁰

Based on the evidence available, Sandra started smoking as a teenager and she smoked 1 to 2 packs daily for 50 years. Sandra's addiction to nicotine led to her accumulating at least 50 pack years of exposure to cigarettes, and ultimately, developing laryngeal cancer. For Sandra, smoking cigarettes sustained her addiction to nicotine and led to serious negative health consequences for her, including cancer. To provide an indication of how addiction causes disease, Sandra's total lifetime exposure to the toxins in cigarette smoke is summarized below with comparison to exposures for someone who is nonaddicted and smoking socially. In her lifetime, Sandra had at least 3.65 million exposures (i.e., cigarette puffs) to the toxins in cigarette smoke.

³⁹² See USDHHS 2014 SGR

³⁹³ USDHHS. 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General.

³⁹⁴ See USDHHS 2014 SGR

³⁹⁵ See USDHHS 2014 SGR

³⁹⁶ ASCO *Laryngeal and Hypopharyngeal Cancer: Risk Factors and Prevention*, 2020

³⁹⁷ ASCO statistics for laryngeal cancers in the United States, 2020

³⁹⁸ USDHHS 2014 SGR

³⁹⁹ See USDHHS 2014 SGR

⁴⁰⁰ Tindle H et al. 2018. Lifetime Smoking History and Risk of Lung Cancer: Results from the Framingham Heart Study JNCI J Natl Cancer Inst (2018) 110(11): djy041

	Quantity	Cigarettes per Year	Cigarettes per Life	Puffs per Cigarette	Lifetime exposure (puffs)
Social Smoking	20 cigarettes per <u>month</u> ⁴⁰¹	240	12,000 (50 years)	10	120,000
Sandra Camacho	20+ cigarettes per <u>day</u> for 50 years	7,300+	365,000+ (50 years)	10	3,650,000+

In my opinion, the reason Sandra smoked for as long as she did and as much as she did is because of the levels of nicotine in the cigarettes that she smoked and because she became addicted. If she had smoked cigarettes that were not addictive or that had substantially reduced nicotine, more likely than not, she would not have become addicted nor sustained her addiction to cigarettes.

If the cigarettes that Sandra smoked had a smoke pH level of 8 or higher, making it difficult to inhale, in my opinion, more likely than not, she would not have become addicted nor sustained her addiction to cigarettes.

Sandra saw and relied on tobacco industry advertising of Liggett, Philip Morris, and R.J. Reynolds, which portrayed smoking as cool and glamorous (SC194, SC231, SC324, SC350, SC356-357, I). Sandra believed the tobacco companies' ads for their products (SC146) and believed filters were safer for her (SC151, SC240, SC332, AC99-100). Sandra heard the tobacco industry's denials that the harms of smoking were proven (SC121, SC126, SC233, SC282, SC342-344) and reasonably expected that the tobacco companies would have informed the public of any knowledge it had that cigarettes are harmful (SC226, SC287, SC291). Sandra relied on the tobacco companies' statements and believes she would "have never smoked" (SC359), would have "kept trying to quit" (SC236), and would have tried harder to quit sooner (SC226) if the tobacco companies had told the truth and not engaged in a campaign of denial. Sandra smoked only filtered cigarettes. That Sandra continued smoking filtered cigarettes for five decades, rather than quitting, shows she was a victim of the tobacco industry's fraud. Sandra stated, "I wish that they would have said to me: don't smoke, it's very addictive" (I).

Sandra did not smoke cigars or pipes or use smokeless tobacco products like dip or chew (I, SC206). Her use of Blu e-cigarettes when trying to quit smoking was brief and of limited exposure (I, SC206). She did not drink alcohol or illicit drugs. Tony testified that he and Sandra smoked cannabis together a few times (AC190). There is no evidence in the record of Sandra being diagnosed with HPV (SC265). No other risk factors compare in scope to the volume and duration of exposures to carcinogens that Sandra received in her 50 or greater pack year history of smoking cigarettes, predominately L&M, Marlboro, and Basic brand cigarettes.

When Sandra was growing up, Marlboro and other cigarettes were advertised on TV and billboards, featured in movies, at point of sale, and on branded merchandise available via the Marlboro Miles program. As a teenager, Sandra initiated smoking with L&M cigarettes. She subsequently smoked L&M cigarettes for 25 years, switched to Marlboro and Basic for several years, and continued smoking Basics until quitting in 2017. Each and every cigarette that Sandra smoked contributed to her nicotine addiction.

It is my professional opinion to a reasonable degree of scientific certainty that Sandra Camacho was addicted to cigarettes containing nicotine that were manufactured by Liggett and Philip Morris; Sandra smoked to sustain that addiction; and Sandra's addiction to nicotine in cigarettes was a sufficient and

⁴⁰¹ Social smoking is one subset of nondaily or intermittent smoking behavior, which is typically defined as smoking primarily in social contexts (Schane et al. 2009 *Am J Prev Med*). There is no set definition with regard to quantity other than nondaily and the smoking tends to occur in social situations. In the example here, at 20 cigarettes per month, this would be less than daily and could be someone smoking about 5 cpd each weekend.

substantial contributing cause of her lung cancer. The reason why Sandra Camacho smoked for as long and as much as she did is because of the amount of nicotine in the L&M, Marlboro, and Basic brand cigarettes she smoked. But for her addiction to nicotine in cigarettes, Sandra Camacho would not have smoked for as long as she did and as much as she did. Sandra became addicted to nicotine as a teenager when her brain was still developing, setting her on the path to heavy, chronic use into adulthood. Assuming Sandra Camacho's laryngeal cancer was caused by cigarette smoking, her addiction to the nicotine in the cigarettes that she smoked was a substantial contributing cause of her laryngeal cancer. But for her addiction to the nicotine in the cigarettes she smoked, she would not have developed laryngeal cancer. With at least 50 pack years of exposure, addiction to nicotine in cigarettes manufactured by Liggett and Philip Morris is a substantial contributing cause of Sandra developing lung cancer.

The foregoing constitutes my opinions in this case. The opinions stated above are all within a reasonable degree of scientific certainty.

VIII. Compensation

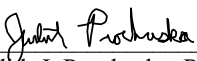
My compensation for work in this case is at a rate of \$500 per hour, except for deposition and trial time where my compensation rate is \$6000 per day.

IX. Summary of Scope

My understanding is that additional fact witnesses for this case are set to be deposed. I reserve the right to expand or modify my opinions as indicated above based upon the availability of additional evidence. In addition, I may testify about the testimony and opinions of any other witnesses and experts including the expression of opinions not explicitly stated in this report.

My reliance materials and digital sources (e.g., SRITA database, Legacy Library) are cited in this report. The ads included in this report are drawn from the SRITA database and are shown simply as examples. Other may be incorporated in my demonstratives.

2/10/2022
Date



Judith J. Prochaska, PhD, MPH

Appendix A. CURRICULUM VITAE

Name: Judith J Prochaska

Position: Professor, University Tenure Line
Department of Medicine
School of Medicine
Stanford University

Address: Medical School Office Building, X316
1265 Welch Road
Stanford, CA 94305-5411
Ph: 650-724-3608 / Fax: 650-725-6247 / email: jpro@stanford.edu

EDUCATION:

1992 - 1995	Duke University, Durham, North Carolina	BA	Psychology Major Spanish Minor Summa Cum Laude
1996 - 1999	San Diego State University	MS	Clinical Psychology
1996 - 2001	San Diego State University	MPH	Public Health
1996 - 2002	San Diego State University & University of California, San Diego, Joint Doctoral Program in Clinical Psychology Major Professor: James F. Sallis, Ph.D.	PhD	Clinical Psychology, Behavioral Medicine Track
2001 - 2002	University of California, San Francisco Clinical Psychology Training Program Langley Porter Psychiatric Institute	Intern	Clinical Psychology
2002 - 2003	University of California, San Francisco Clinical Psychology Training Program Mentor: Sharon Hall, Ph.D.	Fellow	Clinical Psychology
2003 - 2004	University of California San Francisco NIDA Postdoctoral Fellowship in Substance Abuse Treatment and Services Research Mentor: Sharon Hall, Ph.D.	Fellow	Clinical Psychology
2007	UCSF-Coro Faculty Leadership Collaborative 5-mo leadership training (60 hr)	Faculty Fellow	
2013 - 2014	Stanford School of Medicine Faculty Fellows Program on Leadership	Faculty Fellow	
2014 - 2015	Stanford Clayman Institute on Gender Faculty Research Fellowship Program	Faculty Fellow	

LICENSES, CERTIFICATION:

2006	Clinical Psychology License, California, CA PSY 20687 (Active)
2006 - 2012	Medical Privileges, Langley Porter Psychiatric Institute
2017-Present	Medical Privileges, Stanford Hospital & Clinics, with Addiction Medicine Privileges and SHC Staff Status at Lucile Packard Children's Hospital at Stanford

PRINCIPAL POSITIONS HELD:

1993 - 1995	Duke University Medical Center, Durham, NC Pain Management Program	Research Assistant
1996	Centers for Disease Control & Prevention, Division of Reproductive Health, Atlanta, GA	Research Assistant
1998	UCSF San Francisco Treatment Research Center	Research Assistant
1996 - 2001	San Diego State University Adolescent PACE+ and MSPAN Projects	Research Coordinator & Data Analyst
2001 - 2004	UCSF San Francisco Treatment Research Center	Psychology Fellow
2004 - 2008	UCSF Department of Psychiatry	Assistant Professor
2008 - 2012	UCSF Department of Psychiatry	Associate Professor
2010 - 2015	San Francisco VA Medical Center	Research Collaborator
2012	UCSF Department of Medicine	Full Professor
2012 – 2020	Stanford Department of Medicine	Associate Professor
2015 – Present	Stanford Child Health Research Institute	Faculty Member
2015 – Present	Stanford Master's of Science in Community Health & Prevention Research, Department of Medicine	Faculty Director
2017 – Present	Stanford Woods Institute for the Environment	Faculty Affiliate
2017 – 2021	Stanford Prevention Research Center's NHLBI T32 Postdoctoral Training Program in Cardiovascular Disease Prevention	Co-Director
2020 – Present	Stanford Department of Medicine	Full Professor
2020 – Present	Stanford Prevention Research Center	Deputy Director

VISITING POSITIONS HELD:

Winter 2011	Newcastle University, Newcastle, Australia	Visiting Professor
Summer 2016	Peking University, Beijing, China https://international.stanford.edu/info/news/how-teaching-farm-leads-joint-research-collaborations	Visiting Professor

HONORS AND AWARDS:

1992	Smith Scholarship. Duke University
1997	Harry E. Hamber Scholarship. San Diego State University
1999	Trowbridge Scholarship. San Diego State University
1999	Statistical Methods in Psychology taught by J.J. Prochaska rated #49 of 6,149 classes (< 1st percentile) in a survey of the top classes at San Diego State University. The student survival guide: top 100 classes. (First time a statistics course was listed in the top 100 classes.)
2001	Health Promotion Student of the Year. Graduate School of Public Health, San Diego State University.
2003	Society of Behavioral Medicine, Annual Meeting Citation Award
2003	Robert E. Harris Award. UCSF. Department of Psychiatry
2004	Society of Behavioral Medicine, Annual Meeting Citation Award
2006	Presentation Award, 2nd Place Poster. Association for Academic Psychiatry
2007	Society for Research on Nicotine and Tobacco, Jarvik-Russell New Investigator Award
2007	UCSF Cooke Award in the Scholarship of Teaching and Learning, Haile T. Debas Academy of Medical Educators

- 2009 NIDA's Division of Clinical Neuroscience & Behavioral Research Outstanding Early Career Investigator Award (1st time this award was given, focus is on recognizing the research work of outstanding mentored K awardees)
- 2011 University of Newcastle Australia Faculty Research & Research Training Committee Research Visitor Fellowship; 2-wk supported travel for international collaboration
- 2011 Mentor of the Year for Bay Area Clinical Research
- 2015 Teacher of the Year, Department of Medicine, Stanford Prevention Research Center
- 2016 Stanford Center at Peking University, Team Innovation Faculty Fellowship focused on China's Chronic Disease Burden and Prevention
- 2018 Named a Fellow of the Society for Research on Nicotine and Tobacco (SRNT)
- 2020 Stanford Medicine's 2020 Integrated Strategic Plan (ISP) Star Award for our tobacco treatment service recognized for being value focused, digitally driven, and uniquely Stanford
<https://med.stanford.edu/isp/star-award.html>
- 2021-22 Litrownik Distinguished Alumni Scholar Award for exemplifying the highest goals and standards of the UCSD/SDSU Joint Doctoral Program in Clinical Psychology
- 2021 Designated a World Expert based on being in the top 0.1% of scholars writing about smoking over the past 10 years according to Expertscape's PubMed-based algorithms
<https://expertscape.com/ex/tobacco>

RESEARCH GATE PROFILE: https://www.researchgate.net/profile/Judith_Prochaska

KEYWORDS/AREAS OF INTEREST: Smoking cessation, nicotine dependence, addiction, co-occurring disorders, mental illness, medical education, multiple risk behavior change, measurement, intervention, dissemination, quantitative methods, theory, design, community

PROFESSIONAL ACTIVITIES

PROFESSIONAL ORGANIZATIONS

Memberships

- 1995-2009 Society of Behavioral Medicine
- 1997-1998 American Psychological Association, Division 38 Health Psychology
- 1998-2003 American College of Sports Medicine
- 2002 International Society of Behavioral Nutrition and Physical Activity
- 2002-Present Society for Research on Nicotine and Tobacco (SRNT), Fellow (2018-present)
- 2004-2012 UCSF Comprehensive Cancer Center, Tobacco Control Program
- 2008-2012 UCSF Center for Prevention of Heart and Vascular Disease
- 2012-Present Stanford Cancer Institute
- 2014-Present Stanford Research into the Impact of Tobacco Advertising (SRITA)
- 2014-Present Stanford Clayman Institute for Gender Research
- 2015-Present Stanford Child Health Research Institute
- 2015-Present Stanford Tobacco Research Collaborative (STRC)
- 2016-2018 American Psychological Association Div 50 Society of Addiction Psychology
- 2018-2019 American Public Health Association, Alcohol, Tobacco & Other Drugs Section

2019-2020 American Heart Assoc, Professional Member, Council on Epi & Prevention

Service to Professional Organizations

1999	SDSU/UCSD Joint Doctoral Program selection committee	Student Rep
2002-2005	American College of Sports Medicine, Invited Appointment, Strategic Health Initiative Behavioral Strategies Committee	Committee Member
2002-2008	Society of Behavioral Medicine (SBM), Special Interest Group on Multiple Risk Behavior Change	Co-Chair
2002-2008	SBM Annual Conference	Scientific Reviewer
2005-2006	SBM, Special Interest Group Oversight Committee	Committee Member
2006-2007	American Psychological Association, Div 38, Annual Mtg	Scientific Reviewer
2007-2015	Society for Research on Nicotine and Tobacco's (SRNT) Annual Program Committee Scientific Meeting	
2008-2010	SRNT Treatment Advisory Committee and Subcommittee of SRNT members without pharmaceutical-company COI	Committee Member
2011-2012	UCSF Tobacco Education Center	Advisory Board
2012-2013	American Society of Addiction Medicine (ASAM) Committee on Nicotine Addiction Placement Criteria	Expert Consultant
2013-2016	Society for Research on Nicotine & Tobacco	Member Delegate – North America
2013	SAMHSA & UCSF Smoking Cessation Leadership Center	Consultant to states
2013-2014	Society for Research on Nicotine & Tobacco	Program Co-Chair
2014-2015	Society for Research on Nicotine & Tobacco	Program Chair
2016-2017	Society for Research on Nicotine & Tobacco	President-Elect
2017-2018	Society for Research on Nicotine & Tobacco	President
2016-2019	Stanford Health Care, Craving to Quit Smoking Group	Clinical Partner
2017-2018	Optum's Quit for Life Tobacco Quitline	Scientific Advisor
2017-2018	Treatobacco.net, Global Online Resource on the Treatment of Tobacco Dependence	Section Member, Scientific Advisor
2018-Present	Society for Research on Nicotine & Tobacco	Past-President
2018-Present	Stanford Cancer Institute, Tobacco Treatment Service	Program Director
2020-Present	National Comprehensive Cancer Network (NCCN)	Smoking Cessation Guideline Panelist
2021-2022	American Academy of Pediatrics (AAP) Tobacco Consortium	Appointed Member

SERVICE TO PROFESSIONAL PUBLICATIONS:

2003-2006	Reviewer on Editorial Board, <i>Journal of Adolescent Health</i>
2004-2015	Associate Reviewer, <i>American Journal of Health Promotion</i>
2007	Guest Editor <i>Preventive Medicine</i> Special Issue: Multiple Risk Behavior Change
2012-Present	Editorial Board, <i>JAMA Internal Medicine</i>

2018	Guest Editor, <i>JAMA Internal Medicine</i>		
2014-2020	Member, Board of Senior Associate Editors, <i>Tobacco Regulatory Science</i>		
2014-Present	Editorial Board, <i>Current Opinion in Psychology</i> (Elsevier)		
2015	Featured Expert, NEJM Forum on Reduced Nicotine Standards for Cigarettes, https://medstro.com/groups/nejm-group-open-forum/discussions/195/experts		
2017-2020	Author for <i>The Merck Manuals Professional Version (Tobacco Use)</i> and <i>Consumer Version (Smoking Cessation)</i>		
2017-2020	Consulting Editor, <i>Health Psychology</i>		
2017-2020	Editor, Cochrane Tobacco Addiction Review Group		
2020-2021	Guest Editor, Special Issue on Smoking, Vaping and COVID-19 for the <i>International Journal of Environmental Research and Public Health</i>		
1996-Present	Ad hoc referee for:		
	Addiction	J Am College Cardiology	Nature Human Behaviour
	Am J Epi	JAMA	NEJM
	Am J Health-Syst Pharma	JAMA Pediatrics	Nicotine Tobacco Res
	Am J Preventive Med	JAMA Psychiatry	Pediatrics
	Am J Psychiatry	J Am Psych Nurses Assoc	Physical Activity Health
	Am J Public Health	J Cardiopulmonary	Prev Med
	Annals Behavioral Med	Rehabilitation	Psychological Reports
	British J Psychiatry	J Dual Diagnosis	Perceptual Motor Skills
	BMJ	J Gen Internal Med	Psychiatric Services
	Cancer Epi Biomarkers	J Medical Internet Research	Psych, Health & Med
	Prevention	J Physical Activity & Health	Res Quart Exerc Sport
	Chronic Illness	J Psychoactive Drugs	Sports Med
	Drug Alc Dependence	J Subst Abuse Treatment	Schizophrenia Bulletin
	Health Educ Research	Lancet	The Joint Commission J
	Health Psychology	Lancet Respiratory Med	Quality & Patient Safety
	Intern J Behavioral Med	Med Sci Sports Exercise	Tobacco Control
	J Adolescent Health	Milbank Quarterly	Translational Behav Med
			Traumatic Stress

INVITED PRESENTATIONS

INTERNATIONAL LECTURES / ORAL PRESENTATIONS

- 2000 International Congress of Behavioral Medicine, Brisbane, Australia. *Interactive Technology for Promoting Physical Activity & Healthy Nutrition in Adolescents: PACE+*
- 2002 International Society Behavioral Nutrition & Physical Activity, Seattle, WA.
- 2011 Society for Research on Nicotine and Tobacco. Toronto, Canada. *An Online Survey Of Tobacco Use, Intentions To Quit, And Cessation Strategies Among Smokers With Bipolar Disorder*
- 2012 Newcastle University, Australia 3 presentations during visiting faculty lectureship. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders; Addressing Major Risks in High-Risk Populations; Simultaneous vs. Sequential Interventions for Multiple Health Behavior Change*
- 2012 Australasian Society for Behavioural Health and Medicine, Melbourne, Australia. Keynote: *Addressing Major Risks in High-Risk Populations; Workshop: Simultaneous vs. Sequential Interventions for Multiple Health Behavior Change*

- 2012 CAN*ADAPTT Transdisciplinary Tobacco Rounds. Toronto, Canada. *Tobacco Treatment in Smokers with Co-occurring Substance Use Disorders*
- 2012 European Society for Prevention Research Conference. Krakow, Poland. *Invited plenary on quantifying change in multiple risk behaviors*
- 2013 5th Annual Ottawa Conference: State of the Art Clinical Approaches to Smoking Cessation. Ottawa, Canada. *Invited plenary on Treating Tobacco Dependence in the Face of CoMorbidity: Promoting Health & Preventing Harm*
- 2013 Australian Smoking Cessation Conference, Sydney AU Invited keynote & 4-hr workshop on *Treating Tobacco Dependence in Smokers with Co-occurring Mental Illness*
<http://video.armchairmedical.com/V0s7ZztO>
- 2014 Australasian Professional Society on Alcohol and other Drugs, Adelaide, AU Keynote on *Treating Tobacco as an Addiction in Smokers with Mental Health Concerns*
- 2014 Flinders University, Department of Psychiatry, Adelaide, AU, Grand Rounds, on *Treating Tobacco as an Addiction in Smokers with Mental Health Concerns*
- 2015 7th Annual Ottawa Conference: State of the Art Clinical Approaches to Smoking Cessation. Ottawa, Canada. *Invited plenary on Treating Tobacco Dependence in Smokers with Co-occurring Mental Health and Addiction Problems*
- 2015 *Evidence Based Treatments for Tobacco Dependence: Benefits and Risks*, Vancouver, Canada
Invited lecture on *Treating Tobacco Addiction and Neuropsychiatric Concerns*
- 2015 Clinical Smoking Cessation Education Forum, Horizon, Saint John, New Brunswick, Canada.
Invited plenary on Treating Tobacco Dependence in Smokers with Co-occurring Mental Health and Addiction Problems
- 2016 Ontario, CA, Community of Practice Presentation, webinar for workforce collaboration
- 2016 Peking University, Beijing, China, SCPKU Symposium: Non-Communicable Disease Prevention in China, *Tobacco and Emerging Nicotine Products: from the East and West*
- 2016 Society for Research on Nicotine and Tobacco – Europe. Prague, Czech Republic. Invited workshop on tobacco and alcohol co-use. Symposium on tobacco and mHealth
- 2016 World Innovation Summit for Health (WISH) Panel on Behavioral Insights, Doha, Qatar
<https://www.youtube.com/watch?v=4zPTh8wIkZM>
<http://scopeblog.stanford.edu/2017/01/26/stanford-researcher-travels-to-qatar-to-discuss-how-behavior-changes-can-improve-global-health/>
- 2017 Society for Research on Nicotine & Tobacco. Florence, Italy. Invited Presidential Panel
- 2018 Invited speaker and participant at the Pacific Rim Alliance for Population Health (PRAPH) International Meeting. Hangzhou, China
- 2019 Invited keynote at the Programa Interuniversitario de Formación De Especialistas en Tabaquismo. Madrid, Spain
- 2021 Invited panelist for the World Health Organization's (WHO) 10th Global Conference on Health Promotion. "Commit to Quit" Empowering Tobacco Users to Quit. Virtually Held Meeting
- 2022 Invited Speaker 14th Annual Ottawa Conference, State of the Art Clinical Approaches to Smoking Cessation. Novel Digital Interventions for Smoking Cessation. Virtually Held Meeting

NATIONAL LECTURES / ORAL PRESENTATIONS

- 1996 American Public Health Association, New York, NY.
- 1997 Cooper Institute Physical Activity Conference, Dallas, TX.
- 1998 Society of Behavioral Medicine, New Orleans, LA.

- 1999 Society of Behavioral Medicine, San Diego, CA.
- 1999 American College of Sports Medicine, Seattle, WA.
- 2000 Society of Behavioral Medicine, Nashville, TN.
- 2000 American College of Sports Medicine, Indianapolis, IN.
- 2001 Society of Behavioral Medicine, Seattle, WA.
- 2001 AAHPERD National Convention, Cincinnati, OH.
- 2002 Society of Behavioral Medicine, Washington, DC.
- 2002 University of Rhode Island Cancer Prevention Research Center, Kingston, RI. Grand Rounds: *Multiple Risk Behavior Change in Complex Populations*
- 2003 Society of Behavioral Medicine, Salt Lake City, UT.
- 2003 College on Problems of Drug Dependence, Miami, FL.
- 2004 Society for Research on Nicotine & Tobacco, Scottsdale, AZ.
- 2005 Society of Behavioral Medicine. Boston, MA.
- 2005 University of Texas, El Paso, TX. Department of Psychology. Grand Rounds: *Multiple Risk Behavior Change in Complex Populations*
- 2005 Hawaii Psychological Association, Honolulu, HI. *Multiple Risk Behavior Change in Complex Populations*
- 2006 Society of Behavioral Medicine. San Francisco, CA.
- 2006 Washington State Tobacco Prevention Resource Center, Seattle & Vancouver, WA. 2 Full Day Trainings: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2007 State of Washington Co-occurring Disorders Conference, Yakima, WA. Invited Keynote: *Addressing Barriers to Treating Tobacco Dependence in Smokers with Co-occurring Psychiatric or Addictive Disorders*
- 2007 Society for Research on Nicotine & Tobacco, Austin, TX.
- 2007 Society of Behavioral Medicine, Washington DC.
- 2007 National Summit on Smoking Cessation & Wellness, Lansdowne, VA. *Tobacco Industry's Efforts to Promote Tobacco Use in Psychiatric Populations*
- 2007 American Psychiatric Association National Meeting, Association of Gay and Lesbian Psychiatrists. *Treating Tobacco Dependence in Special Populations*
- 2007 Third Annual Conference on Addictive & Health Behaviors Research, Amelia Island, FL. Invited Talk: *Multiple Risk Behavior Change: What Most Individuals Need*
- 2007 VAMC CSP519 Annual Meeting, San Diego, CA.
- 2008 Society for Research on Nicotine & Tobacco, Portland, OR.
- 2008 Society of Behavioral Medicine, San Diego, CA.
- 2008 University of Rhode Island, Cancer Prevention Research Center, Kingston, CA. Grand Rounds: *Stage-Tailored Intervention for Tobacco Dependence in Inpatient Psychiatry*
- 2008 Indiana Tobacco Prevention & Cessation Conference, Indianapolis, IN. Full day training: *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive D/os*
- 2009 American Public Health Association. Philadelphia, PA. *Predictors of subjective social status among smokers with serious mental illness*

- 2009 American Academy of Allergy, Asthma & Immunology, San Francisco, CA. *Evidenced-based Treatments for Tobacco Dependence*
- 2009 American Academy of Addiction Psychiatry, Los Angeles, CA. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2009 National Institute on Drug Abuse. Bethesda, MD. *Addressing Barriers to Treating Tobacco Dependence in Psychiatry*
- 2009 Alaska Native Tribal Health Consortium, Anchorage, AK. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2010 Society for Research on Nicotine & Tobacco, Baltimore, MD. *12-month Outcomes of a Tobacco Treatment Intervention Initiated in Inpatient Psychiatry*
- 2010 American Academy of Addiction Psychiatry, Scottsdale, AZ. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2010 NIDA, Outstanding Early Career Investigator Award. *12-month Outcomes of a Tobacco Treatment Intervention Initiated in Inpatient Psychiatry*
- 2010 Veterans Affairs, National VA-wide training on tobacco treatment, San Diego, CA. *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2010 Association for Behavioral and Cognitive Therapies. San Francisco, CA. *Discussant on Symposium Focused on Web-based Interventions for Tobacco Dependence*
- 2010 American Academy of Addiction Psychiatry, Boca Raton, FL. *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2011 Arizona Behavioral Health Summit on Smoking Cessation, Phoenix, AZ. *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2011 Alaska Native Tribal Health Consortium, Anchorage, AK. Plenary: *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2011 Oregon State Tobacco Control Integration Project / Addictions & Mental Health. Medford, OR. Invited training on *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2011 Society of Behavioral Medicine. Washington, DC. Pre-Conference Invited Speaker: *High Risk Populations in Need of Multiple Risk Behavior Change*
- 2011 SAMHSA/SCLC Webcast on tobacco use in bipolar disorder, > 300 registered
- 2011 Oklahoma Prevention & Recovery Conference. Norman, OK 2 workshops, *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2012 Maryland Tobacco Treatment Best Practices Conference. Columbia, MD. Keynote & Workshop. *Treating Tobacco Dependence in Smokers with Psychiatric Disorders*
- 2012 Massachusetts Tobacco Treatment Specialist Training. Worcester, MA. Keynote & Workshop. *Treating Tobacco Dependence in Smokers with Psychiatric Disorders*
- 2012 University of Rhode Island. Cancer Prevention Research Center, Kingston, CA. Grand Rounds: *Does Treating Tobacco Use Cause Harm? Findings from Two Investigations*
- 2012 Alaska Native Tribal Health Consortium, Anchorage, AK. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2012 American Academy of Addiction Psychiatry Webcast on Nicotine Addiction
- 2012 Legacy Foundation. Moderator and Presenter for their World No Tobacco Day Webinar focused on *Smokers with Mental Illness*; > 800 registered online
- 2012 American Public Health Association. San Francisco, CA. *Tobacco use & employability*

- 2013 Society of Behavioral Medicine. San Francisco, CA. *Chair of a symposium focused on the use of Twitter for behavior change interventions.*
- 2013 Society of Research on Nicotine and Tobacco. Boston, MA. Speaker in 3 symposia on (1) *why meta-analytic reviews on the same topic don't always agree*, (2) *Twitter for smoking relapse prevention*, and (3) *institutionalized abstinence in inpatient psychiatry.*
- 2013 American Psychiatric Association. San Francisco, CA. Two oral presentations on (1) *ADHD diagnosis and engagement in multiple risk behaviors* and (2) *stigma and tobacco use among smokers with serious mental illness*
- 2013 Centers for Disease Control and Prevention. Office on Smoking and Health, Media Network Webinar on Smoking and Mental Illness. Oral presentation on *Addressing Myths and Barriers to Treating Tobacco Dependence in Smokers with Mental Illness*
- 2014 Society of Research on Nicotine and Tobacco. Seattle, WA. Speaker in two symposia – 1) *emerging issues concerning e-cigarettes* and 2) *treating tobacco among adolescents with mental health concerns.* Also co-author on 5 papers and posters
- 2014 Cardiac Safety Research Consortium. Washington, DC, Think tank collaborative, Duke University and the FDA. *Invited oral presentation on Cardiovascular Risk + Varenicline*
- 2014 Cook County Department of Public Health. Chicago, Illinois. Delivered full day training on *Mental Health and Smoking Cessation.*
- 2014 Breathe Easy NC: Tobacco-Free Living in the Behavioral Health Community Conference. Raleigh, NC. Invited Plenary Speaker on *Tobacco Use and Mental Health*
- 2014 Veteran's Affairs 2-Day Systems Change Conference. Atlanta, GA. Increasing Access to Smoking Cessation Treatment for Veterans with Mental Health and Substance Use Disorders; 100 members from 30 regional VAMCs. Invited keynote on *Treating Tobacco Dependence in Smokers with Psychiatric or Addictive Disorders*
- 2014 National Annual Meeting of the Association of Medical Education and Research in Substance Abuse (AMERSA), San Francisco, CA, Oral presentation on *E-cigarette Use among Smokers with Serious Mental Illness*
- 2014 Centers for Disease Control and Prevention, Office on Smoking and Health, Atlanta, GA. Oral presentation on *Tobacco Use among Smokers with Depression and Anxiety.*
- 2015 Hawaii State Tobacco Conference. Honolulu, HI. Invited Keynote on *Tobacco Use and Behavioral Health Populations*
- 2015 Society of Research on Nicotine and Tobacco. Philadelphia, PA. Speaker in a pre-conference workshop (gender & treatment of tobacco addiction) and a paper session (Twitter for treatment of tobacco use)
- 2015 Health Journalism Conference, invited panelist on e-cigarettes, Santa Clara, CA
- 2015 Ohio State University. Columbus, OH. Conference organized by the Health Policy Institute of Ohio. Invited keynote on *Nicotine Addiction, Tobacco Use and Cessation Strategies for People with Mental Illness and Living in Poverty*
- 2015 University of Alaska, Anchorage. Invited lecture for Clinical and Community Psychology Doctoral Program and the School of Public Health on *Tobacco, E-cigarettes, and University Smoking Bans.* Co-presenter with Dr. Neal Benowitz.
- 2015 Norton Sound Health Corporation. Nome, AK. Hospital Grand Rounds on *Treating Tobacco Use in Cardiology.* Co-presenter with Dr. Neal Benowitz.
- 2015 Alaska Native Medical Center. Anchorage, AK. Hospital Grand Rounds on *Treating Tobacco Use in Cardiology.* Co-presenter with Dr. Neal Benowitz.

- 2015 Alaska Native Tribal Health Consortium. Anchorage, AK. Tobacco Treatment Specialist Training, Invited Faculty, 3 Presentations on the Tobacco Epidemic, Cessation Counseling, and the HEALTHH study.
- 2015 University of Vermont, Burlington, VT. Vermont Center on Behavior & Health. 3rd Annual Behavior Change, Health, and Health Disparities Conference. Invited Presenter on *Tobacco and Mental Health*.
- 2016 Society of Research on Nicotine and Tobacco. Chicago, IL. Speaker in 2 symposia on tobacco cessation treatment in smokers with comorbidities and on neuropsychiatric adverse events and associations with tobacco use, cessation and treatment; organizer and presenter for a preconference workshop on grantsmanship for junior investigators.
- 2016 FDA Webinar for Center for Evaluation and Coordination of Training and Research in Tobacco Regulatory Science, *Transitions: from Trainee to Early Career Scientist*
- 2016 National Institutes of Health. Collaborative Research on Addiction (CRAN) Social Media Research Grantee Meeting. *Harnessing Twitter Technology for Health: A tobacco Cessation RCT*. Washington, DC.
- 2016 Keynote for Ohio Department of Health Statewide Tobacco Conference, Columbus
- 2017 Think Tank on Tobacco Addiction, American College of Cardiology, Heart House, Washington, DC. *Engaging Complex Smokers*
- 2017 American Society of Clinical Oncology. Chair and Presenter for Invited Symposium on Social Media & Mobile Technology for Cancer Prevention and Treatment. Chicago, IL
- 2017 Society of Behavioral Medicine. San Diego, CA. Presenter on Invited Panel on Tobacco-Related Health Disparities; Chair for symposium on social media
- 2017 The E-cigarette Summit: Science, Regulation & Public Health, Washington DC – Invited speaker on patient-provider interactions on e-cigarettes
- 2017 National Cancer Institute – Rockville, MD – Invited talk to NCI’s fellows’ program – focus on digital health tools for health behavior change
- 2018 Smoking Cessation Leadership Center & Truth Initiative Invited presentation. Business or Exploitation? Exposure of the Tobacco Industry’s Exploitation of Individuals with Mental Health Conditions. Webinar with > 1000 registrants
- 2018 Society for Research on Nicotine and Tobacco. Baltimore, MD. Moderator for FDA CDER/CTP session on nicotine and tobacco regulation from product to therapeutic.
- 2018 Smoking Cessation Leadership Center. Invited webinar on *Vaping and Ecigs among Behavioral Health Populations: Research Evidence and Research Needs*. >1200 registered and 788 signed on for the live presentation. <https://smokingcessationleadership.ucsf.edu/webinar/vaping-and-ecigs-among-behavioral-health-populations-research-evidence-and-research-needs>
- 2018 Alaska Native Tribal Health Consortium. Anchorage, AK. Tobacco Treatment Specialist Training, Invited Faculty, 3 Presentations on Nicotine Addiction, Cessation Counseling & Relapse Prevention, and Treating Smoking in Persons with Mental Illness/Addictions
- 2019 North American Cannabis Summit. Los Angeles, CA. Chair and presenter for a symposium on local jurisdiction cannabis policies in California
- 2019 Society for Research on Nicotine and Tobacco. San Francisco, CA. Chair and presenter for pre-conference session on JUUL use among young people
- 2019 Association of Black Cardiologists (ABC). Washington, DC. Value-Based Care to Address Health Disparities and Device Underutilization. Invited presentation on stage-based approaches for engaging diverse populations in cardiovascular disease prevention research trials (presented remotely)

- 2019 ACHV: Post Phase II Investor Day, Cytisinicline. Invited Panel Expert. New York, NY
<https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2019/ACHV-Post-Phase-II-Investor-Day/default.aspx>
- 2020 American Society for Addiction Medicine. Invited Panel led by the CDC. Planned for Denver, CO but COVID cancelled and recorded for online. Presentation: Evolution of Tobacco Treatment (Counseling and Pharmacotherapy)
- 2020 NIH-supported *Intervention Research to Improve Native American Health Conference*. Planned for Washington DC, but COVID altered and presented virtually. Presentation: Telemedicine-delivered Cardiovascular Disease Prevention Counseling in the Norton Sound Region of Alaska
- 2020 UCSF Smoking Cessation Leadership Center Webinar with CME/CE credit. Integrating Tobacco Treatment within the Stanford Cancer Center: An NCI Moonshot Initiative
<https://smokingcessationleadership.ucsf.edu/webinar/integrating-tobacco-treatment-within-stanford-cancer-center-nci-moonshot-initiative>
- 2020 ACHV: Cytisinicline – Smoking Cessation Virtual Roundtable. Invited Panel Expert
<https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2020/ACHV-Achieve-Hosts-Smoking-Cessation-KOL-Call-article/default.aspx>
- 2021 Society for Research on Nicotine and Tobacco. Virtual Meeting (COVID-19). Presenter for a symposium on advancing women in science and poster on dual use of e-cigarettes among adults in 30 major US cities. Mentor on multiple presentations.
- 2021 Society of Behavioral Medicine. Virtual Meeting (COVID-19). Oral presentation on a trial evaluating a therapeutic conversation agent for reducing substance misuse
- 2021 Grand Rounds for Medical University of South Carolina (MUSC) Cancer Center
- 2021 Grand Rounds for UCSD School of Public Health
- 2021 Alaska Native Health Research Conference, oral presentation: Tobacco treatment outcomes from a telemedicine-delivered cardiovascular disease prevention intervention in the Norton Sound region of Alaska
- 2021 University of Vermont, Burlington, VT. Vermont Center on Behavior & Health. 9th Annual Behavior Change, Health, and Health Disparities Conference. Invited Presenter on *Tobacco and Mental Health*.
- 2021 Pennsylvania Tobacco-Free Recovery is Recovery Statewide Conference, Invited Keynote on the Evidence-base for Treating Tobacco in People with Behavioral Health Conditions

REGIONAL AND OTHER INVITED PRESENTATIONS

- 2000 Research Fellows Conference, American Cancer Society, California Division, Pasadena, CA. *Interactive Technology for Promoting Physical Activity & Healthy Nutrition in Adolescents: PACE+*
- 2001 Stanford Prevention Research Center, Stanford University, Stanford, CA. *Interactive Technology for Promoting Physical Activity & Healthy Nutrition in Adolescents PACE+*
- 2001 California State University Student Research Competition, San Jose, CA. *Interactive Technology for Promoting Physical Activity & Healthy Nutrition in Adolescents PACE+*
- 2003 California Psychological Association, San Jose, CA. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2006 California Society Addiction Medicine Review Conference, San Francisco, CA. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*

- 2007 UCSF Academy of Medical Educators Education Day Event. *A Standardized Patient Examination of Medical Students' Treatment of Tobacco Dependence*
- 2008 It's About a Billion Lives Annual Conference Event. UCSF Center for Tobacco Control Research & Education *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2008 Alta Bates Summit Medical Center, Berkeley, CA. Grand rounds: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2008 West Side Crisis, San Francisco, CA. Grand rounds: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2008 Northern California Psychiatric Society Annual Meeting, Monterey, CA. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive D/os*
- 2008 CSAM-sponsored Dual Diagnosis Treatment Conference, San Francisco, CA. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2008 San Mateo County Mental Health Services, San Mateo, CA. Full day and half-day trainings: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2009 Santa Clara County Medical Association, San Jose, CA. Half-day training: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive D/os*
- 2010 San Diego VA Health Care System Inpatient Services. Grand rounds: *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive D/os*
- 2010 UC Fresno (Medicine Grand Rounds) *Evidence-based Tobacco Treatment*
- 2010 UC Fresno (Psychiatry Grand Rounds) *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2011 Psychiatric Occupational Therapy Action Coalition (POTAC)/SF VAMC. San Francisco, CA *Treating Tobacco Dependence in Smokers with Co-occurring D/os*
- 2013 SRI International Grand Rounds. *Treating Tobacco Dependence in the Face of CoMorbidities: Promoting Health & Preventing Harm*
- 2013 Genentech. Invited grand rounds on *Use of Social Media for Health Interventions*
- 2013 Stanford University Department of Psychiatry Grand Rounds. *Treating Tobacco Dependence in Smokers with Co-Occurring Psychiatric or Addictive Disorders*
- 2013 Stanford University 19th Annual Healthy Living Retreat for Women @ Fallen Leaf Lake. *Motivating and Sustaining Health Behavior Change*
- 2013 Tobacco-Free Coalition of Santa Clara County. San Jose, CA. Keynote Speaker for event on Homeless Health & Wellness: Empowering Diverse Populations around Health, Advocacy, and Community Action with a Tobacco Control Framework.
- 2014 InnVision Staff Training on *Treating Tobacco among Smokers who are Unhoused with Behavioral Health Concerns*, Menlo Park, CA
- 2014 Stanford University Postdoc Academic Chat with Dr. Rick Reis on *Hitting the Ground Running as a New Professor - What To Do & NOT Do* (best attendance for the year)
- 2015 Full Day Training on *Treatment of Tobacco Dependence in Smokers with Behavioral Health Concerns*, San Mateo County, Caminar for Mental Health Nonprofit
- 2015 Stanford University Postdoc Academic Chat with Dr. Rick Reis on *Successful Start-Up Strategies For New Professors*
- 2015 State of California Tobacco Related Disease Research Program bi-Annual Meeting.

- Sacramento, California. Invited presenter on *Tobacco and Employability*.
- 2016 Santa Clara University, Psychology Department Grand Rounds on *Social Media and Tobacco Cessation*. Santa Clara, CA

CONFERENCE POSTER PRESENTATIONS:

INTERNATIONAL POSTERS:

- 2003 International Society Research in Child and Adolescent Psychopathology. Sydney, AU
- 2005 Society for Research on Nicotine and Tobacco. Prague, Czech Republic
- 2009 Society for Research on Nicotine and Tobacco. Dublin, Ireland. (2 posters)
- 2011 Society for Research on Nicotine and Tobacco. Toronto, Canada. Mentor on 4 posters
- 2013 Medicine 2.0 Conference, London, England
- 2013 Social Media & Society conference. Dalhousie University, Halifax, Nova Scotia, CA
- 2017 Society for Research on Nicotine and Tobacco. Florence, Italy. Mentor on 4 posters

NATIONAL POSTERS:

- 1995 Society of Behavioral Medicine, San Diego, CA.
- 1995 American Pain Society, Los Angeles, CA.
- 1998 American College of Sports Medicine, Orlando, FL.
- 1998 American Psychological Association, San Francisco, CA.
- 1999 Cooper Institute Physical Activity Conference, Dallas, TX.
- 2000 College on Problems of Drug Dependence, San Juan, Puerto Rico.
- 2001 Cooper Institute Physical Activity Conference, Dallas, TX.
- 2002 Society for Research on Nicotine & Tobacco, Savannah, GA.
- 2003 Society for Research on Nicotine & Tobacco, New Orleans, LA.
- 2003 American College of Sports Medicine, San Francisco, CA.
- 2004 Society of Behavioral Medicine, Baltimore, MD.
- 2006 American Association of Directors of Psychiatric Residency Training. San Diego, CA.
- 2006 Annual Meeting of the Association for Academic Psychiatry. San Francisco, CA.
- 2007 Society for Research on Nicotine & Tobacco, Austin, TX.
- 2007 American Association Directors Psychiatric Residency Training. San Juan, Puerto Rico
- 2007 Society of Behavioral Medicine, Washington DC.
- 2007 American Psychological Association, San Francisco, CA. (2 posters)
- 2008 Society for Research on Nicotine & Tobacco, Portland, OR. (3 posters)
- 2008 American Association of Directors of Psychiatric Residency Training. New Orleans, LA.
- 2008 College on Problems of Drug Dependence. Puerto Rico
- 2009 Association for Psychological Science. San Francisco, CA
- 2009 Addiction Health Services Research Conference. San Francisco, CA
- 2010 Society for Research on Nicotine & Tobacco, Baltimore, MD. Mentor on 2 posters
- 2010 Society of Behavioral Medicine, Seattle, WA. Mentor on a poster

2010 Flight Attendant Medical Research Institute Annual Meeting. Miami, FL
 2010 American Public Health Association. Denver, CO. Mentor on a poster
 2011 College for Problems of Drug Dependence. Hollywood, FL. Mentor on 2 posters
 2012 Society for Research on Nicotine & Tobacco, Houston, TX. Mentor on 6 posters
 2013 Society of Behavioral Medicine, San Francisco, CA. Mentor on 6 posters
 2013 Society of Research on Nicotine and Tobacco. Boston, MA. Mentor on 4 posters
 2015 Society of Research on Nicotine and Tobacco. Philadelphia, PA. Mentor on 5 posters
 2016 Society of Research on Nicotine and Tobacco. Chicago, IL. Mentor on 4 posters
 2017 Society of Behavioral Medicine. San Diego, CA. Mentor on 3 posters
 2018 American Public Health Association, San Diego, CA. Mentor on poster & talk
 2019 Society of Research on Nicotine and Tobacco. San Francisco, CA. Mentor on 6 posters
 2019 North American Cannabis Summit. Los Angeles, CA. Mentor on 3 posters
 2021 Society of Research on Nicotine and Tobacco. Virtual (COVID-19). Mentor on 4 posters
 2021 Society of Behavioral Medicine. Virtual (COVID-19). Mentor on 2 posters
 2021 College on Problems of Drug Dependence. Mentor on 2 posters

REGIONAL POSTERS:

2003 California TRDRP Annual Investigators Meeting. San Diego, CA.
 2005 California TRDRP Annual Investigators Meeting. Los Angeles, CA.
 2007 California TRDRP Annual Investigators Meeting. Sacramento, CA.
 2007 Bay Area Clinical Research Symposium, San Francisco, CA.
 2007 UCSF Academy of Medical Educators Education Day Event
 2009 Bay Area Clinical Research Symposium, San Francisco, CA.
 2010 It's About a Billion Lives Annual Conference Event. UCSF CTCRE (2 posters)
 2011 It's About a Billion Lives Annual Conference Event. UCSF CTCRE (3 posters)
 2011 UCSF Academy of Medical Educators Education Day Event (2 posters)
 2011 WGEA/WGSA/WOSR/WAAHP AAMC Western Regional Conference, Stanford, CA.
 2012 It's About a Billion Lives Annual Conference Event. UCSF CTCRE (3 posters)
 2012 California TRDRP Annual Investigators Meeting. Sacramento, CA.
 2013 It's About a Billion Lives Annual Conference Event. UCSF CTCRE (3 posters)

GOVERNMENT and OTHER PROFESSIONAL SERVICE:

1999	Institute of Medicine (IOM) Specialty Workshop on Health, Communications, and Behavior. Irvine, CA	Commissioned to summarize proceedings
2004	Columbia University. NIH funded SBIR	Consultant
2004 - 2018	California Health Interview Survey	Child Technical Advisory Committee Member
2004 - 2007	University of California, Berkeley. RWJF study	Consultant
2004 - 2016	The Cooper Institute's FITNESSGRAM / ACTIVITYGRAM	Scientific Advisory Board Member

2006 - 2011	NCI/SAMHSA Research-tested Intervention Program	Program Reviewer
2008	University of Minnesota TTURC	External Grant Reviewer
2009	National Institute on Drug Abuse. RFA DA 09-013 and 014 on "Interactions between Physical Activity and Drug Abuse" R01 and R03	Ad-Hoc Grant Review
2010	Women's Health Research Program. Yale University	Grant Reviewer
2010	Australia National Health Medical Research Council	Grant Reviewer
2011	National Institute on Drug Abuse - K Committee	Grant Reviewer
2012	NIH, Center for Scientific Review, RPIA-N Committee	Grant Reviewer
2012 - 2017	Pfizer, Inc. Chantix	Advisory Board Member
2013 - 2016	FDA's PhenX Tobacco Regulatory Research Panel	Co-Chair
2014	NIH grant review, RPIA-N	Reviewer
2014 - 2016	Centers for Disease Control and Prevention, Office on Smoking and Health	Advisor on CDC TIPS Campaign
2015 - 2016	National Cancer Institute, Division of Cancer Control and Population Sciences: (http://cancercontrol.cancer.gov/pdf/nci-tobacco-control-research-priorities-rpt-feb-2016.pdf)	Advisor, tobacco control research priorities for the next decade
2015	Hawaii State Department of Health state legislature efforts to fund cessation treatment in mental health	Cited researcher
2015-2016	World Innovation Summit for Health (WISH), an initiative of the Qatar Foundation	Advisor and Presenter, on Behavioural Insights
2016	FDA Advisory Committee on Tobacco Cessation Medications and Neuropsychiatric Safety	Presenter
2017	NIH grant review, NIDA PAR 17-156 on E-cigarettes	Reviewer
2018	Federal Trade Commission (FTC) Bureau of Consumer Protection	Expert Advisor on Tobacco Products
2018	Congressionally-mandated Federal Advisory Interagency Committee on Smoking and Health, Behavioral Health and Tobacco Control, US Department of Health and Human Services. Identifying federal actions to address disparities in tobacco use among behavioral health populations.	Invited Presenter and Panelist
2019	NIH grant review, NIDA Special Emphasis Panel ZRG1 RPHB-U (56) on E-cigarettes	Reviewer
2019	Centers for Disease Control & Prevention's Office on Smoking and Health	Invited Advisor in Advancing Health Equity in Tobacco Control
2020	Smoking Cessation: A Report of the Surgeon General	Contributing Author
2020	NIDA grant review for PAR-18-874/848	Chair & Reviewer
2020	NIH grant review for RPHB-W 57 Special Emphasis Panel on Risk, Prevention and Health Behavior	Chair & Reviewer
2021-2022	World Health Organization (WHO) No Tobacco Unit	Consultant

2021	National Academy of Sciences, Engineering & Medicine Consensus Study Report on Premium Cigars	Expert Reviewer
2021-2022	Achieve Life Sciences Ongoing Research of Cytisinicline for Addiction (ORCA)	Data Safety Monitoring Committee Member
2021-2022	University of Ottawa Heart Institute, Pilot RCT of cytosine compared to combination nicotine replacement therapy to reduce cigarette consumption in relapsed smokers	Data Safety Monitoring Board Member

UNIVERSITY AND PUBLIC SERVICE

UNIVERSITY SERVICE

CAMPUS-WIDE

2010	Grant Reviewer. UCSF Resource Allocation Program	
2011 - 2012	Member. UCSF Committee on Privilege and Tenure	
2015-2019	Faculty Co-Chair, University-wide Community Advisory Board on Clinical Research, <i>new campus initiative</i>	
2015-2019	Faculty co-PI, Stanford Research Registry	
2017-2020	Judicial Panel Pool, Office of Community Standards	
2017-2021	Academic Council Committee on Graduate Studies (C-GS)	

DEPARTMENTAL SERVICE

2002 - 2003	UCSF Clinical Psychology Training Program	Fellow Representative
2003	UCSF Department of Psychiatry Research Retreat	Presenter
2004	UCSF Depression Center Conference	Presenter
2005	UCSF Addiction Research Retreat	Presenter
2005	UCSF Depression Retreat	Presenter
2005	UCSF Department of Psychiatry Research Retreat	Presenter
2005 - 2006	Langley Porter Psychiatric Institute Inpatient and Partial Hospitalization Program Services	Dual Diagnosis Advisory Group Member
2006	UCSF New Frontiers in Depression Research	Presenter
2007	UCSF Department of Psychiatry Research Retreat	Presenter
2007	UCSF Psychiatry Department Faculty Retreat	Workshop Leader
2007 - 2012	Compensation Plan Advisory Committee	Member and Chair
2009 - 2015	Data Safety Monitoring Board for NIMH-funded trial (PI: Stuart Eisendrath) Applying Mindfulness-Based Cognitive Therapy to Treatment-Resistant Depression	Chair
2011	UCSF Department of Psychiatry Research Retreat (mentor on 4 posters)	Presenter
2011	SFGH Community Psychiatry Research Seminar	Presenter
2011 - 2015	NIDA P50 San Francisco Treatment Research Center	Co-Director
2013 - present	SPRC Matriculated Programs	Faculty Director

2013 - 2016	SPRC's Stanford Health 4 All http://scopeblog.stanford.edu/2014/09/05/first-health-4-america-fellows-celebrate-completion/	Founding Faculty Member
2015-present	Stanford Medical School Scholarly Concentration Application in Prevention Research	Faculty Director
2015-2017	National Comprehensive Cancer Center Network Clinical Practice Guideline on Smoking Cessation	Expert Reviewer for Stanford Cancer Instit
2015	Stanford Biosciences Grant Writing Academy	Faculty Reviewer
2016	SPRC Finance Committee	Faculty Member
2020	Stanford Medicine, Division of Cardiology Grand Rounds, <i>Vaping & Cardiovascular Health</i>	Presenter
2020	Stanford School of Medicine, Department of Psychiatry and Behavioral Sciences, <i>Dialogue: JUUL</i>	Co-Presenter
2020	Stanford Prevention Research Center	Deputy Director

PUBLIC SERVICE

2005	Planning Committee Member for WHO World No Tobacco Day at UCSF
2007	Worked with condominium complex to establish a no smoking ordinance on entire community grounds including all privately and communally owned areas
2008	Wrote a proposal and testified to support the addition of nicotine replacement therapies to the formulary for San Francisco Community Behavioral Health Services and the San Francisco Mental Health Plan.
2009-2011	Board President, The Little School, Southern Marin, CA (nonprofit preschool)
2010	Presentation on Tobacco Use and Mental Illness for the San Mateo County Chapter of the National Alliance on Mental Illness (NAMI)
2011	Member of the Apple Computer Customer Pulse Panel (a panel of high-level users of Apple Computer products to provide user feedback to the company)
2016	Med School 101 open campus event with high school students, class on e-cigarettes
2016	Speaker at Stanford's Community Health Matters Event
2018	Interviewed expert for local HS student documentary on ecigs/Juul, https://www.youtube.com/watch?v=oSL-47Pxl1c
2018	Met with head of the Marin Board of Supervisors to inform development of an ordinance to ban all flavored tobacco products in unincorporated areas of Marin; the ordinance was comprehensive (without exemptions) and ultimately passed
2019	Testified at Corte Madera Town Council meeting in support of a flavor ban on all tobacco products, which was passed ending sales of menthol and other flavored tobacco including cigarettes, cigars, smokeless, and e-cigarettes/vapes
2020	Med-IQ Online Event: <i>Using E-cigarettes to Quit Smoking: What's the Evidence?</i> Panelist with Councilmember Gabe Albornoz from Montgomery County in Maryland
2020	Virtual Center for Pharmaceutical Education (DCRx) Tobacco Cessation Faculty Member, offers CME/CPE credits for physicians, pharmacists, and other prescribers
2020	JC Phelps S. Kentucky blogger engagement to promote evidence based strategies for quitting smoking https://jcpeats.com/2020/07/09/smoking-cessation-addressing-a-health-crisis-in-the-commonwealth-of-kentucky/

- 2020 Participation in Invitation-Only Summit of the California Department of Public Health, California Tobacco Control Program, *California Quits Together: Creating a Nicotine Free Future Cessation Summit*
- 2020 Outdoor Art Club NICOTEEN: Curbing the Youth Nicotine Vaping Epidemic
<https://youtu.be/SfBkNmtdBMg>

PRESS ACTIVITIES

- 2004 Live radio interview on Bay Area KCBS 740AM on meta-analysis paper
- 2007 Live TV interview on national program ABC News Now on varenicline
- 2007 Interview with the Sacramento Bee on a hospital going smoke-free
- 2007 Interview with Oakland Tribune for the Great American SmokeoutThe story also appeared in the Marin IJ and San Mateo County Times
- 2008 Interview with the Independent on Sunday, London, England
- 2008 Interview with Clinical Psychiatry News, Sacramento, CA
- 2008 Interview with the APA Monitor
- 2008 Interview with Health.com, the new health website from Time Inc
- 2008 Interview on smoking & mental illness with CrossCurrents, a national mental health & addiction magazine of the Centre for Addiction & Mental Health, Toronto, Canada
- 2008 Interview for 3 piece series on treating tobacco dependence in Parents Magazine
- 2008 Interview w/ Women's Health magazine on physical activity for smoking cessation
- 2008 Interview with Miller-McCune national public policy magazine
- 2008 Radio Interview with Steve Simpson 93.1 WIBC FM. Indianapolis, IN
- 2008 Interview w/ Florida Times-Union on multiple health behavior change. Jacksonville, FL
- 2009 Article in More Magazine on study of physical activity for smoking cessation
- 2009 Article in Psychology Today on study of resisting tempting foods & smoking behavior
- 2010 Google search on 4/7/10 indicated 440 news hits for coverage of the article by Cataldo, Prochaska, Glantz (2010) in the Journal of Alzheimer's Disease (e.g., Medical News, Science Daily, Senior Journal, SF Citizen)
- 2010 Men's Health article on study of physical activity for smoking cessation
- 2010 Interview on addiction counselor's knowledge of bupropion for smoking cessation for Medicine, Lifestyle and Home Design
- 2010 MedLinx posting summarizing my 2010 article on Tobacco and Harm Reduction
- 2010 Research study highlighted on Joanne Silberner's National Public Radio blog
- 2011 Interview with HealthDay on JAMA editorial on tobacco treatment in PTSD patients. Story picked up by Business Week, Digital News Release, Web MD, Science Daily, ABBA Network, Medscape, Med Page Today, the Clinical Advisor, and others

- 2011 Interview with Dr. Joseph Galati on Clear Channels 740 KTRH in Houston broadcasted throughout the SW of Texas , Louisiana, and Oklahoma and streamed on iHeart Radio (www.iheartradio.com) and www.ktrh.com. www.yourhealthfirst.com
- 2012 Interview with Australian Broadcasting Association (ABC) in Newcastle, Australia on taking psychiatric hospitals smoke-free
- 2012 Research study on young adult smokers' use of marijuana featured on ABCnews, HealthMSN, ScienceDaily, Philly Inquirer, Doctors Lounge, and other news outlets
- 2012 Research on varenicline safety and cardiovascular disease: frontpage of SF Chronicle, Reuters, Baltimore Sun, Albany Times, and a number of online news sites and blogs (8300 hits on Google)
- 2013 Research on varenicline safety and CVD risk featured in the ACP Journal Club, a bimonthly publication of the American College of Physicians – American Society of Internal Medicine, aimed at helping internists keep up to date by abstracting high quality research from key journals of relevance to internal medicine.
- 2013 Research on marijuana and tobacco co-use in young adults: Patterns and thoughts about use. *APA Division 50: The Addictions Newsletter*
- 2013 Up in smoke: The link between smoking and mental illness isn't inevitable. *American Psychiatric Association Review*
- 2013 Interview and article with Reuters about efficacy and safety of cessation medications: <http://www.reuters.com/article/2013/05/30/us-quit-smoking-idUSBRE94T16I20130530>
- 2013 Interview and article with Reuters about quitting smoking and surgical outcomes: <http://www.reuters.com/article/2013/06/25/us-surgery-risks-for-smokers-may-dissipa-idUSBRE95O0WM20130625>
- 2013 Front page article in NY Times on treatment of tobacco in inpatient psychiatry and efforts by the tobacco industry to promote tobacco use in this population
http://www.nytimes.com/2013/02/07/health/psychiatric-hospitals-alter-rules-on-patient-smoking.html?_r=0
- 2013 Interview and article with Psychiatric Annals: <http://www.healio.com/psychiatry>
- 2013 NIDA K23 funded tobacco treatment trial outcome findings, covered by over 35 news outlets including: US News & World Reports: <http://health.usnews.com/health-news/news/articles/2013/08/15/quit-smoking-programs-work-for-psychiatric-patients>; Reuters: <http://www.reuters.com/article/2013/05/30/us-quit-smoking-idUSBRE94T16I20130530>; USA Today: <http://theusatodaynews.com/quit-smoking-programs-work-for-psychiatric-patients/>; and the SF Chronicle: <http://www.sfgate.com/default/article/Immune-response-protein-linked-to-Alzheimer-s-4747380.php#page-2>
- 2014 Interview with Reuters regarding a new clinical trial of combining varenicline and bupropion for smoking cessation <http://www.newsdaily.com/health/b458c65a1a92e97bd6d50116c9ccdd79/adding-bupropion-to-varenicline-doesnt-improve-smoking-quit-rates>
- 2015 FairWarning online article -- interview for news piece on tobacco use in smokers with mental illness, <http://www.fairwarning.org/2015/01/long-ago-stripped-glamorous-image-smoking-keeps-tight-grip-mentally-ill/>
- 2015 Coverage of our article in JMIR on development of our Twitter-based smoking cessation intervention (Tweet2Quit) – MSN, Mirror, OC Weekly, Digital Journal, India Times, radio
- 2015 Coverage of Presentation at 2015 Health Journalism Conference, Santa Clara, CA, <http://www.californiahealthline.org/capitol-desk/2015/4/ecigarette-bill-hearing-today>
- 2015 Interview with VOX regarding e-cigarettes, <http://www.vox.com/2015/6/26/8832337/e-cigarette-health-fda-smoking-safety>
- 2015 Radio interview with KNOM in Nome, Alaska on the HEALTHH Study
<http://www.knom.org/wp/blog/2015/09/22/knom-exchange-tobacco-in-western-alaska/>

- 2015 The Clayman Institute for Gender Research, Gender News: Social Networks Help Women Quit Smoking? <http://gender.stanford.edu/news/2015/social-networks-help-women-quit-smoking>
- 2016 Reuters Health article on commentary I published re: Low-value Health Care Services <http://www.gihealthfoundation.org/reuters/article.cfm?article=20151229plt1077008415&cat=pltl&dstate=GI>
- 2016 Interview with The Influence, highlighting a paper I published back in 2007 - <http://theinfluence.org/not-yet-kicked-the-consequences-of-big-tobaccos-targeting-of-mentally-ill-people/>
- 2016 Tweet2Quit study noted in Time's Health and Addiction section: <http://time.com/4275325/twitter-can-help-you-quit-smoking-study/?xid=homepage>
News Wise: <http://www.newswise.com/articles/view/650608/?sc=rsla>
Science Daily: <https://www.sciencedaily.com/releases/2016/03/160329113432.htm>
- 2016 Broad press coverage on tobacco and employment JAMA Intern Med paper
Outlets: Reuters, CBS, NBC, US News & World Report, Fox, Guardian, Yahoo, Money Magazine, Glamour, and radio coverage (CBS, KGO, Cape Town S Africa, Pittsburgh PA) <http://www.reuters.com/article/us-health-smoking-employment-idUSKCN0X82J2>
<http://www.cbsnews.com/news/smoking-affects-employment-job-prospects-wages/>
<http://www.capetalk.co.za/articles/12770/if-you-want-a-job-with-good-pay-consider-quitting-smoking-claims-study>
Altmetric score > 630
- 2016 Commentary on UK Royal College of Physicians' report recommending e-cigarettes for cessation <https://www.lifezette.com/healthzette/to-quit-smoking-lets-all-vape/>
- 2016 WebMD interview on youth and e-cigarettes
- 2016 Stanford Medicine Magazine: <http://stanmed.stanford.edu/2016summer/the-end-game.html>
- 2016 Press coverage on editorial for a study of incentives for quitting smoking:
Reuters, US News & World Report, Chicago Tribune, Philadelphia Inquirer, TCTMD
<http://www.tctmd.com/show.aspx?id=136042>
<http://health.usnews.com/health-care/articles/2016-08-15/paying-smokers-to-quit-may-pay-off>
<http://www.chicagotribune.com/lifestyles/health/ct-pay-smokers-to-quit-health-0823-20160816-story.html>
http://www.philly.com/philly/health/topics/HealthDay713902_20160815_Paying_Smokers_to_Quit_May_Pay_Off.html
<http://www.reuters.com/article/us-health-incentives-smoking-cessation-idUSKCN11027M>
- 2016 Centers for Disease Control advert for health care providers to treat tobacco in mental health populations -- cited research plowsharegroup.com/psa-silo/download_file.php?fid=8582
- 2016 Coverage of study published in AJPM on patient-provider interactions on e-cigarettes
WISTV, WebMD, HealthDay, KTen, Vocativ, Science Daily, Motherboard
<http://www.webmd.com/smoking-cessation/news/20160826/doctors-divided-on-safety-use-of-electronic-cigarettes>
<http://www.vocativ.com/353117/doctors-e-cigarettes/>
- 2016 Reuters interview on harms of even low volume smoking <http://www.reuters.com/article/us-health-smoking-risk-idUSKBN13U2MP>
- 2017 Stanford Blog Posts on 2 Natural American Spirit Editorials
<http://scopeblog.stanford.edu/2017/03/01/false-advertising-natural-cigarettes-are-bad-for-nature-stanford-researchers-say/>
<http://scopeblog.stanford.edu/2017/04/13/false-advertising-suggests-that-natural-cigarettes-are-safer-new-research-shows/>
- 2017 US News & World Report interview on procrastination and behavior change <http://health.usnews.com/wellness/slideshows/6-reasons-youre-procrastinating-on-your-health-goals-and-how-to-stop>
- 2017 Reuters interview on failure to treat smoking in patients hospitalized with heart disease <https://www.reuters.com/article/us-smoking-cessation-cardiac-idUSKCN1B125C>
- 2017 US News & World Report interview on "hardcore smokers" <https://health.usnews.com/health-care/patient-advice/articles/2017-11-15/hardcore-smokers-actually-want-to-quit-too>
- 2018 Reuters interview on study of cigar and pipe health harms <https://www.reuters.com/article/us-health-smokingmortality-cigars-pipes/cigars-and-pipes-tied-to-same-risks-as-cigarettes-idUSKCN1G52AA>

- 2019 Reuters interview on study of use of olfactory stimuli to reduce cigarette craving
<https://www.reuters.com/article/us-health-smoking-cravings/pleasant-smells-may-curb-cigarette-cravings-idUSKCN1RT24K>
- 2019 CNN story on SF ordinance requiring FDA approval of e-cigarettes sold in the city/county
<https://www.cnn.com/2019/06/26/health/e-cigarette-ban-san-francisco-health-experiment/index.html>
- 2019 Reuters interview on Scotland's smoking ban and heart attack decline over 10 years
<https://www.reuters.com/article/us-health-smoking-scotland-idUSKCN1UE1U1>
- 2019 Stanford News Coverage on our research on health perceptions of the pro-environment marketing of Natural American Spirit cigarettes
<https://news.stanford.edu/2019/08/05/pro-environment-cigarette-marketing-works/>
<https://medicalxpress.com/news/2019-08-cigarettes-pro-environment.html>
- 2019 USA Today article on e-cigarettes <https://www.usatoday.com/in-depth/news/health/2019/10/09/vaping-safer-than-smoking-studies-differ-lung-injury-cases-rise/3821982002/>
- 2019 The Guardian, Nicotine sickness: the latest vaping scare
<https://www.theguardian.com/society/2019/nov/30/nicotine-sickness-the-latest-vaping-scare>
- 2020 Reuters. Commentary on study concerning smoking bans in cars in the UK
<https://www.reuters.com/article/us-health-teens-secondhand-smoke/teens-breathe-less-secondhand-smoke-after-car-smoking-ban-idUSKBN1ZR2P5>
- 2020 MSN coverage of our research on cannabis and pregnancy in J Women's Health
<https://www.msn.com/en-au/news/other/doctors-reveal-the-most-surprising-questions-about-marijuana-use-and-pregnancy-they-have-gotten-like-will-it-keep-me-skinny/ar-BBZDZeY>
- 2020 Reuters. Commentary on study of smoking following weight-loss surgery
<https://www.reuters.com/article/us-health-smoking-gastric-bypass/many-smokers-quit-before-weight-loss-surgery-but-start-up-again-afterward-idUSKBN20X38L>
- 2020 Stanford Department of Medicine Annual Report, article on my lab
<http://medicine.stanford.edu/2020-report/new-approaches-to-tobacco-control.html>
- 2020 Stanford Scope article on my lab <https://scopeblog.stanford.edu/2020/10/16/improving-heart-health-decreasing-tobacco-use-in-alaska/>
- 2021 Media coverage of my research on a therapeutic conversational agent for addressing problematic substance use – Health IT Analytics, Psychiatric Times, MobiHealthNews, FirstWord MedTech, Business Wire
- 2021 Stanford Department of Medicine Annual Report, article on CHPR
<https://medicine2021report.stanford.edu/ar2021/diversity-is-central-to-masters-degree-in-community-health-and-prevention-program/>
- 2021 Merck Manuals Medical Myths Podcast, Season 3 <https://podcasts.apple.com/us/podcast/medical-myths-podcast-season-3-trailer/id1460407685?i=1000520406801>
- 2021 AP News Story on Treating Tobacco in Oncology, includes attention to our work with the Stanford Cancer Institute <https://apnews.com/article/science-health-cancer-smoking-dda02a87195436afaa03275193a5d295>

TEACHING AND MENTORING

2013–2016	Stanford Health 4 All	Teaching Faculty
2015–present	Masters of Science Program in Community Health and Prevention Research (CHPR), Stanford University	Faculty Director
2015-present	Stanford Medical School Scholarly Concentration Application in Prevention Research	Faculty Director

2015-2021	SPRC NHLBI T32 Postdoctoral fellowship in Cardiovascular Disease Prevention	Co-Director
2015-2021	Human Biology Curriculum Committee	Faculty Member

TEACHING/FORMAL SCHEDULED CLASSES

Graduate, Graduate Medical Education, & Postdoctoral Level

UCSF:

Academic Yr	Course Number and Title	Teaching Contribution	Class Size
2002 - 2010	Clinical Seminar, UCSF Clinical Psychology Training Program (CPTP) for Pre and Postdoctoral Fellows	Co-Leader; fourteen 2-hr classes a year	10-45
2004 - 2004	UCSF Fellowship of Fellows Program	Faculty: four 3-hr sessions	8 - 30
2004 - 2008	Research Seminar, NIDA Postdoctoral Fellowship	Faculty: thirty 1.5 hr sessions	6
2004 - 2012	UCSF CTCRE Tobacco Policy Research Group	Faculty: annual presentation	15
2005 - 2005	Research Seminar, UCSF Center for Tobacco Control Research and Education Postdoctoral	Co-Leader; six 1.5-hr sessions	6
2005 - 2011	Research Seminar Sessions for UCSF Psychology/Medicine Postdoc Program, SFGH Substance Abuse Fellowship, UC-Berkeley Alcohol Research Postdoc Fellowship; CARTA fellowship program; Annual CTCRE seminar; UCSF Psychiatry Residents, Evidence Based Medicine Seminar; UCSF Cardiology Fellows Training to Treat Tobacco	Guest Lecture/Faculty, 1-2 hrs	6-35
2005 - 2007	Treating Nicotine Dependence in Psychiatry, UCSF Adult Psychiatry Residency Training Prog	Course developer and lecturer: four 1-hr sessions	18
2005-2020	Nicotine Addiction and Its Treatment	Co-Faculty with Dr. Neal Benowitz	8-16
2008 - 2008	Research Seminar for the UCSF CTCRE	Faculty, ten 1.5 hr sessions	18
2010 - 2010	UCSF Medical Residents	Faculty, 1 hr quarterly	25
2010-2012	CPTP Research Seminar for Pre and Postdocs	Faculty, 1 hr biweekly	9

STANFORD:

Academic Yr	Course Number and Title	Teaching Contribution	Class Size
2014-2015	SOMGEN 240 Science of Healthy Living; HRP 236 Epidemiology Research Seminar	Led seminar sessions on Behavioral Science	10-15
2013-2016	SPRC NHLBI T32 Postdoc Seminar; Postdoc Mentoring Workshop (Dr. Sofie Kleppner, Assist Dean Posdoc Affairs & Emily Lilo); Postdoc Academic Chats (organized by Rick Reis, PhD sponsored by the Office of Postdoctoral Affairs)	Various	5 – 40
2016-Present	Theoretical Foundations and Design of Behavioral Intervention Trials (CHPR 228)	Developed & leading this core course of CHPR MS	10-28
2016 Summer	SCP KU Graduate Seminar on “Cancer and cardiovascular disease prevention in China: A multi-disciplinary and cross-national approach”	Co-developed & co-taught 3-week summer class at Peking University, Beijing	14
2017-Present	Psychiatry Residents’ Addiction Seminar (led by Dr. Keith Humphreys), Nicotine Addiction Didactic	Develop and deliver didactic and materials	10-20

ORAL PHD EXAMINATION CHAIR

2015 Stephan Risis, Stanford History Department
Committee Members: Robert Proctor, PhD (History), Jessica Riskin, PhD (History), Tom Mullaney, PhD (History), Angela Garcia, PhD (Anthro)

DISSERTATION COMMITTEE EXAMINER

2015	Della Rowley, MS Public Health Doctoral Student Supervisor: John Coveney	Flinders University, School of Health Sciences Adelaide, Australia
2017	Joanna Burtner, MPH Doctoral Student in Epidemiology Supervisor: Dan Brooks	Boston University School of Public Health Boston, MA
2018-2021	Kayla Jimenez, M.S. Doctoral Candidate in Clinical Psych Supervisor: Nancy Haug	PGSP-Stanford Psy.D. Consortium Palo Alto, CA

Undergraduate, Post-Baccalaureate, & Undergraduate Medical Education Level

Academic Yr	UCSF Course Number and Title	Teaching Contribution	Class Size
2002 - 2003	Psychiatry Clerkship Rotation, UCSF School of Medicine (SOM)	Anchor Attending, six 1-hr consultations per student (2)	3
2002 - 2005	Culture & Behavior Small Group Series, UCSF SOM	Small Group Leader; eight 1 to 2-hr sessions	15
2004 - 2012	Smoking Cessation Didactic and Small Group, UCSF SOM Cancer Block	Course Organizer; 1 to 2-hr didactic & 2-hr small group	150
2005 - 2005	Brain, Mind & Behavior Apprenticeship, UCSF SOM	Apprenticeship Leader; two 3-hr sessions	6

Academic Yr	UCSF Course Number and Title	Teaching Contribution	Class Size
2005 - 2011	Stages of Change and Motivational Interviewing, UCSF SOM MS1 and MS2 med students	Faculty, 2 hr lecturer	140
2011	Interprofessional Health Education Summer Experience, UCSF Schools of Medicine, Nursing, Dentistry, and Pharmacy	Faculty Mentor & Developer, 60 hrs	6

Academic Yr	Stanford Course Number and Title	Teaching Contribution	Class Size
2012-2015	HUM BIO126 Promoting Health over the Life Course; SOMGEN 240 Science of Healthy Living	Led seminar sessions on Behavioral Science	18-65
2014	d.school fellows' orientation week	Guest lecture, behavior change	8
2015	MED 199	Research Advisor	1
2015	MedScholar	Research Advisor	1
2013 - 2015	SH4A Design 4 Community	Developed & taught the class	14-18
2013 - 2016	SH4A Theory & Application of Behavior Change	Developed & taught the class	14-18

MENTORING

High School, Undergraduate, & Post-Baccalaureate

Dates	Name	Program or School	Role	Current Position
2004 - 2006	Christianne Wa	San Francisco University HS	Mentor	USC Medical School, Ophthalmology Resident, University of Arizona
2005 - 2005	Desiree Leek	UC Santa Barbara	Mentor	UCSD Psychiatry Assist Prof
2006 - 2006	Katie Chipungu	Howard University	Mentor	University of Miami Doctoral Program in Psychology
2007 - 2007	Amanda Schweizer	SFSU Psychology undergrad	Mentor	UCSD/SDSU Clinical Psych Doctoral Prog
2007 - 2007	Dixie Hu	UT-El Paso	Mentor	Ohio State University Clinical Psych Doctoral Prog
2007 - 2007	Martha Walter	U South Florida	Mentor	Undergraduate
2008 - 2009	Anayansi Lombardero	SFSU Psychology undergrad	Mentor	U Montana Clinical Psych Doctoral Program, New Mexico Intern
2009 - 2010	Jennifer LaDuke	SFSU Psychology undergrad	Mentor	UCSF Research Assoc
2009 - 2012	Romina Kim	UCSF post-baccalaureate	Mentor	Mich State Med, MS4; Kaiser-LA Peds Residency; Kaiser Fellow
2009 - 2010	Rosemary Taing	UCSF post-baccalaureate	Mentor	UCSF post-bacc student

Dates	Name	Program or School	Role	Current Position
2009 - 2011	Nicholas Orozsco	UCSF post-baccalaureate	Mentor	UCSF-UC Berkeley JMP medical student, USC-Emergency Med Resident
2010 - 2014	Amardeep Sekhon	UC Berkeley undergrad	Mentor	Palo Alto University Clinical Psych Doctoral Student
2010 - 2011	Ashley Souza	UC Berkeley Undergrad	Mentor	Applicant to physician assistant programs
2010 - 2011	Dorrie Swanson	Volunteer	Mentor	UCSF nursing student
2011 - 2011	Julia Rose-Ramo	Head-Royce High School	Mentor	USC undergrad
2011 - 2011	Susan Iyican	UC Berkeley Undergrad	Mentor	Univ of Houston Clinical Psych Doctoral Program
2010 - 2011	Hayley Beckett	Summer research fellow	Mentor	Whitman College undergrad
2011 - 2012	Christina Wa	USC Undergraduate	Mentor	UC Davis Law School
2011 - 2012	Van Vu	UCSF Post-bacc	Mentor	UCLA Med School, UCSF Family Medicine Resident
2012 - 2013	Danielle Pandika	UCSD	Mentor	U Arizona Clinical Psych Doctoral Program
2012 - 2013	Rachel Schuck	UC-Berkeley	Mentor	SJSU Masters Program
2012-2013	Nicole Anzai	U-Santa Clara	Mentor	U Hawaii Med School; NYU Psychiatry Residenc
2014-2016	Nicole Jeffery	Stanford University	Mentor	Alaska WWAMI School of Medical Education
2014-2016	Peter Soyster	UC-Berkeley	Mentor	Research Associate
Summer 2014	Sam Hayward	Carlton College	Mentor	College Junior
2015-2017	Beatriz Anguiano	Stanford Health 4 All Fellow; Stanford Research Coord., TRDRP diversity fellow	Mentor	UCSF Research Staff Member; Stanford Genetics masters student
2015	Kathleen Yang	Stanford Health 4 All Fellow	Mentor	Stanford HR
2015	Christina McFadden	Stanford Health 4 All Fellow	Mentor	Design consulting
2016-2018	Sarah Stinson	Stanford University	Mentor	California Northstate U. College of Medicine

Graduate Students

Dates	Name	Program or School	Role	Current Position
2003 - 2004	Lindsay Fletcher	UCSF MS Neuroscience	Mentor	University of Nevada, Reno Psychology Doctoral Program
2007 - 2007	Ryan Matlow	SFSU Psychology MS	Mentor	University of Denver Psychology Doctoral Program
2009 - 2010	Jessica Clifton	SFSU Psychology MS	Mentor	University of Vermont, Clinical Psychology Doctoral Program
2008 - 2012	Kathleen Gali	SFSU GSPH	Mentor	UC Merced Psychology Doctoral Program

Dates	Name	Program or School	Role	Current Position
2009 - 2010	Jessica Hamon	Yale GSPH	Thesis Adv	UC Davis Medical School
2010 - 2011	Andres Olide	SFSU MS Psychology	Mentor	UC-Riverside Doctoral Student in Education
2011 - 2011	Joanna Burtner	UCLA GSPH	Mentor	Boston University DrPH
2012-2014	Carson Benowitz-Frederics	Johns Hopkins GSPH	Mentor	UCSF Research Associate
2014-2015	Dale Maglalang	SFSU MPH student	Mentor	Brown U Postdoctoral Fellow
2015-2017	Allison DeCastro	Stanford CHPR MS	Thesis Adv	Amazon
2015-2017	Tim Schulz	Stanford CHPR MS	Thesis Adv	Vanderbilt Medical School
2016-2017	Ruth Narode	Stanford CHPR MS	Thesis Adv	Health Care Consulting
2017-2018	Adrienne Lazaro	Stanford CHPR MS	Thesis Adv	Stanford Resarch Associate
2017-2019	Samantha Wong	Stanford CHPR MS	Thesis Adv	UC Davis Medical School
2017-2018	Caleb Kumar	Stanford CHPR MS	Thesis Adv	Tech Company
2018-2019	Vanna Hovanky	Stanford CHPR MS	Thesis Adv	Stanford Resarch Associate
2018	Muzzammil Imran Muhammad Shittu	Stanford CHPR MS	Thesis Rdr	Stanford CHPR Student
2019	Sabina Aliev	Stanford CHPR MS	Thesis Rdr	Stanford CHPR Student
2019-present	Kayla Jimenez	PGSP-Stanford Psy.D. Consortium	Mentor	Stanford Postdoctoral Fellow
2019	James Winter	Stanford Enviro Engineering + Science	Mentor	PhD Candidate, Environmental Engineering and Science

Medical Students

Dates	Name	Program or School	Role	Current Position
2006 - 2006	Akpen Gbegnon	UCSF Medical School	Mentor	General Surgery University of Iowa
2006 - 2006	Jacob Gregerson	UCSF Medical School	Mentor	Pediatrician, La Maestra Community Health Center
2014-2016	Anita Lowe	Stanford Medical School	Med Schlr Mentor	MS3
2013-2015	Nicholas Orozco	UCSF/UC-Berkeley PRIME Program	Thesis Advisor Research Mentor	Resident LAC+USC Med Center in Emergency Med
2015-2016	Romina Kim	Michigan State University	Research Mentor	Community Peds Fellow
2018-2019	Jessica Hawkins	Stanford Medical School	Mentor	Stanford MS4
2019-present	Luis Garcia	Stanford Medical School	Mentor	Stanford MS3

Postdoctoral Fellows and Residents:

Dates	Name	Fellowship	Faculty Role	Current Position
2004 - 2005	Wendy Cheng, PhD	UCSF NIDA T32 Postdoc Fellow	Advisor on postdoctoral grant	Assistant Professor, Cal State East Bay
2005 - 2005	Dejana Braithwaite, PhD, MS	UCSF Dept of Surgery & Institute	Advisor on postdoctoral grant	UCSF Assistant Professor Dept of Epi & Biostatistics

Dates	Name	Fellowship	Faculty Role	Current Position
		Health Policy		
2006 - 2009	Dikla Shmueli, PhD	UCSF NIDA Postdoc Fellow	Primary Mentor	EMMES / NIDA Coordinating Center
2006 - 2007	Janine Cataldo, PhRN	UCSF NCI R25 Postdoc Fellow	Primary Mentor	Assistant Professor UCSF School of Nursing
2008 - 2009	Maryam Najafi, MD, MPH	MD from Iran, MPH from UC Berkeley	Primary Mentor	Psychiatry Resident University in Chicago
2008 - 2011	Norval Hickman, PhD	UCSF NCI R25 Postdoc Fellow	Primary Mentor	TRDRP Program Officer
2008 - 2011	Rebecca Schane, MD	UCSF NCI R25 Postdoc Fellow & Pulmonary Fellow	Secondary Mentor	Pulmonologist, San Francisco Free Clinic
2008 - 2010	Peter Hendricks, PhD	UCSF NIDA T32 Postdoc Fellow	Secondary Mentor	UAB School of Public Health Faculty
2009 - 2012	Danielle Ramo, PhD	UCSF CPTP & NIDA T32 Postdoc	Primary Mentor	HopeLab Research Dir; UCSF Assoc Professor
2010 - 2014	Rachel Grana, PhD, MPH	UCSF NCI R25 Postdoc Fellow	Primary Co-Mentor	NCI Program Officer
2011-2015	Ashley Sanders-Jackson, PhD	UCSF NCI R25 Postdoc Fellow	Secondary Mentor	Associate Professor, Michigain State University, Communications Dept
2012-2014	Kelly Young-Wolff, PhD, MPH	SPRC NHLBI T32 Postdoc Fellow	Primary Mentor	Kaiser Division of Research Oakland Research Scientist II
2012-2016	Catie Brown-Johnson, PhD	UCSF NCI R25 Postdoc Fellow	Primary Mentor	Stanford Div of Gen Med Disciplines Res Scientist
2012–2013	Sara Hitchman, PhD	UCSF NCI R25 Postdoc Fellow	Faculty Mentor	King’s College London, Lecturer & Researcher in Addictions
2012–2015	Smita Das, MD, PhD, MPH	Stanford Psychiatry Resident, PGY-2-4	Research Mentor	Medical Director, Lyra Health; Stanford Clinical Assistant Professor
2014–Present	Marilyn Opezzo, PhD	SPRC NHLBI T32 Postdoc Fellow	Primary Mentor	SPRC Instructor of Medicine, K-awardee
2014–2016	Drea Burbank, MD	Stanford Health 4 All Fellow	Primary Mentor	MD-technologist + serial entrepreneur
2015-2016	Lorra Garey, PhD	Postdoc Fellow	Mentor on F32	University of Houston
2016	Shani Isaac, MD	Stanford Psychiatry Resident, PGY-3	Research Mentor	La Selva Staff Psychiatrist
2016-2018	Eric Daza, PhD	SPRC NHLBI T32 Postdoc Fellow	Secondary Mentor	Clarify Health Solutions Statistician
2016-2019	Anna Epperson, PhD	SPRC NHLBI T32 Postdoc Fellow	Primary Mentor	UC-Merced Assistant Professor
2018-Present	Kathleen Gali, PhD	SPRC NHLBI T32 Postdoc Fellow	Primary Mentor	SPRC NHLBI T32 Postdoc Fellow

Dates	Name	Fellowship	Faculty Role	Current Position
2017-2019	Erin Vogel, PhD	UCSF T32 Postdoc	Secondary Mentor	USC Research Scientist
2019-2021	Erin Vogel, PhD	SPRC Postdoc	Primary Mentor	USC Research Scientist
2018-2020	Priya Fielding-Singh, PhD	SPRC NHLBI T32 Postdoc Fellow	Assistant Professor	University of Utah, Assist Prof, Dept of Family & Consumer Studies
2020-2021	Dale Maglalang, PhD, MA, MSW	SPRC NHLBI T32 Postdoc Fellow	Primary Mentor	Brown U Postdoc

Faculty Mentoring

Dates	Name	Mentoring Role	Current Position
2007-2018	Janine Cataldo, PhD	Mentor on grants & career	Professor & Chair, School of Nursing UCSF
2012-Present	Danielle Ramo, PhD	Mentor on grants & career	Associate Professor of Psychiatry, UCSF Director of Research Operations, Hopelab
2010-2017	Peter Hendricks, PhD	Mentor on papers & career	Assistant Professor, School of Public Health, University Alabama - Birmingham
2013-2019	Mark Rubinstein, MD	Mentor on grants & career	Emeritus Professor of Pediatrics, UCSF
2013-2017	Theresa Allison, MD	Mentor on grants & career	UCSF Assistant Professor of Medicine and Family & Community Medicine
2015-Present	LaTrice Montgomery, PhD	Mentor on K23 award	Res Associate Professor, School of Human Services, University of Cincinnati
2015-2019	Ashley Sanders-Jackson, PhD	Mentor on grants & career	Associate Professor, Michigan State U, Department Advertising & Public Relations, College of Communication Arts & Sciences
2017-2019	Smita Das, MD, PhD, MPH	Mentor on papers & career	Medical Director, Lyra Health; Stanford Clinical Assistant Professor

Other Visiting Fellows & Faculty Supervised

2011 - 2012	Maxie Ashton, Scholar with the Tobacco and Mental Illness Project	Central Northern Adelaide Health Service, Mental Health Directorate, Department of Health, South Australia, Australia
2015	Annette Burns, PhD student Visiting Research Scholar	Royal College of Surgeons in Dublin Ireland
2017	Yi Song, MD, PhD, Assoc Prof Liubai Li, MD, PhD, Assoc Prof Yi Xing, MD, PhD, Assoc Prof	Institute of Child and Adolescent Health, Peking University, Beijing, China
2017	Shou Liu, PhD, Research Assoc	Beijing Office for Cancer Prevention and Control, Beijing, China, Beijing Cancer Hospital

TEACHING AIDS/CURRICULA:

Stanford Medicine Online CME *E-Cigarettes: Harmful or Harm-Reducing?*

Available at <https://tinyurl.com/stanfordocme>

This CME activity focuses on the science of e-cigarettes – particularly health risks and benefits. Online learners are engaged through video role-plays, expert interviews, and interactive activities. Free

registration with 1.5 CME credits are offered. Over 1000 individuals have completed the CME to date representing >90 countries.

To increase delivery of evidence-based tobacco treatment in clinical care, Dr. Prochaska developed, evaluated, and is disseminating curricula in psychiatry and cardiology training programs as part of the *Rx for Change* curriculum suite with over 10,000 registrants and 200,000 file downloads (<http://rxforchange.ucsf.edu>). International adaptation of the *Cardiology Rx for Change* curriculum was disseminating to cardiology care providers in South America, China, and the Middle East through collaboration with the World Heart Federation.

- *Treating Nicotine Dependence in Psychiatry*, 4-hr didactic and interactive curriculum with slides, lecture notes, and supporting materials for Adult Psychiatry Residency Training Programs, funded by the California Tobacco-Related Disease Research Program (TRDRP) and being disseminated via our website: <http://rxforchange.ucsf.edu>.
- *Treating Nicotine Dependence in Cardiology*, 1-hr didactic and interactive curriculum with slides, lecture notes, and supporting materials for Cardiology Training Programs, funded by the Flight Attendant Medical Research Institute (PI: William Grossman) and disseminated via our website: <http://rxforchange.ucsf.edu>.

Online interactive individual learning module (ILM) for the UCSF Surgery 110 Clerkship with Surgery faculty and patient actors modeling tobacco cessation interventions based on the 5-As (ask, advise, assess, assist, arrange follow up). Cases focus on tobacco's adverse effects on surgical outcomes. The ILM is required for all third year UCSF medical students and will be evaluated for impact on student learning and clinical performance. Disseminated online: https://surveys.ucsf.edu/Surgery110Tobacco_public.ucsf

Creation and evaluation of 2 miniCPX cases (2006 and 2010) centered on tobacco cessation counseling for third year UCSF medical students. Involvement included scripting of the case, training of the standardized patient actors, creation of the interstation evaluation exercises, submission for IRB approval for use of the data in research, data analysis, and writing up findings, published in Gen J Intern Med.

Regional, State, and National Trainings for Clinicians: Dr. Prochaska provides educational trainings to health care professionals (physicians, pharmacists, psychologists, nurses, social workers), residents, and students in the California Counties of San Mateo, Santa Clara, San Francisco, Alameda, Marin, San Diego, and Fresno; nationally with the Veterans Affairs Healthcare System, the Centers for Disease Control and Prevention, the Legacy/Truth Foundation, and the National Institute on Drug Abuse; and through state departments of health and allied agencies in Alaska, Arizona, Hawaii, Illinois, Indiana, Massachusetts, Maryland, North Carolina, Ohio, Oklahoma, Oregon, Washington state, and Washington DC; and internationally in Adelaide, Beijing, Hangzhou, Krakow, Madrid, Melbourne, New Brunswick, New Castle, Ottawa, Prague, Sydney, and Vancouver.

TEACHING AND MENTORING AWARDS AND NOMINATIONS:

- 1999 Statistical Methods in Psychology taught by J.J. Prochaska rated # 49 of 6,149 classes (1st percentile) in a survey of the top classes at San Diego State University. The student survival guide: top 100 classes. First time a statistics course was listed in top 100 classes.
- 2007 UCSF Cooke Award in the Scholarship of Teaching and Learning from the Haile T. Debas Academy of Medical Educators
- 2010 Nominated for the UCSF Outstanding Faculty Mentorship Award
- 2011 Mentor of the Year for Bay Area Clinical Research
- 2015 Stanford Department of Medicine SPRC Teaching Award

RESEARCH AND CREATIVE ACTIVITIES

GRANTS/RESEARCH AWARDS

CURRENT

09/1/17-08/31/22	STUDY: Retail Environment for Tobacco and Marijuana in California: Impact on College Student Use ROLE: Co-Investigator
R01 CA217165 Score = 1.0 Percentile = 1%	TYPE: Investigator-initiated institution (R01) SPONSOR: National Cancer Institute SUBJECTS: up to 200,000 college students NCT ID: n/a
05/1/18-04/30/23	STUDY: ASPIRE: Advancing Science & Practice in the Retail Environment ROLE: Co-Principal Investigator on Project 2 of this Center grant TYPE: Investigator-initiated institution (P01)
P01 CA225597	SPONSOR: National Cancer Institute SUBJECTS: N=2400 adult smokers in 30 major metropolitan areas NCT ID: n/a
06/1/20-05/31/22	STUDY: Enhancement of the Stanford Cancer Institute Tobacco Treatment Service ROLE: Program co-Lead
P30CA124435-13S2 NCI Moonshot 2 Supplement	TYPE: Supplement to Investigator-initiated institution (P30) SPONSOR: National Cancer Institute SUBJECTS: Adult patients at Stanford Cancer Institute NCT ID: n/a
11/01/17-6/30/22	STUDY: Tweet4Wellness: Development and RCT of Mobile Social Support Groups for Sedentary Behavior Reduction ROLE: Primary Mentor
1K01HL136702	TYPE: Investigator-initiated institution (K01) SPONSOR: National Heart, Lung and Blood Institute SUBJECTS: 75 NCT ID: n/a
09/1/19-08/30/22	STUDY: RCT of Woebot for Substance Use Disorders ROLE: Site PI
R44DA048712	TYPE: Investigator-initiated small business innovation research (SBIR) SPONSOR: National Institute on Drug Abuse SUBJECTS: 50 individuals with substance use problems NCT ID: n/a

* Supplemental funding awarded to conduct an RCT of the Woebot SUDs intervention relative to a waitlist control for addressing problematic substance use during the COVID-19 pandemic and safer-at-home period with study of the associated social, psychological, and economic effects

11/1/20-10/31/21	STUDY: Smoking and COVID-19 onset and severity in a US integrated healthcare delivery system ROLE: Site PI
R01RG3724	TYPE: COVID-19 Continuation Funding SPONSOR: Tobacco-Related Disease Research Program

SUBJECTS: Kaiser patient population
NCT ID: n/a

AWARDED & DECLINED

08/1/17-06/30/20 STUDY: Perceptions of Native, Natural, 100% Additive-Free Tobacco Marketing
ROLE: Mentor PI: Epperson
26FT-0027 TYPE: Investigator-initiated institution (Postdoctoral Fellowship Award)
Approved for SPONSOR: Tobacco-Related Disease Research Program
funding but unable SUBJECTS: Overall subject enrollment 1500 young adult smokers
to award, overlap NCT ID: n/a

COMPLETED

07/01/97-06/30/98 STUDY: Psychometric Evaluation of Assessment Tools for the Adolescent PACE+ Project
ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH
Student Oncology TYPE: Investigator-initiated single institution
Grant SPONSOR: American Cancer Society, California Division
SUBJECTS: Overall subject enrollment 300 subjects in San Diego, CA
NCT ID: n/a

07/01/99-06/30/00 STUDY: PACE+ School Study
ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH
Dissertation TYPE: Investigator-initiated single institution
Research Award SPONSOR: American College of Sports Medicine
SUBJECTS: Overall subject enrollment 250 subjects in San Diego, CA
NCT ID: n/a

07/01/99-06/30/00 STUDY: PACE+ School Study
ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH
Predoctoral TYPE: Investigator-initiated single institution
Fellowship Award SPONSOR: American Cancer Society, California Division
SUBJECTS: Overall subject enrollment 138 subjects in San Diego, CA
NCT ID: n/a

07/01/00-06/30/01 STUDY: PACE+ Teacher Study
ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH
Predoctoral TYPE: Investigator-initiated single institution
Fellowship Award SPONSOR: American Cancer Society, California Division
SUBJECTS: Overall subject enrollment 300 subjects in San Diego, CA
NCT ID: n/a

08/01/02-07/31/04 STUDY: Study of Smoking among Psychiatric Inpatients
ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH
Pilot Study TYPE: Investigator-initiated single institution
SPONSOR: UCSF Treatment Research Center Pilot Study Program
SUBJECTS: Overall subject enrollment 250 subjects at UCSF
NCT ID: n/a

07/01/02-06/30/04 STUDY: Multibehavioral Changes for Disease Prevention Among Smokers

11FT-0013	<p>ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH</p> <p>TYPE: Investigator-initiated single institution</p> <p>SPONSOR: California Tobacco-Related Disease Research Program</p> <p>SUBJECTS: Overall subject enrollment 2326 subjects from Rhode Island</p> <p>NCT ID: n/a</p>
09/30/03-06/30/04	<p>STUDY: Drug Abuse Treatment/Services Research Training Program</p> <p>ROLE: Fellow on the training PI: Sharon Hall, PhD</p>
T32 DA07250	<p>TYPE: Investigator-initiated single institution training grant</p> <p>SPONSOR: NIH/National Institute on Drug Abuse</p> <p>SUBJECTS: n/a</p> <p>NCT ID: n/a</p>
11/15/04-11/14/05	<p>STUDY: Training in Nicotine Dependence Treatment in Psychiatry: A Survey of Residency Training Directors</p> <p>ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH</p>
ACS Individual Research Award	<p>TYPE: Investigator-initiated single institution</p> <p>SPONSOR: American Cancer Society Institutional Research Grant</p> <p>SUBJECTS: Overall subject enrollment 114 subjects, national sample</p> <p>NCT ID: n/a</p>
07/07/05-05/01/06	<p>STUDY: Increasing the Impact of Behavioral Medicine on Physical and Mental Health</p> <p>ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH</p>
ACS Individual Research Award	<p>TYPE: Add-A-Day Conference Grant</p> <p>SPONSOR: American Psychological Association</p> <p>SUBJECTS: n/a</p> <p>NCT ID: n/a</p>
07/01/06-09/30/07	<p>STUDY: Modernizing the UCSF School of Medicine's Teaching on Tobacco Effects and Treatment across Disciplines and All 4 Years of Training</p> <p>ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH</p>
Haile Debas Grant	<p>TYPE: Curriculum Innovations Grant</p> <p>SPONSOR: UCSF</p> <p>SUBJECTS: n/a</p> <p>NCT ID: n/a</p>
07/01/04-06/30/08	<p>STUDY: Curriculum for Treating Nicotine Dependence in Psychiatry</p> <p>ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH</p>
13KT-0152	<p>TYPE: Investigator-initiated single institution (New Investigator Award)</p> <p>SPONSOR: California Tobacco-Related Disease Research Program</p> <p>SUBJECTS: Overall subject enrollment 55 subjects (UCSF, CPMC, SM)</p> <p>NCT ID: n/a</p>
07/01/07-08/20/10	<p>STUDY: Treating Tobacco Dependence in Adolescents with Co-Occurring Psychiatric Disorders</p> <p>ROLE: PI for the developmental study Center Director: Sharon Hall, PhD</p>
P50 DA009253	<p>TYPE: Center Grant Developmental Study</p> <p>SPONSOR: California Tobacco-Related Disease Research Program</p> <p>SUBJECTS: Overall subject enrollment 60 subjects from SF Bay Area</p> <p>NCT ID: NCT00618943</p>

05/25/05-04/30/11	STUDY: Treating Tobacco Dependence in Inpatient Psychiatry ROLE: PI for the developmental study Center Director: Sharon Hall, PhD K23 DA018691 TYPE: Center Grant Developmental Study SPONSOR: NIH/National Institute on Drug Abuse SUBJECTS: Overall subject enrollment 60 subjects from SF Bay Area NCT ID: NCT00136812
07/01/09-06/30/12	STUDY: Economic Impact of Smoking for Persons with Mental Disorders ROLE: Co-I on the overall study PI: Hai-Yen Sung, PhD 18XT-0092 TYPE: Investigator-initiated single institution (Research Award) SPONSOR: California Tobacco-Related Disease Research Program SUBJECTS: Analysis of publicly available epidemiological data NCT ID: n/a
07/01/08-06/30/12	STUDY: Improving Clinical Attention to Tobacco Use and Secondhand Smoke Exposure in Cardiology ROLE: Co-I on the overall study PI: William Grossman, MD Cahan Award TYPE: Investigator-initiated single institution (Cahan Award) SPONSOR: Flight Attendant Medical Research Institute (FAMRI) SUBJECTS: Overall subject enrollment 250 subjects, all from UCSF NCT ID: n/a
07/01/08-09/30/12	STUDY: Dissemination of the Rx for Change in Psychiatry Curriculum ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH 17RT-0077 TYPE: Investigator-initiated single institution (Research Award) SPONSOR: Tobacco-Related Disease Research Program SUBJECTS: Overall subject enrollment plan 300 subjects; 200 enrolled to date (Western US psychiatry & graduate psychiatric nursing programs) NCT ID: n/a
07/01/11-06/30/14	STUDY: Twitter-enabled Mobile Messaging for Smoking Relapse Prevention ROLE: PI on UCSF subcontract PI: Connie Pechmann, PhD, MBA R34DA030538 TYPE: Investigator-initiated single institution (R34) SPONSOR: NIDA / NIH SUBJECTS: Overall subject enrollment 240 subjects, national sample NCT ID: in process
02/01/11-10/15/14	STUDY: A Two-Part Pilot Study of Dosing, Safety and Efficacy of Varenicline Initiated during an Acute Smoke-free Hospitalization and Continued Post- Hospitalization ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH WS981308 TYPE: Investigator-initiated single institution SPONSOR: Pfizer, Inc. SUBJECTS: Overall subject enrollment plan 80 subjects, all at UCSF NCT ID: NCT01413516
07/01/09-01/31/15	STUDY: Evaluation of Tobacco Treatment Strategies for Inpatient Psychiatry ROLE: PI for the overall study PI: Judith Prochaska, PhD, MPH 1R01MH083684 TYPE: Investigator-initiated single institution (R01) SPONSOR: NIMH / NIH

SUBJECTS: Overall subject enrollment plan 1100 subjects; 575 enrolled to date (UCSF and Alta Bates Hospital)
NCT ID: NCT00968513

06/01/12-08/31/15
1026421
STUDY: Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: a randomised controlled trial
ROLE: Co-Investigator PI: Jenny Bowman, PhD
TYPE: Investigator-initiated single institution
SPONSOR: Australia National Health Medical Research Council
SUBJECTS: Overall subject enrollment 560 subjects from Australia
NCT ID: in process

08/01/12-07/30/15
21BT-0018
STUDY: Tobacco Treatment for Employable Californians
ROLE: PI on the overall study PI: Judith Prochaska, PhD, MPH
TYPE: Investigator-initiated single institution (Pilot CARA)
SPONSOR: Tobacco-Related Disease Research Program
SUBJECTS: 200 unemployed smokers and nonsmokers; 500 employers
NCT ID: n/a

07/01/08-09/30/15
P50DA09253
STUDY: Extended Care Treatment of Multiple Risk Behaviors in Complex Patients
ROLE: PI for Center Component Center Prog Dir: Joseph Guydish, PhD
TYPE: Investigator-initiated single institution (P50 Center Component)
SPONSOR: NIDA / NIH
SUBJECTS: Overall subject enrollment plan 300 subjects from SF VAMC
NCT ID: NCT01415206

07/1/15-06/31/16
STUDY: E-Cigarettes: Harmful or Harm-Reducing? Online Medical Education in Electronic Nicotine Delivery Products
ROLE: co-PI on the overall study PI: Jackler/Prochaska
TYPE: Investigator-initiated single institution (Research Award)
SPONSOR: Stanford Center for CME
SUBJECTS: 50 physicians
NCT ID: n/a

01/05/15-09/30/17
STUDY: Dejar de Fumar con Twitter
ROLE: Principal Investigator PI: Judith Prochaska, PhD, MPH
TYPE: Investigator-initiated single institution, intramural award
SPONSOR: Stanford Cancer Institute
SUBJECTS: Overall subject enrollment 192 subjects from Santa Clara and San Mateo Counties
NCT ID: in process

05/01/16-04/30/19
R34 DA041637
STUDY: Using Facebook to Address Smoking & Heavy Drinking in Young Adults
ROLE: PI on Stanford subAward PI: Ramo
TYPE: Investigator-initiated institution (R34)
SPONSOR: NIH/NIDA
SUBJECTS: Young adult smokers with heavy alcohol use across the US
NCT ID: n/a

11/01/17-06/30/19	STUDY: Establishing the Health Impact of Policy Changes in CA ROLE: Site PI
14-10214	TYPE: Supplement to Investigator-initiated institution (P30)
GG3004-4-01	SPONSOR: California Department of Public Health
78-1 (Ashe)	SUBJECTS: n/a NCT ID: n/a
09/1/17-06/30/19	STUDY: Impact of Tobacco Industry Pro-Environment Messages on Behavior ROLE: Co-Principal Investigator PIs: Prochaska & Lambin TYPE: Investigator-initiated intramural mini-grant SPONSOR: Stanford Woods Institute Environmental Venture Project SUBJECTS: Overall subject enrollment 1000 NCT ID: n/a
07/01/15-06/30/19	STUDY: Tobacco Treatment for Employable Californians ROLE: PI on the overall study PI: Judith Prochaska, PhD, MPH TYPE: Investigator-initiated single institution (Research Award) SPONSOR: Tobacco-Related Disease Research Program SUBJECTS: 350 unemployed smokers and nonsmokers NCT ID: n/a
24RT-0035	
*Plus a Cornelius Hopper Diversity Supplement Award for Beatriz Anguiano, a Stanford Health 4 All Fellow Alum	
07/1/17-08/31/19	STUDY: Stanford University: Assessment of Tobacco Use, Attitudes Towards Use, and Dialog on Policy Options ROLE: PI TYPE: Investigator-initiated institution SPONSOR: American Cancer Society SUBJECTS: n/a NCT ID: n/a
07/1/16-12/31/19	STUDY: Toward Equity in Smokefree Worksite Policies, SHS Exposure & Retail Density ROLE: PI for the overall study PI: Prochaska TYPE: Investigator-initiated single institution (Research Award) SPONSOR: Tobacco-Related Disease Research Program SUBJECTS: Analysis of existing data sources, state survey 17,000+ combined with novel coding of policy and tobacco retailer density data NCT ID: n/a
25IR-0032	
01/01/20-03/31/20	STUDY: Health Prevention Screening Project ROLE: co-I TYPE: Investigator-initiated SPONSOR: Facebook SUBJECTS: n/a planning grant for future RCT study NCT ID: n/a
PR799396	
SPO 171685	
09/15/15-06/30/20	STUDY: Applying Novel Technologies and Methods to Inform the Ontology of Self-Regulation

1UH2AG052168	ROLE: co-I PI: Poldrack, Stanford SubC (Lisa Marsch on overall award) TYPE: Innovation Award Cooperative Agreement SPONSOR: NIH/NIDDK SUBJECTS: 1000 adult smokers NCT ID: n/a
08/1/17-06/30/20	STUDY: Put it Out Project for Sexual and Gender Minority Smokers ROLE: PI on Stanford subAward PI: Ramo TYPE: Investigator-initiated institution (Research Award) SPONSOR: Tobacco-Related Disease Research Program SUBJECTS: Overall subject enrollment 120 sexual and gender minority young adult smokers NCT ID: n/a
26IR-0004 Former postdoc	
08/1/17-07/30/20	STUDY: A Facebook Intervention for Young Sexual & Gender Minority Smokers ROLE: PI on Stanford subAward PI: Ramo TYPE: Investigator-initiated institution (R21) SPONSOR: NIH/NIDA SUBJECTS: Overall subject enrollment 160 sexual and gender minority young adult smokers NCT ID: n/a
R21DA042222 Former postdoc Score=17 (2 nd %tile)	
04/15/14-03/30/21	STUDY: Technology Innovations for Supporting Health in Alaska Native People ROLE: Contact PI for the overall study PI: Judith Prochaska, PhD, MPH TYPE: Investigator-initiated multiple PI and institution (R01) SPONSOR: NHLBI/NIH SUBJECTS: Overall subject enrollment 300 subjects in Bristol Bay, AK NCT ID: n/a
R01HL117736-01	
**Plus 3 Diversity Supplement Awards for Madeline Hess (now a freshman at Dartmouth) and Jordan Skan and Maria Crouch (Alaska Native doctoral students in Clinical-Community Psychology at the University of Alaska, Anchorage and University of Alaska, Fairbanks)	
03/01/16-02/28/21	STUDY: Social Media Technology for Treating Tobacco Addiction ROLE: PI for the overall study PI: Prochaska/Pechmann TYPE: Investigator-initiated multiple PI and institution (R01) SPONSOR: NIH/NCI SUBJECTS: Overall subject enrollment 960 adult smokers across the US NCT ID: n/a
R01CA204356 Score=15 (2%tile)	
09/1/17-03/31/21	STUDY: Social Media Intervention to Promote Smoking Treatment Utilization and Cessation Among Alaska Native Smokers ROLE: Site PI TYPE: Investigator-initiated institution (R34) SPONSOR: National Institute on Drug Abuse SUBJECTS: focus groups and pilot with Alaska Native smokers NCT ID: n/a
R34DA046008	

* Supplemental funding awarded to develop, pilot and evaluate COVID-19/tobacco messaging on a Facebook platform and study tobacco use during the COVID-19 pandemic among Alaska Native men and women who smoke

06/1/18-05/31/21	STUDY: Integrating Tobacco Cessation Treatment within the Stanford Cancer Center
	ROLE: Program co-Lead
P30CA124435-1S2	TYPE: Supplement to Investigator-initiated institution (P30)
	SPONSOR: National Cancer Institute
NCI Moonshot Supplement	SUBJECTS: N>600 adult patients at Stanford Cancer Institute
	NCT ID: n/a

PEER REVIEWED ORIGINAL RESEARCH ARTICLES:

H-index=61, with 20,800 citations (per Google Scholar search 1/28/2021)

ORCID 0000-0001-7925-326X

* 46 articles cited >100 times, ** 7 articles cited >500 times, *** 1 article cited >5000 times

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199. Vogel EA, Prochaska JJ. (in press). Perceptions of cigarette smoking and overweight status in hypothetical hiring decisions. Health Psychology
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PEER-REVIEWED REVIEW ARTICLES & EDITORIALS

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Note: 8 review articles (Sallis, Prochaska & Taylor, 2000; Prochaska, Delucchi, & Hall, 2004; Cataldo, Prochaska & Glantz, 2010; Ramo, Liu & Prochaska, 2012; Prochaska & Hilton, 2012; David, Lancaster, Stead, Evins & Prochaska, 2013 and David, Lancaster, Stead, Evins & Prochaska, 2014; Mills, Thorlund, Eapen, Wu & Prochaska, 2014) are quantitative reviews and thus listed under peer-reviewed research articles. The Sallis, Prochaska, & Taylor (2000) article has been cited >2700 times according to the Web

of Science Citation Indexes (accessed 11/18/19). The Prochaska, Delucchi & Hall (2004) meta-analysis has been cited 365 times. The Prochaska and Hilton (2012) meta-analysis has been cited 123 times.

BOOK CHAPTERS

1. Elder, J.P., Ayala, G.X., Zabinski, M.F., Prochaska, J.J., & Gehrman, C.A. (2001). Theories, models, and methods of health promotion in rural settings. In S. Loue & B. E. Quill (Eds.), Handbook of Rural Health (pp. 295-314). New York: Kluwer Academic/Plenum Publishers.
2. Prochaska, J.J., & Sallis, J.F. (2005). Channels for delivering behavioral programs. In L.A. Kaminsky (Ed.), ACSM Resource Manual for Exercise Testing and Prescription (5th edition). pp 558-564. Philadelphia: Lippincott Williams & Wilkins.
 - Prochaska, J.J., & Sallis, J.F. (2009). Channels for delivering behavioral programs. In L.A. Kaminsky (Ed.), ACSM Resource Manual for Exercise Testing and Prescription (6th edition). pp 734-740. Lippincott Williams & Wilkins: Philadelphia
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4. Prochaska, J.J., Pate, R.R., & Sallis, J.F. (2008). Correlates of youth physical activity. In G.J. Welk & M.D. Meredith (Eds.), Fitnessgram/Activitygram Reference Guide (pp. Internet Resource). Dallas: The Cooper Institute.
5. Prochaska, J.J., Prochaska, J.M., & Prochaska, J.O. (2013). Building a science for multiple risk behavior change. In J. Okene, K. Riekert & S. Shumaker, The Handbook of Health Behavior Change (4th Edition). (pp. 245-267). New York: Springer Publishers.
6. Prochaska, J.J., Young-Wolff, K.C., & Alles, W. (2013). Self-efficacy: broad implications for research and practice. In M.P. O'Donnell (Ed.), Health Promotion in the Workplace (4th edition) Available at: <https://www.artsciencehpi.com/books>
7. Prochaska, J.M., Prochaska, J.O., Prochaska, J.J. (2015). Transtheoretical model guidelines for families with child abuse and neglect. In A.R. Roberts (ed.), Social Workers' Desk Reference, 3rd edition. (part IX, chp 90). New York: Oxford University Press.
8. Rubinstein, M.L., Prochaska, J.J. (2016). Tobacco. In L. Neinstein, D.K. Katzman, T. Callahan, C. Gordon, A. Joffe & V. Ricert (Eds.), Neinstein's Adolescent and Young Adult Health Care: A Practical Guide (6th edition). Lippincott Williams & Wilkins (pp. 536-546). *Named British Medical Association Book of the Year for 2017 and received the 1st Place prize in Paediatrics*
9. Das, S., & Prochaska, J.J. (2016). Smoking, nicotine, health, and mental health. In H. Friedman (Ed.), Encyclopedia of Mental Health (2nd edition). Vol. 4, Waltham, MA: Academic Press (pp.300-313).
10. Prochaska, J.J., Coughlin, S.S., & Lyons, E.J. (2017). Social media and mobile technology for cancer prevention and treatment. American Society of Clinical Oncology Educational Book; 37, 128-137.
11. Campbell LF, Giuliano AJ, Norcross JC, Prochaska JJ. (2018). Instructor's Resource Manual for Prochaska & Norcross' Systems of Psychotherapy: A Transtheoretical Analysis, 9th Edition. New York, NY: Oxford University Press.

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13. Prochaska JJ, Benowitz NL. (2022). Nicotine addiction and its treatment. In S Hecht & D Hatsukami (Eds.), Tobacco and Cancer: The Science and the Story. Singapore: World Scientific Publishing.
14. Gali K, Prochaska JJ. (2022). Treating tobacco use in cancer survivors. In L Schapira (Ed.), Essentials of Cancer Survivorship: A Guide for Medical Professionals. Abingdon, UK: CRC Press, (pp. 141-157).
15. Prochaska JJ & Vogel EA. (in press). Tobacco. In DK Katzman, CM Gordon et al (Eds.), Neinstein's Adolescent and Young Adult Health Care: A Practical Guide (7th edition). Philadelphia, PA: Lippincott Williams & Wilkins

FEDERAL REPORTS

Contributing Author to: U.S. Department of Health and Human Services. Smoking Cessation: A Report of the Surgeon General. Atlanta, GA: USDHHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

INTERNATIONAL REPORTS

Boyle RG, Prochaska JJ. (2021). Application for the inclusion of bupropion hydrochloride on the WHO Model List of Essential Medicines (EML) for the treatment of tobacco dependence as an aid to stopping smoking and tobacco use. World Health Organization (WHO) Expert Committee on the Selection and Use of Essential Medicines.

OTHER CREATIVE ACTIVITIES: The PACE+ physical activity measure (Prochaska et al., 2001, Arch Ped & Adol Med) has been translated into more than 20 different languages. In a multinational epidemiological study of adolescent health behaviors conducted in 35 countries and regions in the WHO European Region and North America, the measure was the strongest correlate of childhood obesity (Janssen et al., 2005, *Obesity Reviews*). The publication for the measure has been cited 459 times (updated 11/18/19).

Advisor to Truth Initiative documentary-styled campaign on tobacco industry exploitation
<https://www.youtube.com/watch?v=Qf06zBeWgRM>

Merck Medical Myths Podcast, Season 3, Vaping and Smoking Myths

STATISTICAL SKILLS: Randomized Regression Models, Generalized Estimating Equations, Principal Component Analysis & Factor Analysis, Logistic & Loglinear Analysis, Discriminate & Cluster Analysis, Reliability & Validity Analyses, Latent Transition Analysis, Structural Equation Modeling, Meta-Analysis, Decision Analysis, Cost-Effectiveness

Appendix B
Previous Testimony by Dr. Prochaska from September 5, 2014 to present
California, Florida, Illinois, Massachusetts, Nevada, New Mexico, Pennsylvania,
and Other Court Cases: 16 trials; >50 depositions

Court cases for which disclosed (deposition and trial testimony dates)	Law Firms	Venues
Perrotto (9/5/14, 9/17/14, 9/19/14, 11/2/14)	Schlesinger Law Offices, P.A.	Miami-Dade County, FL
McCoy (1/7/15, 1/30/15, 6/29/15, 6/30/15)	Schlesinger Law Offices, P.A.	Broward County, FL
Pijuan (1/16/15, 3/7/15)	Schlesinger Law Offices, P.A.	Miami-Dade County, FL
Lima (12/8/16, 4/12/17)	Schlesinger Law Offices, P.A.	Hillsborough County FL
Oshinsky (1/8/16, 2/19/16, 9/15/16)	Schlesinger Law Offices, P.A.	Broward County, FL
Letizia	Schlesinger Law Offices, P.A.	Broward County, FL
Dubins (7/28/17, 11/7/17)	Schlesinger Law Offices, P.A.	Miami-Dade County, FL
Cossick (1/18/17, 5/3/17)	Schlesinger Law Offices, P.A.	Broward County, FL
Kaplan (12/20/16, 4/18/17, 6/15/18, 6/18/18)	Schlesinger Law Offices, P.A.	Broward County, FL
Caprio (6/28/17, 7/18/17, 7/9/19, 10/29/19)	Schlesinger Law Offices, P.A.	Broward County, FL
Calloway (7/17/18)	Schlesinger Law Offices, P.A.	Broward County, FL
Neff (1/16/19, 3/11/19)	Schlesinger Law Offices, P.A.	Broward County, FL
Dawes (1/23/19, 8/26/19)	Schlesinger Law Offices, P.A.	Broward County, FL
Muro (3/2/21)	Schlesinger Law Offices, P.A.	Martin County, FL
Floyd	Schlesinger Law Offices, P.A.	Palm Beach County, FL
Horenstein	Schlesinger Law Offices, P.A.	
McKennie	Schlesinger Law Offices, P.A.	
NesSmith	Schlesinger Law Offices, P.A.	US District Court for the Middle District of FL
Ewing (11/20/15, 1/24/16)	Rick Diaz & JB Harris, P.A.	Escambia County, FL
Bryant (1/24/17, 11/27/17)	Rick Diaz & JB Harris, P.A.	Escambia County, FL
Conniff	Rick Diaz & JB Harris, P.A.	Escambia County, FL
Harris (1/25/19, 2/21/19)	Rick Diaz & JB Harris, P.A.	Gadsden County, FL
Eisen (9/9/20)	Rick Diaz, P.A.	Miami-Dade County, FL
Posner (8/15/19, 1/17/20)	Rick Diaz, P.A.	Broward County, FL
Gould (9/20/17)	JB Harris & Rick Diaz	Miami-Dade County, FL
Purdo (2/29/16, 3/7/16)	The Alvarez Law Firm	Palm Beach County, FL
Rey	The Alvarez Law Firm	Miami-Dade County, FL
Mitchell	The Alvarez Law Firm	Cook County, IL
Stoklosa	The Alvarez Law Firm	Cook County, IL
Bukowski	The Alvarez Law Firm	Cook County, IL
Wallace (2/9/16, 10/6/17)	Gordon & Doner, PA, Dolan,	Brevard County, FL
Alshouse	Dobrinsky & Roseblum	Seminole County, FL
Hensley (1/23/20)	Velasquez – Dolan - Arias	Miami-Dade County, FL
Babaletos	Roseblum LLP	Middlesex, MA
Fontaine	Roseblum LLP	Middlesex, MA
Mooney (3/29/16, 6/15/16)	The Ferraro Law Firm	Miami-Dade County, FL
Bazelaïs (5/23/16)	The Ferraro Law Firm	Miami-Dade County, FL
Ellis (5/24/17, 12/4/18)	The Ferraro Law Firm	Hillsborough County FL
McFall (8/6/18, 8/31/18, 10/15/18)	The Ferraro Law Firm	Palm Beach County, FL

Hoffner	Kelley & Ferraro LLP	Miami-Dade County, FL
Wilkinson (12/13/18, 1/18/19)	Kelley Uustal Trial Attorneys	Miami-Dade County, FL
McHugh (11/21/19, 1/20/20, 2/12/20)	Kelley Uustal Trial Attorneys	Broward County, FL
O'Keefe (9/12/19)	Kelley Uustal Trial Attorneys	Broward County, FL
Palmieri	Kelley Uustal Trial Attorneys	Broward County, FL
Tibbs (2/19/20, 3/4/20)	Kelley Uustal Trial Attorneys	Polk County, FL
Sutton	Kelley Uustal Trial Attorneys	Broward County, FL
Tully (2/10/22)	Kelley Uustal Trial Attorneys	Clark County, NV
Clark	Kelley Uustal Trial Attorneys	Clark County, NV
Camacho	Kelley Uustal Trial Attorneys	Clark County, NV
Byerly (2/13/19)	Ruth/Gunn/Brannock	Hillsborough County FL
Main (10/4/19, 12/10/19)	Hausfeld	Suffolk County, MA
DeRoo	Hausfeld	Suffolk County, MA
Rita Jones	Hausfeld	Suffolk County, MA
Kinnally (12/21/20)	Public Health Advocacy Inst.	Suffolk County, MA
Hunt (8/25/20)	Stephen R. Fine Esq	Middlesex, MA
Jackson (7/15/20, 11/2/21, 11/3/21)	Bruster PLLC	Santa Fe, NM
Johnson	Bruster PLLC	Santa Fe, NM
Ferrer (1/31/22)	Bruster PLLC	Socorro, NM
Hoefling (3/24/21)	Robert Spohrer, Esq	US District Court Eastern District of PA
Cardiff	Federal Trade Commission	US District Court Central District of CA
JUUL Labs, Inc., Marketing Sales Practices, And Products Liability Litigation: General (10/28/21, 10/29/21)	MDL PL Counsel CO Schlesinger Law Offices, P.A.	US District Court Northern District of CA
JUUL Labs, Inc., Marketing Sales Practices, And Products Liability Litigation: Bain (10/29/21)	MDL PL Counsel CO Schlesinger Law Offices, P.A.	US District Court Northern District of CA
JUUL Labs, Inc., Marketing Sales Practices, And Products Liability Litigation: Pesce (11/9/21)	MDL PL Counsel CO Schlesinger Law Offices, P.A.	US District Court Northern District of CA
JUUL Labs, Inc., Marketing Sales Practices, And Products Liability Litigation: Fish (12/8/21)	MDL PL Counsel CO Schlesinger Law Offices, P.A.	US District Court Northern District of CA
JUUL Labs, Inc., Marketing Sales Practices, And Products Liability Litigation: Westfaul (12/20/21)	MDL PL Counsel CO Schlesinger Law Offices, P.A.	US District Court Northern District of CA
Stephens	Schlesinger Law Offices, P.A. Rice Harbut Elliott	Supreme Court of British Columbia

APPENDIX C

SANDRA CAMACHO MEDICAL RECORDS

	xDesert Radiology-109805.pdf
	xEric Wikler, DO (PCP) 10-27-16 thru 11-19-19-109804.pdf
	xGhulam Kashef, MD (Oncologist)-112545.pdf
	xHeart Center of Nevada 02-13-19-.pdf
	xOperative Report - Laryngoscopy & Bilateral True Vocal Cords 06-15-17-111879.pdf
	xPulmonary Associates 04-26-13 thru 07-16-18-.pdf
	xRandall Weingarten, MD (ENT) 07-05-17 thru 07-27-19-.pdf
	xSt. Rose Dominican-Siena Hospital-109789.pdf
	XAffiliated Podiatry (Produced by Marker Group - Bates No. 201600.343.0001 - 201600.343.0006)-115951.pdf
	XAloha Med Ctr (Produced by Marker Group - Bates No. 201600.086.0001 - 201600.086.0131)-114764.pdf
	XAssociated Pathologists Chartered Legal Dept (Produced by Marker Group - Bates No. 201600.149.0001 - 201600.149.0007)-114696.pdf
	XAurora Diagnostics (Produced by Marker Group - Bates No. 201600.108.0001 - 201600.108.0004)-115165.pdf
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	XAurora Diagnostics (Produced by Marker Group - Bates No. 201600.109.0008 - 201600.109.0009)-117070.pdf
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	XChuang, Rita B., M.D. (Produced by Marker Group - Bates No. 201600.049.0002 - 201600.049.0013)-114585.pdf
	XCommunity Ambulance (Produced by Marker Group - Bates No. 201600.295.0001 - 201600.295.0007)-115176.pdf
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	XComprehensive Cancer Ctrs of Nevada (Produced by Marker Group - Bates No. 201600.024.0001 - 201600.024.0073)-114562.pdf
	XComprehensive Cancer Ctrs of NV (Produced by Marker Group - Bates No. 201600.024.0075 - 201600.024.0095)-116824.pdf
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	XDawood, Moniz M., M.D. (Produced by Marker Group - Bates No. 201600.020.0001 - 201600.020.0003)-115003.pdf
	XDesert Radiology (Produced by Marker Group - Bates No. 201600.026.0008 - 201600.026.0008)-117479.pdf
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APPENDIX D
Interview March 27, 2020, 2p-3:20p

Interview conducted via Skype with video. Ms. Camacho had her voice box removed due to laryngeal cancer. For communicating, our interview was conducted with a combination of my reading her lips and Ms. Camacho's use of a marker and whiteboard. To confirm responses, I repeated back what I read when lip-reading and from the whiteboard. Ms. Camacho's daughter Laura was on-hand as needed for repeating my questions or responses if any challenges hearing. We would call for her when needed. Ms. Camacho was highly engaged and expressive with nonverbals. Her responses tended to be brief, which seemed due to the challenges with communicating. Several times Ms. Camacho needed to take a break to clear her stoma. When needed, Ms. Camacho indicated she could not recall, typically when reflecting on events from many decades ago. Ms. Camacho's husband was in the room toward the end of the interview. I was able to ask and gain responses to all the questions I had planned, and the degree of detail provided by Ms. Camacho in our 1 hr 20 min interview was more than sufficient for me to render my opinion and determination of her addiction to nicotine in cigarettes. This interview was conducted during COVID-19 sheltering-in-place.

Please let me know if you have any difficulty hearing me. Is there any reason that you would have difficulty answering questions that I will be asking this morning, based on any medication you took today or otherwise how you feel? No

If you need a break, we can stop at any time and resume later. I read the medical records provided so I have some understanding of your medical and smoking history.

TO START, TELL ME A BIT ABOUT YOURSELF – AGE, HOBBIES, FAMILY. 74 in April; my husband and my daughter and her husband and 2 kids – in Las Vegas. I like playing poker, also Scrabble and Yahtzee and Bananagrams.

WHERE WERE YOU BORN? Chicago IL **SIBLINGS?** 2 sisters **LIVING?** Yes **SMOKE?**
Donna did; she quit
WHO RAISED YOU, PARENTS? Yes **DID THEY SMOKE?** both did **WHAT BRANDS?** Pall Mall

TELL ME ABOUT YOUR EARLY SMOKING HISTORY

WHEN DID YOU START SMOKING? HOW OLD WERE YOU? I think 17 or 18

WHAT BRAND? L&M Filtered? yes

Where did you get it? A girlfriend, Patty Cook *Where did Patty get it from?* I don't know

Where did you smoke your first cigarette? In the woods – across the street from the house

How did the first cigarette made you feel? I wanted another one; light-headed a little bit

Inhaled? Yes *Coughed?* once

How long until had another cigarette? The next day, back to the woods

Still in high school? yes

How soon until smoking every day? within a day or two smoking every day

What age buying cigarettes yourself? 18

Vending machines? Yes, but later

When could buy own cigs, what brand? L&M

Why L&M? they weren't strong and they weren't light

Other brands? Marlboro - fine, a little stronger, Basic full flavor, they were later

EVER GIVEN CIGARETTES/SAMPLING? No

WHY STARTED SMOKING? Everybody was doing it

How smoking portrayed? The in thing, with the Marlboro man and Philip Morris – the bell hop Johnny

HOW LONG UNTIL SMOKING 1 PPD? 20 years old

WHEN BUYING WHAT BRAND? L&M

EVER SMOKE UNFILTERED? I tried, Camel – too strong (made face)

EVER SMOKE MENTHOL CIGARETTES? I tried, didn't like it (made face), somebody else's

EVER SMOKE CIGARETTES MARKETED AS LIGHT? Marlboro Light – sucked really on it – too light (puckered lips/sucking)

IF YES, WHY? They were out of the regulars and I tried the lights

EVER SMOKE CIGARETTES MARKETED AS ULTRA-LIGHTS? No

WHAT EARLY IMAGES OF SMOKING DO YOU RECALL? Everybody was smoking

In movies, on TV, radio? Yes – cowboy movies, John Wayne **Magazines?** yes **Billboards?** yes

Coupons to the home? Yes – a lot, a lot – used them yes

Merchandising? Yes – Marlboro duffle bags, camping stuff, flashlights, knives, tools, shoes - mt climbers – husband got things **Marlboro Miles?** yes **Whose Marlboros?** Mine

When did you start smoking Marlboros? When they stopped L&M or at least harder to get, I switched to Marlboro – or at least harder to get in Vegas – about 30 yrs ago – 1990s

Other brands? Eventually switched from Marlboro to Basic – smoked both – depended on what was available. Then switched to Basic because Marlboro getting expensive. Eventually switched to Basic full time.

Ever smoke more than 1 ppd? When Jim was here smoked more - pack and a half was Basic. Jim was a friend that lived with us about 2 years. Sitting and talking - smoking together.

Did your husband smoke? He was a social smoker

How many days in a month would he smoke? Maybe 4 days in a month

WHAT WERE THE RULES ABOUT SMOKING AT SCHOOL? Couldn't smoke at school

Did you smoke at school? No

EDUCATION ON HARMS OF SMOKING IN SCHOOL? Nothing

WHEN YOU STARTED SMOKING, WHAT DID YOU KNOW ABOUT THE HEALTH HARMS OF SMOKING? (Hands up) Nothing

WHAT DID YOU KNOW RE: NICOTINE ADDICTION WHEN YOU STARTED? Nothing (shaking head)

WERE THERE CAUTIONARY OR WARNING LABELS ON CIG PACKS WHEN YOU STARTED? No

SMOKE IN THE HOME WITH PARENTS AS A TEENAGER? I did smoke in the house, but I don't remember at what age

WHEN YOU FIRST STARTED SMOKING, INTEND TO SMOKE >50 YEARS? I tried to quit, I didn't intend to smoke that long

DID YOU EVER CHAIN SMOKE? YES (nodding head, eyebrows up)

WHAT WAS THAT LIKE FOR YOU? Lit one off butt of another, smoked one right after another

DID YOU EVER HAVE CRAVINGS TO SMOKE? yes

DESCRIBE WHAT CRAVING CIGARETTES WAS/IS LIKE FOR YOU Terrible – tense, agitated, mean. When I was in the hospital for surgery and I couldn't smoke: terrible. The whole time in hospital 10 days – couldn't smoke. **NRT?** No **Waited until you left the hospital to smoke?** I had to **EVER FEEL LIKE YOU COULD NOT THINK OF ANYTHING OTHER THAN SMOKING?** Yes (strong head nod)

HOW SOON WOULD YOU SMOKE UPON WAKING? Right away, first thing, before brushing my teeth **Where keep the cigarettes?** in the kitchen

HOW MANY MINUTES FROM WAKING TO LIGHTING YOUR CIGARETTE? 30 seconds

EVER WAKE UP AND SMOKE IN THE MIDDLE OF THE NIGHT? Yes (big head nods)

DID YOU EVER SMOKE IN BED? No, husband wouldn't allow it

EVER HAVE ANY BURN MARKS IN YOUR CLOTHING? yes

IN YOUR HOME, ANY BURN HOLES IN THE COUCH, RUG, ON TABLES OR COUNTERS? yes

EVER SMOKE WHEN DRIVING IN THE CAR? Yes, I couldn't drive without one

ANY BURN HOLES IN FLOOR OR SEATS OR ELSEWHERE IN THE CAR? Yes, on the ceiling and on the seat – 2 holes **EVER SMOKE PUMPING GAS?** No

TIME SPENT SMOKING: About 8 mins x 20 cigs – 160min – 2.5+ hrs a day? x 50+ yrs = 48K hrs? (nods head) Yes

PLACES WHERE COULD NOT SMOKE? when started could smoke everywhere

Church? Walking to the car to go home would smoke

Movies? Didn't smoke in the movies, drive-in and smoked at the drive-in, would smoke in the lobby at the movies

Restaurants? smoked in restaurants, sat in the smoking section, when smoke-free, would go outside to smoke

Friends' homes? Smoked in friends' homes, even if they didn't smoke (Jan)

DID YOU WORK OUTSIDE OF THE HOME? Yes, 3 years as a hairdresser, then as a waitress – 15 years with Denny's, 1 year at another restaurant. Moved to Vegas 30 years ago and worked as a cashier 9 years with Texaco, 4 years at 7/11, 1 year at another 7/11.

Could you smoke at work? Yes

Hairdresser – could smoke inside the salon

Waitressing – could smoke in the back, needed to take a break to smoke; 8 hr shift – 2 breaks, lunch and another break, but I would go back there and smoke; 10 min break, 30 min lunch (2 cigs) and maybe 20 mins later, go back and smoke again and go out and smoke when I could; when the kids went to school down to 6 hr shift, 9-3

Cashier - Smoked in the back **Did you sell cigarettes?** yes

SMOKE WHEN PREGNANT? Yes

ADVISED TO QUIT? No

DID YOU QUIT SMOKING FOR GOOD IN SEPT 2017 (PER MEDICAL RECORD)? Yes 2017 – choking off my airway, I would cough and cough and cough - the tumor was behind the airway – the smoke irritation made it worse. **Stopped then?** I had to. I quit smoking because I couldn't breathe. The tumor was growing so I couldn't smoke. I quit before I knew that it was cancer – that's how I found out – I couldn't inhale anymore. **When was your cancer diagnosed?** laryngeal cancer finally dx March 2018

SMOKE AFTER DX WITH TOBACCO-RELATED HEALTH CONDITION?

Had bronchitis – still smoked – years ago

EVER MAKE EFFORTS TO CUT DOWN ON THE AMOUNT YOU WERE SMOKING?

It never worked. I tried at least two times when I was 28 and maybe when I was 65. I couldn't do it – would last 1 hr. **Why trying to cut back when 28?** Boyfriend, lasted 1 hr, that was the end of him

WHAT WAYS ATTEMPTED TO QUIT SMOKING?

MEDICATIONS – used the nicotine gum, didn't work, OTC, used it a couple of hours, didn't work

Other quit smoking medications? No

COLD TURKEY – tried, didn't work

OTHER TOBACCO PRODUCTS (CIGARS, SMOKELESS, PIPE) - no

E-CIGARETTES – e-cigarettes yes, I didn't like it, Blu brand – not the same with the nicotine

I wanted to try it – I thought would be safer than smoking cigarettes – but they're not (shakes head)

HYPNOSIS - no

ACUPUNCTURE – no

QUIT SMOKING GROUP - no

QUIT LINE – no, wouldn't help me, I was too far gone

GREAT AMERICAN SMOKEOUT - no

THROW AWAY CIGS, LIGHTERS, ASHTRAYS – yes

ORAL SUBSTITUTES (CANDY, REG GUM, TOOTHPICK, STRAW) - no

BEFORE YOU QUIT SMOKING FOR GOOD, WHAT WAS THE LONGEST YOU'D GO WITHOUT SMOKING? Not even a day, 2 or 3 hrs

EXPERIENCE WITHDRAWAL SYMPTOMS WHEN WOULD GO WITHOUT CIGS OR WHEN TRYING TO QUIT? YES

WHAT WAS THAT LIKE FOR YOU?

– **gain weight?** Lost 50 lbs because of health problems

– **difficulty concentrating?** Yes, yes

- **irritable?** when hospitalized prior – yes mean

- **restless?** Yes, yes

- **depressed mood?** Depressed, depressed, cry everyday

- **sleep problems?** difficulty sleeping, had to sleep in a chair until a month ago, couldn't lay flat

– **anxiety?** Got Ativan

DID THESE WITHDRAWAL SYMPTOMS INTERFERE WITH YOUR FUNCTIONING? Yes, couldn't do what normally would do

ARE THERE THINGS THAT YOU SEE OR SMELL IN THE ENVIRONMENT THAT MAKE YOU WANT TO SMOKE A CIGARETTE? Yes **WHAT KINDS OF THINGS?** Not anymore. But before - driving, seeing other people smoke, coffee

DISAGREEMENTS/CONFLICT WITH FRIENDS/FAMILY/COWORKERS DUE TO SMOKING?

My daughter used to yell all of the time; and my mom quit smoking, and she would get on me about wanting to quit; my husband would get on me to quit – that didn't work – arguments

GIVE UP ACTIVITIES IN ORDER TO SMOKE, LIKE GRANDCHILDREN'S ACTIVITIES?

No, I would go outside when I needed one

EVER NOT HIRED BECAUSE A SMOKER? No **TAKE SMOKE BREAKS?** Yes

CLIENTS EVER COMPLAIN ABOUT YOUR SMOKING? No

DID YOU TYPICALLY PURCHASE BY THE PACK OR CARTON? If had money, I would get carton, otherwise a couple of packs at a time **HOW MUCH COST PER PACK/CARTON?** I can't remember

DID YOU EVER PAY BILLS LATE BECAUSE YOU SPENT MONEY ON CIGARETTES? No

DID YOU EVER HAVE DIFFICULTY FULFILLING ACTIVITIES AT HOME BECAUSE OF SMOKING? No

ANYTHING ELSE LIKE TO TELL ME ABOUT YOUR SMOKING THAT I HAVE NOT ASKED?

I'd like to go on tv and tell people to quit smoking. I wish that they would have said to me: don't smoke, it's very addictive.

END