Free markets. Real solutions.

R STREET POLICY STUDY NO. 124
December 2017

EXPECTED SAVINGS TO MEDICAID FROM SUBSTITUTING ELECTRONIC FOR TOBACCO CIGARETTES

Richard B. Belzer

CONTENTS

INTRODUCTION

Smoking is well established as the cause of numerous health effects including cancer, coronary heart disease, and respiratory ailments such as chronic obstructive pulmonary disease and emphysema. Vaping poses essentially none of these risks because it involves no products of combustion. For this reason, numerous reports make the case that switching smokers to vaping would greatly reduce or eliminate these health risks.

Most medical care expenditures on smoking-related ailments are made by third-party insurers and are substantially passed through to insureds, though under applicable federal regulations forbidding proper risk-rating, nonsmokers bear a substantial share of these costs. The exceptions are Medicare and (especially) Medicaid, where expenditures are made by taxpayers but are not passed through. This creates a strong incentive for governments to take a more active role to manage the financial consequences of smoking.

Accordingly, the present study provides state-level estimates of the cost savings to Medicaid programs that could be realized if enrollees who smoke switched to e-cigarettes. A stylized example is created in which 1% of smokers within each of eight demographic groups permanently switch.[1] For this standardized cohort, the present value of estimated cost savings to Medicaid programs is about $2.8 billion, with the median state's present value cost savings exceeding $32 million. For a series of ten annual standardized 1% switch cohorts, the present value of nationwide cost savings is 10 times greater, or $28 billion, with the median state saving about $320 million. These estimates provide a foundation for state-specific estimates based on state-specific circumstances and defined program features or market behaviors. Resulting estimates would be multiples of the estimates from the standardized cohort analysis.

GENERAL METHODOLODY AND ANALYTICAL BASELINE

Conventional practice in a benefit-cost analysis is to estimate the full range of social benefits and costs, so as to ensure that decisions, whether public or private, are informed by a full

1. This percentage was chosen because it is too small to have a substantial income effect on the states (resulting, for example, from the loss of tobacco tax revenues), lower than favorable reports of the success rate of nicotine replacement therapies (~4%), and much lower than the sustained substitution rates observed in experimental studies on e-cigarettes (~10-30%).

accounting of all effects. There are circumstances, however, in which it can be useful and informative to examine a subset of benefits and costs, or even to consider only costs or transfers. One example is the analysis of public programs in which the consideration of benefits and costs is not germane to decision-making at the margin.

The federal/state Medicaid program is one such example. Total Medicaid spending exceeded $550 billion in FY 2015.[2] Policy making today primarily concerns managing public expenditures. Therefore, noncontroversial insight can be gleaned by examining the extent to which public expenditures could be reduced, especially if this can be done while improving the health of enrollees.

There is evidence that e-cigarettes[3] can substantially reduce the health risks associated with tobacco cigarettes.[4] Accordingly, expenditures on medical care can be expected to decline when smokers quit or switch to e-cigarettes. Reductions in risk translate to lower Medicaid expenditures, though these reductions do not occur immediately because the consequences of past smoking are slow to attenuate. Any estimate of cost savings must therefore account for the cessation lag in the realization of health benefits, of which medical care expenditures are a lagging indicator.

This analysis provides estimates of the reduction in state-level expenditures that can be reasonably expected if a standardized cohort of adult Medicaid enrollees switches from tobacco to e-cigarettes. The standardized cohort consists of 1% of the estimated number of smokers in each of eight demographic subpopulations participating in Medicaid. Subpopulations were chosen to match smoking prevalence estimates produced using the best available federally sponsored survey containing state-specific samples. This magnitude of switching behavior is deliberately small, so as to enable the construction of more refined state-level estimates that could be applied to both market-driven switching behavior and state-level program initiatives. As the size of the standardized cohort increases, the potential for confounders becomes more difficult to ignore. For example, reductions in tobacco smoking increase longevity and thus raise expected outlays for Medicare and Social Security. For states, the chief expenditure confounders are the loss of tobacco tax revenue that would accompany switching and an increase in expected pension outlays for state and local government employees.

Cost-savings estimates have significant uncertainties that are not accounted for here. State-level estimates of Medicaid enrollees are highly precise but their accuracy has not been validated. Estimates of the demographic composition of the Medicaid enrollee population appear to have serious information-quality concerns. One reason for this is that in classifying enrollees' race and ethnicity, the states follow a range of generally undocumented practices. This would not matter except that like sex, race and ethnicity are statistically significant predictors of smoking prevalence. Age and educational attainment are also statistically significant predictors of smoking prevalence, and the magnitude of each effect is very large compared to race and ethnicity. But there appear to be no reliable public estimates of the age or educational attainment distributions of Medicaid enrollees who smoke. Accordingly, workarounds have been employed here, but these are a source of both uncertainty and potential bias.

The Centers for Medicare and Medicaid Services (CMS) collect data that others have used to estimate medical expenditures per enrollee, however these estimates seem low.[5] For example, average expenditure per non-aged and non-disabled adult enrollee nationwide was $3,955 in FY 2014.[6] However, CMS' estimate of U.S. per-capita healthcare costs was $8,045,[7] a factor of two greater. Meanwhile, the National Center for Health Statistics (NCHS) estimates that per-capita "health consumption expenditures" was $9,523 in 2014.[8] It is difficult to ascertain which of these figures is correct. Therefore, in this analysis, the CMS figure for Medicaid is used based on the logic that it is identical to the expenditure statistic desired, whereas the other figures are not. But if the NCHS figure is more reliable, cost savings estimates here will be understated by about twofold.

Other important assumptions have been made that should be acknowledged. First, it is assumed that existing state and federal taxes and other policies that directly or indirectly affect tobacco or e-cigarettes will remain in place. These polices are briefly discussed below. In addition, institutional

2. "Total Medicaid Spending: FY 2016," The Henry J. Kaiser Family Foundation, 2017. http://kff.org/medicaid/state-indicator/total-medicaid-spending.

3. E-cigarettes are also sometimes referred to as Electronic Nicotine Delivery Systems (ENDS) or Electronic Non-Nicotine Delivery Systems (ENNDS).

4. See, e.g., Health & Wellbeing Directorate, *E-Cigarettes: A New Foundation for Evidence-Based Policy and Practice, Public Health England*, 2015. https://www.heartland.org/_template-assets/documents/publications/ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf; and "Underpinning evidence for the estimate that e-cigarette use is around 95% safer than smoking: authors' note," Public Health England, 2015. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456704/McNeill-Hajek_report_authors_note_on_evidence_for_95_estimate.pdf.

5. "Medicaid Spending by Enrollment Group; FY 2014," The Henry J. Kaiser Family Foundation, 2017. (http://kff.org/medicaid/state-indicator/medicaid-spending-by-enrollment-group/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

6. "Medicaid Spending Per Full-Benefit Enrollee, FY 2014," The Henry J. Kaiser Family Foundation, 2017. (https://www.kff.org/medicaid/state-indicator/medicaid-spending-per-full-benefit-enrollee/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

7. "Health Care Expenditures Per Capita by State of Residence: Timeframe 2014," The Henry J. Kaiser Family Foundation, 2017 http://kff.org/other/state-indicator/health-spending-per-capita/?currentTimeframe=0.

8. National Center for Health Statistics, "Table 93: Gross Domestic Product, National Health Expenditures, Per Capita Amounts, Percent Distribution, and Average Annual Percent Change: United States, Selected Years 1960-2014," Centers for Disease Control and Prevention, 2015. https://www.cdc.gov/nchs/data/hus/2015/093.pdf0.

forces that became strong during the decades-long campaign to reduce smoking are now arrayed against e-cigarettes and thus the present study assumes that these will affect rates of e-cigarette usage in a similar manner.

FEDERAL AND STATE TAX POLICIES

Tobacco cigarettes are subject to substantial federal and state excise taxes. The federal excise tax on small cigarettes is $50.33/1000 ($1.01/pack).[9] In 2015, the last year for which annual domestic volume is available, approximately 239 billion domestically produced and 8.5 million imported small cigarettes were removed for U.S. sale, yielding revenue of about $12 billion.[10] Currently, there are no federal excise taxes on e-cigarettes.

State excise taxes range from $0.017/pack in Missouri to $4.35/pack in New York, with several states allowing local governments to impose their own taxes.[11] High tobacco taxes create a financial incentive for smokers to switch to e-cigarettes, as well as incentives for counterfeiting and arbitrage. As a result, jurisdictions such as New York City have high excise tax rates but also have substantial smuggled supplies of tobacco,[12] secondary crimes that result from smuggling, and relatively high concentrations of Medicaid beneficiaries. Whatever salutary effect high tobacco taxes might have on e-cigarette consumption are reduced by counterfeiting and arbitrage, especially if Medicaid participants are disproportionate consumers of illegal tobacco. The poor have higher smoking prevalence rates and smoking is addictive, so tobacco taxes are not just highly regressive, they may also be a cause of poverty.

THE FDA "DEEMING RULE"

With the 2009 Tobacco Control Act (TCA), Congress substantially expanded the Food and Drug Administration's authority to regulate "tobacco products," which were defined as:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).[13]

The TCA specifically includes several products besides cigarettes (e.g., smokeless tobacco, cigars and little cigars, and pipe tobacco) but is silent about e-cigarettes and their constituent parts. Moreover, beginning in 2011, Semiannual Regulatory Agenda entries published by the FDA described future implementation regulations in ways that did not inform the public that the agency intended to include e-cigarettes.[14]

The Food and Drug Administration promulgated its regulation "deeming" e-cigarettes to be "tobacco products" in May 2016.[15] Unless the FDA's authority to add products to the list is statutorily unbounded, this action should have been controversial, particularly because FDA's deeming authority is expressly limited. According to the language of the TCA, the FDA is only allowed to add "any other [presumably new] tobacco products that the Secretary by regulation deems to be subject to this chapter"[16] if they are "made or derived from tobacco that is intended for human consumption."[17] However, the nicotine in e-cigarettes is not derived from tobacco and thus they are expressly outside the bounds of the FDA's TCA authority.[18] For these reasons, and perhaps unsurprisingly, the Deeming Rule is subject to ongoing litigation in federal court.[19]

Like many other major rules, the FDA's Deeming Rule was accompanied by a Regulatory Impact Analysis (RIA). However, the RIA is not helpful for understanding likely impacts

9. Alcohol and Tobacco Tax and Trade Bureau, "Tax and Fee Rates," U.S. Dept. of the Treasury, March 4, 2016. https://www.ttb.gov/tax_audit/atftaxes.shtml. "Small cigarettes" are those weighing not more than three pounds per thousand. The tax rate on "large cigarettes" is $105.69 per 1000. The higher tax rate has eliminated the supply of large cigarettes. Federal excess taxes yield about $130 million in annual revenue.

10. Alcohol and Tobacco Tax and Trade Bureau, "Statistical Report – Tobacco: December 2015," U.S. Dept. of the Treasury, July 7, 2016. https://www.ttb.gov/statistics/2015/201512tobacco.pdf. Taxes are based on removals from inventory plus imports.

11. "State Excise Tax Rates on Cigarettes," Federation of Tax Administrators, January 1, 2017. http://www.taxadmin.org/assets/docs/Research/Rates/cigarette.pdf.

12. See, e.g., Klaus von Lampe and Marin Kurti, "The Illegal Cigarette Trade in New York City," *Trends in Organized Crime* 19:3 (2016), 329-50 http://dx.doi.org/10.1007/s12117-016-9291-2.

13. TCA § 101(a), adding 21 U.S.C. § 321(rr)(1). Drugs and devices defined under § 321(g)(1) and (h), respectively, were explicitly exempted from the definition of "tobacco product."

14. See, e.g., 76 Fed. Reg. 130 (July 7, 2011), pp. 40061-52; 77 Fed. Reg. 29 (Feb. 13, 2012), pp. 7952-53; 78 Fed. Reg. 5 (Jan. 8, 2013), pp. 1579, 44257; 79 Fed. Reg. 4 (Jan. 7, 2014), p. 1162; 79 Fed. Reg. 114 (June 13, 2014); 79 Fed. Reg. 245 (Dec. 22, 2014), pp. 76724-25; 80 Fed. Reg. 117 (June 18, 2015); 80 Fed. Reg. 240 (Dec. 15, 2015); 81 Fed. Reg. 247 (Dec. 23, 2015); and 81 Fed. Reg. 111 (June 9, 2016). The statutory purpose of the Regulatory Agenda (part of the Regulatory Flexibility Act of 1980) is to provide small entities (such as e-cigarette manufacturers) early warning of major regulations. See, 5 U.S.C. § 602. However, subsection (d) permits agencies to publish misleading entries and take major actions for which no advance warning was published in the Agenda.

15. 81 Fed. Reg. 90 (May 10, 2016), 28974-9106.

16. TCA § 901(b).

17. TCA §101(a).

18. In its deliberation on the bill that became the TCA (H.R. 1256), the 111th Congress considered alternative bills and amendments that included references to e-cigarettes, but none were approved.

19. *See Nicopure LLC, et al. v. Food and Drug Administration*, et al., (2017), p. 26. In July 2017, the district court ruled that the "FDA was well within its statutory authority to regulate" when it deemed e-cigarettes and their constituent components as a "tobacco product." A notice of appeal has been filed. See, e.g., Nicopure Labs, "Nicopure Labs Files a Notice of Appeal in Their Case against the FDA Deeming Rule - Nicopure Labs LLC," Press Release, Aug. 30,2017. https://www.nicopure.com/news/nicopure-labs-is-filing-a-notice-of-appeal-in-their-case-against-the-fda-deeming-rule.

because it makes no distinction between e-cigarettes and tobacco products in its regulatory rationale, it implicitly denies the existence of public health benefits from e-cigarettes and it includes no benefit or cost estimates for the e-cigarette components of the rule.[20]

If the Deeming Rule is upheld in court, it will have several adverse effects. First, the Rule will significantly increase e-cigarette manufacturing production costs, raise minimum sustainable market prices and ultimately reduce quantities demanded. Second, because e-cigarettes are substitutes for tobacco cigarettes, increases in the relative price of e-cigarettes will discourage tobacco users from switching and will lead current and prospective vapers to switch to tobacco cigarettes—with predictable adverse health consequences. Third, at a minimum, forcing e-cigarette manufacturers to satisfy burdensome premarket approval requirements will impose disproportionately high costs on small entities and give large tobacco companies a competitive advantage.[21] This will result in product homogeneity and deter innovation.[22] Fourth, if the FDA denies premarket approvals in a manner consistent with its bureaucratic opposition to e-cigarettes, all e-cigarettes will be driven from the market. To the extent that anything remains of the e-cigarette market, manufacturers will compete on margins other than harm reduction, such as aesthetics, style, convenience and flavorings.[23] These restrictions will further deter innovation and make e-cigarettes less desirable substitutes. Fifth, the Rule will thwart the reduction in the trade of illicit tobacco products that e-cigarettes are capable of producing.[24] Sixth, by forbidding the communication of truthful information about health risk without prior FDA approval, the Rule sustains consumers' exaggerated risk perceptions about e-cigarettes and prevents them from obtaining scientifically correct information.[25]

Finally, the Deeming Rule also will likely increase Medicaid expenditures on smoking-related illness. Whereas e-cigarettes provide an opportunity to lower health risks and thus reduce these expenditures, the Rule reduces these cost savings and if e-cigarettes are driven out of the marketplace, would eliminate them entirely. For these reasons, the Deeming Rule presents an analytic quandary for the estimation of cost-savings to Medicaid if enrollees switch from tobacco to e-cigarettes. In particular, it renders impossible the task of estimating the magnitude of voluntary switching behavior. Estimates cannot be based on market phenomena such as own- and cross-price elasticities because the Deeming Rule replaces the market with regulatory allocation.

OTHER FEDERAL POLICIES THAT DISCOURAGE E-CIGARETTES

The FDA Deeming Rule is just one of many federal policies arrayed against e-cigarettes. First, the Department of Health and Human Services (DHHS) has established and maintained longstanding policies intended to deter and prevent tobacco cigarette consumption and it has now extended these policies to e-cigarettes despite the absence of tobacco and their established lower health risks. Second, DHHS has built and sustains a cottage industry in nicotine replacement therapies (NRTs) that appear to be much less effective than advertised. Further, the Department has prevented e-cigarettes from being accepted as NRTs despite their superior performance in reducing the harms from tobacco. Third, the Department's multiple bureaucracies have established a near-unified opposition to e-cigarettes.[26]

DHHS-wide tobacco-restriction policies

Over the past several years, DHHS and its constituent agencies have engaged in a coordinated plan to discourage tobacco use. In addition to the FDA, this includes the Public Health Service (Office of the Surgeon General) and the Centers for Disease Control and Prevention (CDC—Office

20. U.S. Food and Drug Administration, *Deeming Tobacco Products to Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements*, Docket No. FDA-2014-N-018, U.S. Dept. of Health and Human Services, April 2014. https://www.fda.gov/downloads/AboutFD.../UCM394933.pdf. The RIA does not even minimally comply with the Office of Management and Budget (OMB) guidance on the preparation of RIAs. See, e.g., "Circular A-4: Regulatory Analysis," Office of Management and Budget, 2003. http://www.whitehouse.gov/omb/circulars_a004_A-4. For a brief nontechnical critique, see Michael L. Marlow, "Regulating a Less Unhealthy Cigarette," *Regulation* 37:3 (Fall 2014), 28-32. https://object.cato.org/sites/cato.org/files/serials/files/regulation/2014/10/regulationv37n3-5.pdf; and Michael L. Marlow, " Deeming Tobacco Products to Be Subject to the Food, Drug, and Cosmetic Act, Mercatus Center, June 27, 2014. https://www.mercatus.org/publication/deeming-tobacco-products-be-subject-federal-food-drug-and-cosmetic-act.

21. See, e.g., Duff Wilson, "A Tobacco Bill, Backed by Philip Morris, Faces Vote," *The New York Times*, March 31, 2009. http://www.nytimes.com/2009/04/01/business/01tobacco.html.

22. See, e.g., Public Health Service Office of the Surgeon General, *E-Cigarette Use among Youth and Young Adults: A Report of the Surgeon General*," U.S. Dept. of Health and Human Services, 2016, p. 3. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

23. Flavorings other than menthol are prohibited in tobacco cigarettes. E-cigarettes may thus appeal to a segment of the prospective market in which tobacco cigarettes cannot legally compete. The FDA also may impose burdensome testing requirements on inert ingredients and flavorings, or ban flavorings it does not think are appropriate.

24. The TCA Amendments directed FDA to "consider ... information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand." See TCA § 907(b)(2). The RIA (fn. 20) does not include any analysis of the Rule's effects on illicit tobacco trade.

25. Prior FDA approval of reduced-risk claims is required by TCA § 911(g).

26. The Centers for Medicare and Medicaid Services (CMS), the DHHS agency responsible for funding the Medicaid program, does not appear to be a party to this bureaucratic consensus.

on Smoking and Health). These endeavors have grown so large that they comprise a cottage bureaucratic industry. For example, in fiscal year 2016, Congress appropriated $1,117 million to DHHS for chronic disease prevention and health promotion, including tobacco control and another $599 million to implement the TCA.[27]

For this reason, bureaucratic opposition to tobacco is entrenched, committed and permanent within the DHHS. The Department's views on tobacco enjoy substantial social resonance that likely carries over to e-cigarettes as a result of the FDA's decision to deem e-cigarettes as "tobacco products." Therefore, the market for e-cigarettes is impaired insofar as it must overcome systematic opposition from the nation's public health authorities. Potential savings to Medicaid programs reported here do not account for this institutional opposition and therefore are less likely to be realized.[28]

Public Health Service

The two most recent Surgeon General's reports published by the Public Health Service (PHS) discuss e-cigarettes differently. The 2014 Report briefly mentions e-cigarettes as substitutes for tobacco cigarettes[29] and ambiguously calls them a "regulatory challenge"[30] without identifying any statutory authority for regulation. By contrast, the 2016 Report fully embraces the FDA's Deeming Rule in its statement that "e-cigarettes are tobacco products that deliver nicotine" and its later assessment that "e-cigarette use among U.S. youth and young adults is now a major public health concern."[31]

Indeed, the tenor of the 2016 Report treats the FDA's regulatory decision as if it were scientifically obvious. Prior leadership within the Office of the Surgeon General has expressed the view that there are no circumstances in which the benefits of using tobacco products exceed the costs, and because the FDA has deemed e-cigarettes as "tobacco products," that opinion extends without reservation or qualification to e-cigarettes. Therefore, it appears to be established DHHS policy that the optimal consumption of both tobacco and e-cigarettes is zero. Accordingly, the 2016 Report clearly announced a campaign to deny e-cigarettes a stable (much less growing) market, relying on a scientifically unsupported "slippery slope" argument.[32] This reinforces the expectation that few or no e-cigarettes will receive premarket approval from the FDA.

Centers for Disease Control and Prevention

The Center for Disease Control and Prevention's (CDC's) Office on Smoking and Health (OSH) is the federal agency through which Congress subsidizes state tobacco control programs at the rate of over $200 million per year.[33] In addition to republishing information originally produced by other CDC offices, OSH maintains a public portal that provides access to several CDC datasets related to smoking and e-cigarette use.[34]

Active state programs funded by OSH appear to be heavily weighted with few carrots (nicotine replacement therapies, or NRTs) and many sticks (all-encompassing tobacco use restrictions), and OSH is committed to defending these programs. For example, the OSH portal cites approvingly a study purporting to show that the California Tobacco Program resulted in health care expenditure savings of $134 billion in the fiscal years between 1989 and 2008.[35] However, the referenced study suffers from a disclosed conflict of interest (its authors are employed by the program)[36] and has numerous, important methodological limitations that are likely to inflate its estimates.[37] OSH also has published a guide for tobacco control program evaluation,[38] and a review of the

27. "Fiscal Year 2017 Budget in Brief: Strenthening Health and Opportunity for All Americans," U.S. Dept. of Health and Human Services, 2016. https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf. Funds appropriated to implement the TCA come from user fees on manufacturers.

28. New FDA Commissioner Scott Gottlieb has announced a "harm reduction" approach to e-cigarettes. This prospective new policy, and the likely bureaucratic and political barriers to its implementation, are described briefly below.

29. Public Health Service Office of the Surgeon General, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, U.S. Department of Health and Human Services, 2014. https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

30. Ibid., p. 873.

31. See, Vivek H. Murthy, "Preface," *E-Cigarette Use Among Youth and Young Adults*, p. v. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

32. Ibid.

33. Centers for Disease Control and Prevention. "Justification of Estimates for Appropriation Committees: FY 2017," Washington DC: DHHS, 2016 (https://www.cdc.gov/budget/documents/fy2017/fy-2017-cdc-congressional-justification.pdf).

34. "Office on Smoking and Health's Interactive Data Dissemination Tool: OSHData," Centers for Disease Control and Prevention, 2017. https://www.cdc.gov/oshdata.

35. See, e.g., Office on Smoking and Health, "National Tobacco Control Program Funding," Centers for Disease Control and Prevention, 2017. https://www.cdc.gov/tobacco/stateandcommunity/tobacco_control_programs/ntcp/index.htm.

36. James Lightwood and Stanton A. Glantz, "The Effect of the California Tobacco Control Program on Smoking Prevalence, Cigarette Consumption, and Healthcare Costs: 1989–2008," PLoS ONE 8:2 (Feb. 13, 2013), e47145. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0047145.

37. Methodological limitations include (a) use of aggregate data on tobacco consumption and health care expenditures; (b) the attribution of all temporal state-level effects to the California Tobacco Programs; (c) insufficient control of known confounders; (d) specific tobacco control program elements are not included; and (e) weak association is inferred as causal. Lightwood and Glantz claim that an additional $1 in cumulative per capita tobacco control funding reduces smoking prevalence by 0.0497 percentage points and per capita tobacco cigarette consumption by 1.39 packs/year. OSH cites no other evidence that indicates these programs are effective.

38. Goldie MacDonald, Gabrielle Starr et al., "Introduction to Program Evaluation for Comprehensive Tobacco Control Programs," Centers for Disease Control and Prevention, November 2001. https://www.cdc.gov/tobacco/stateandcommunity/tobacco_control_programs/surveillance_evaluation/evaluation_manual/pdfs/evaluation.pdf.

program evaluation literature,[39] which asserts that these programs perform superlatively despite a stubborn lack of decline in smoking prevalence.

The Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is the DHHS agency responsible for conducting, sponsoring, publishing and publicizing "research and evidence that makes health care safer and improves quality."[40] The treatment of "tobacco use and dependency" is a major programmatic component of this mission.[41] Clinical practice guidelines published by AHRQ include evaluations of the effectiveness of alternative NRTs but do not include evaluations of e-cigarettes as NRTs.[42]

While the World Health Organization (WHO) is obviously not a subsidiary of DHHS, its actions are the product of intergovernmental cooperation in which DHHS plays a substantial role. Like DHHS, WHO has designated certain NRTs (but not e-cigarettes) as "essential medicines,"[43] which it defines as:

> those that satisfy the priority health care needs of the population [...] selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness [...] intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.[44]

Also like DHS, WHO adopts the Department's zero-use mantra, but unlike DHHS it recognizes that e-cigarettes are substantially less risky than tobacco cigarettes.[45]

DHHS endorsement of Nicotine Replacement Therapies (NRTs)

In 2008, DHHS published guidelines recommending that clinicians "encourage all patients attempting to quit [smoking] to use effective medications for tobacco dependence treatment except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness."[46] However, the studies cited in support of NRTs were acknowledged to have serious methodological limitations[47] and the cited evidence of effectiveness was weak.[48] Despite these problems, the clinical practice guidelines panel gave the strength of evidence an "A" grade.[49]

These guidelines appear not to have been updated. However, since then, a substantial amount of literature has been published that suggests that FDA-approved NRTs are much less effective than they were claimed to be in 2008, and there is evidence that physicians are not adhering to the clinical guidelines.[50]

For example, a 2010 study attempted to estimate the effectiveness on Medicaid enrollees of a 2006 Massachusetts statute that mandated that all insurers provide NRTs.[51] At that time, an estimated 16% of Massachusetts residents participated in Medicaid. The authors estimate a 15% per-year

39. Nicole M. Kuiper et al., "Evidence of Effectiveness: A Summary of State Tobacco Control Program Evaluation Literature," Centers for Disease Control and Prevention, 2005. https://www.cdc.gov/tobacco/tobacco_control_programs/program_development/sustainingstates/pdfs/lit_review.pdf.

40. Agency for Healthcate Research and Quality, "Research and Tools Data," U.S. Dept. of Health and Human Services, 2017. https://www.ahrq.gov/research/index.html.

41. Agency for Healthcate Research and Quality, "Treating Tobacco Use and Dependence: 2008 Update," U.S. Dept. of Health and Human Serivces, 2008. https://www.AHRQ.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html#Clinic.

42. See, e.g., Michael C. Fiore et al., "Clinical Practice Guideline—Treating Tobacco Use and Dependence: 2008 Update," U.S. Dept. of Health and Human Services, 2008. https://bphc.hrsa.gov/buckets/treatingtobacco.pdf. At the time, the FDA was actively preventing the importation of e-cigarettes on the grounds that they were unapproved drug-device combination products. See, e.g., *E-Cigarette Use Among Youth and Young Adults*. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

43. World Health Organization, "Who Model Lists of Essential Medicines," March 2017. http://www.who.int/medicines/publications/essentialmedicines/en.

44. See World Health Organization, "Essential Medicines, 2017. http://www.who.int/medicines/services/essmedicines_def/en/.

45. WHO's language appears to be a compromise intended to give both sides something: "If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, *and eventually stop using it*, this would represent a significant contemporary public health achievement" (emphasis added). See World Health Organization, "Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)," FCTC/COP/7/11, Conference of the Parties to the WHO Framework Convention on Tobacco Control, August 2016, 2. http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1&ua=1. A different WHO report offers support for e-cigarettes with minimal caveats. See, e.g., World Health Organization, "WHO Study Group on Tobacco Product Regulation," *WHO Technical Report Series* No. 989, 2015. http://apps.who.int/iris/bitstream/10665/161512/1/9789241209892.pdf?ua=1&ua=1.

46. Fiore et al., 106.

47. e.g., self-selection and confounding

48. Fiore et al. Estimated mean abstinence effectiveness rates for studies of front-line monotherapy NRTs ranged from 19% to 33% with low odds ratios [1.5 to 3.1]. Results from studies of combination therapies had reported abstinence effectiveness rates ranging from 7.3% to 36.5%, and odds ratios ranging from 2.0 to 3.6. The effect of specific NRTs is difficult or impossible to discern in combination studies, and non-probability samples make odds-ratio calculations statistically suspect because they presume sample properties not demonstrated to be present.

49. An "A" grade means "[m]ultiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings." See, Fiore et al.

50. Kelly L. Kandra, Leah M. Ranney et al., "Physicians' Attitudes and Use of E-Cigarettes as Cessation Devices, North Carolina, 2013," PLoS ONE 9:7 (July 29, 2014), e103462. http://dx.doi.org/10.1371%2Fjournal.pone.0103462

51. Thomas Land, Donna Warner et al., "Medicaid Coverage for Tobacco Dependence Treatments in Massachusetts and Associated Decreases in Smoking Prevalence," *PLOS ONE* 5:3 (March 18, 2010), e9770. http://dx.doi.org/10.1371%2Fjournal.pone.0009770.

reduction in smoking prevalence, with notable differences by age, race and ethnicity but not by sex. The authors infer that this reduction was the result of the NRT program, but their methodology included no data on NRTs. Further, they did not control for such likely confounders as the universal nature of the initiative, other program elements besides NRT, extensive public service announcements and advertising by NRT manufacturers or the $1 per-pack increase in the state's cigarette tax.

Subsequently, four Cochrane Collaborative systematic reviews of NRT effectiveness have been performed to assess the evidence.[52] The authors concluded that all FDA-approved NRTs were effective. Odds ratios for increases in quit rates were estimated at 1.74 (2002) and 1.77 (2004),[53] and in later studies relative risks (for abstinence) were estimated at 1.58 (2008) and 1.60 (2012).[54] These results are contested, as others have found very little evidence of effectiveness in "real-life" situations (as opposed to placebo controlled trials).[55] In a probability sample of 787 Massachusetts adult smokers who had recently quit smoking, the rate of relapse was the same whether or not they used NRTs.[56] A randomized, placebo-controlled design to study the effect of NRTs on over 1,000 pregnant women revealed no enduring effect of nicotine patches on smoking.[57] A meta-regression analysis of the studies in one of the Cochrane reviews found multiple sources of systematic bias[58] that were associated with increases in reported effectiveness. Higher quality studies reported much smaller effects, and the methods in the Cochrane review had given undue weight to studies that contained one or more systematic biases. Only 4% of the studies had an 80% chance of detecting the claimed 50% effect.[59] For these reasons, confidence in studies that report high effectiveness rates for NRTs therefore may be misplaced.[60]

In sum, evidence supporting the effectiveness of NRTs appears to be much weaker than advertised, but this is not well known.[61] Whereas regulatory agencies normally impose demanding evidentiary standards for the approval of pharmacologic agents and devices, that stringency appears to be lacking when it comes to NRTs. Accordingly, an interesting research question that is not undertaken here is whether e-cigarettes would fare as well as NRTs if they were subjected to the same standard of review. This question is relevant because it speaks to the likelihood that premarket review applications submitted to the FDA by e-cigarette manufacturers will be approved.

Affordable Care Act inclusion of NRTs as "essential benefits"

The Affordable Care Act (ACA) delegated to DHHS the authority to determine what medical care services were "preventative" and mandate that private insurers include first-dollar coverage for them. Specifically, section 2502(a) mandates that private insurers cover NRTs. However, the ACA did not impose this requirement on state Medicaid programs. Rather, DHHS "encourages our state partners" to include them, typically on the grounds that doing so would

52. See, e.g., C. Silagy, T. Lancaster et al., "Nicotine Replacement Therapy for Smoking Cessation," *The Cochrane Database of Systematic Reviews* 4 (2002). https://www.ncbi.nlm.nih.gov/pubmed/12519537; C. Silagy, T. Lancaster et al., "Nicotine Replacement Therapy for Smoking Cessation," *The Cochrane Database of Systematic Reviews* 3 (2004). https://www.ncbi.nlm.nih.gov/pubmed/15266423; Linsday F. Stead, Rafael Perera et al., "Nicotine Replacement Therapy for Smoking Cessation," *Cochrane Database of Systematic Reviews* 11 (Nov. 14, 2012). https://www.ncbi.nlm.nih.gov/pubmed/23152200; and Lindsay F. Stead, Rafael Perera et al., "Nicotine Replacement Therapy for Smoking Cessation," *Cochrane Database of Systematic Reviews* 1 (2008). http://www.ncsct.co.uk/usr/pub/nicotine-replacement-therapy.pdf.

53. Silagy, Lancaster et al. (2002), 1; and Silagy, Lancaster et al. (2004), 1.

54. Stead, et al. (2008), abstract; Stead, et al. (2012), 2.

55. See, e.g., Giuseppina Casella, Pasquale Caponnetto et al., "Therapeutic Advances in the Treatment of Nicotine Addiction: Present and Future," *Therapeutic Advances in Chronic Disease* 1:3 (2010), 95-106. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513862/pdf/10.1177_2040622310374896.pdf. The authors have also conducted research on e-cigarettes and have recommended their adoption to reduce health risks from smoking. See, e.g., Riccardo Polosa, Pasquale Caponnetto et al., "Effect of an Electronic Nicotine Delivery Device (E-Cigarette) on Smoking Reduction and Cessation: A Prospective 6-Month Pilot Study," *BMC Public Health* 11:1 (2011), 1. https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-786; Pasquale Caponnetto, Davide Campagna et al., "The Emerging Phenomenon of Electronic Cigarettes," *Expert Review of Respiratory Medicine* 6:1 (February 2012), 63-74. https://www.researchgate.net/profile/Pasquale_Caponnetto2/publication/221783238_The_emerging_phenomenon_of_electronic_cigarettes/links/544912920cf2f6388080d08c.pdf; Pasquale Caponnetto, Davide Campagna et al., "Efficiency and Safety of an Electronic Cigarette (Eclat) as Tobacco Cigarettes Substitute: A Prospective 12-Month Randomized Control Design Study," *PloS one* 8:6 (June 2013), e66317. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0066317; Riccardo Polosa, Brad Rodu et al., "A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette," *Harm Reduction Journal* 10:1 (2013), 19. https://harmreductionjournal.biomedcentral.com/articles/10.1186/1477-7517-10-19; and Riccardo Polosa, Jaymin B Morjaria et al., "Effectiveness and Tolerability of Electronic Cigarette in Real-Life: A 24-Month Prospective Observational Study," *Internal and Emergency Medicine* 9:5 (July 2013), 537-46. https://www.researchgate.net/publication/250924522_Effectiveness_and_tolerability_of_electronic_cigarette_in_real-life_A_24-month_prospective_observational_study.

56. Hillel R. Alpert, Gregory N. Connolly et al., "A Prospective Cohort Study Challenging the Effectiveness of Population-Based Medical Intervention for Smoking Cessation," *Tobacco Control* 22:1 (2013), 32-37. http://tobaccocontrol.bmj.com/content/22/1/32.info.

57. Sue Cooper, Sarah Lewis et al., "The Snap Trial: A Randomised Placebo-Controlled Trial of Nicotine Replacement Therapy in Pregnancy – Clinical Effectiveness and Safety until 2 Years after Delivery, with Economic Evaluation," *Health Technology Assessment* 18:54 (August 2014). https://www.ncbi.nlm.nih.gov/books/NBK262433.

58. e.g., publication, reporting and small-sample

59. T.D. Stanley and Shelby Massey, "Evidence of Nicotine Replacement's Effectiveness Dissolves When Meta-Regression Accommodates Multiple Sources of Bias," *Journal of Clinical Epidemiology* 79 (November 2016): 41-45. http://www.jclinepi.com/article/S0895-4356(16)30075-0/abstract. This study analyzes the same NRT studies reviewed by Stead et al. (2012), 41. https://www.ncbi.nlm.nih.gov/pubmed/23152200.

60. See, e.g., Cameron A. MacKenzie, "Summarizing Risk Using Risk Measures and Risk Indices," *Risk Analysis* 34:12 (2014), 2143-62. https://calhoun.nps.edu/bitstream/handle/10945/39503/MacKenzie Summarizing Risk Using Risk Measures and Risk Indices.pdf?sequence=1.

61. As of January 2017, the four iterations of the Cochrane Collaborative review had been cited thousands of times; Stanley and Massey's meta-regression analysis (2016) had been cited only three times other than by the authors themselves.

save them money.[62] Promotion of e-cigarettes as NRTs likely would save the states money, too, but there is no public evidence that DHHS is willing to permit this.

Institutional opposition to e-cigarettes within the DHHS

DHHS officials have been opposed to e-cigarettes since at least 2009.[63] This opposition has several substantive elements. First, e-cigarettes contain chemicals other than nicotine that may pose health risks. Second, e-cigarettes that contain nicotine pose the same addiction risks as tobacco cigarettes. Third, consumers of e-cigarettes may switch to tobacco cigarettes. Fourth, e-cigarettes may be appealing to underage consumers, particularly because of added flavorings not found in tobacco products. And finally, e-cigarettes may cause underage consumers to take up smoking.[64]

It is possible, therefore, that savings to Medicaid programs that result from smokers switching to vaping could be diminished due to incipient vaping risks. Based on the available evidence, however, this concern appears to be speculative. Even under reasonable worst-case scenarios, programmatic expenditures on treating unknown future illnesses caused by e-cigarettes appear to be trivial compared to expenditures treating known smoking-related harms.

Opposition to e-cigarettes also has important strategic elements. For example, until promulgation of the Deeming Rule, e-cigarettes were not regulated by the FDA. This left market forces to determine the extent to which e-cigarettes could substantially drive tobacco out of the nicotine market through competition. But the absence of regulation is commonly viewed as problematic within the public health community generally, and in its anti-tobacco wing, in particular.[65]

A second, and possibly transcendent aspect of the public health establishment's growing opposition to e-cigarettes is the result of its long war with "Big Tobacco." For e-cigarettes to substantially displace tobacco, only major companies have the capital, manufacturing capacity and distribution networks necessary to market e-cigarettes at the intensity required. For many, opposition, then, is justified and must be sustained irrespective of the public health benefits e-cigarettes offer because Big Tobacco is an inherently immoral force. But this community also is convinced of the opposite position: that Big Tobacco will never voluntarily relinquish its primary business. Reconciling these contradictory positions is hard but not theoretically impossible.[66]

In sum, DHHS and the broader public health establishment have sustained decades of opposition to both smoking and the firms that manufacture tobacco products and with limited exceptions they have extended that opposition to e-cigarettes. This institutionalized opposition can be expected to aggressively defend this position within the academy, scholarly journals, federal grant cycles and the regulatory state. Further, the FDA's Center for Tobacco Products, established by the TCA, is not led by a political appointee so it can be expected to resist alternative executive branch leadership. For example, as of December 2016, 33 applications had been submitted seeking FDA approval to market what the TCA calls "modified risk tobacco products."[67] None were for e-cigarettes, and in any case the Center had not approved a single application.

There is some evidence that the public health establishment's systemic disapproval of e-cigarettes is not shared by practicing physicians. In response to a representative survey, about two-thirds of North Carolina physicians agreed that e-cigarettes lower cancer risk.[68] Physicians who are frequently asked about e-cigarettes by their patients were significantly more likely to recommend them.[69] Moreover, CMS does not appear to have played a significant role in the DHHS position. To the extent that CMS has its own interest in controlling expenditures on smoking-related illnesses, however, it has an incentive to be wary of—if not opposed to—the establishment's position.

Neither the FDA Deeming Rule nor other DHHS policies and initiatives go so far as to redefine vaping as "smoking."

62. The CMS claims that the "'cost per quit' of smoking cessation interventions ranges from a few hundred to a few thousand dollars, while the average cost for treating a single case of lung cancer can be over $40,000." However, no source for these figures is cited. DHHS also cites a Massachusetts Medicaid program reported to have reduced smoking from 37% to 28%, with a $2.12 return on each $1.00 invested. However, the program evaluation from which these results are obtained is not identified. See, e.g., "Tobacco Cessation," Centers for Medicare and Medicaid Services, 2017. https://www.medicaid.gov/medicaid/quality-of-care/improvement-initiatives/tobacco/index.html.

63. See, e.g., U.S. Food and Drug Administration, "FDA and Public Health Experts Warn About Electronic Cigarettes," Press Release, July 22, 2009. https://web.archive.org/web/20090724133750/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm; and U.S. Food and Drug Administration, "FDA Warns of Health Risks Posed by E-Cigarettes," July 2009. https://www.deanza.edu/healthservices/ecigarettes_0709.pdf.

64. If true, the fifth substantive element (e-cigarettes as a gateway to smoking) would increase Medicaid expenditures, but the likelihood of its occurrence is diminished to the extent that the fourth substantive element (underage consumers are attracted by flavorings) is true. Flavorings except menthol are not permitted in tobacco cigarettes.

65. See, e.g., Anna Trtchounian and Prue Talbot, "Electronic Nicotine Delivery Systems: Is There a Need for Regulation?", Tobacco Control 20 (2011), 47. http://tobaccocontrol.bmj.com/content/20/1/47.info.

66. For a simultaneous recital and endorsement of these contradictory views, see Nathan K. Cobb and David B. Abrams, "The FDA, E-Cigarettes, and the Demise of Combusted Tobacco," *New England Journal of Medicine* 371:16 (Oct. 16, 2014), 1469-71. http://www.nejm.org/doi/full/10.1056/NEJMp1408448 - t=article.

67. U.S. Food and Drug Administration, "Modified Risk Tobacco Products: Summary of MRTP Application Actions," U.S. Dept. of Health and Human Services, May 24, 2017. https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm304465.htm.

68. Kandra, Ranney et al., 1. http://dx.doi.org/10.1371%2Fjournal.pone.0103462.

69. Ibid.

However, an implicit redefinition appears to be underway. For example, the 2016 Surgeon General Report approvingly cites examples of local government ordinances that make little or no distinction between smoking and vaping.[70] Also, the CDC has redefined tobacco use to include e-cigarettes and has issued reports that are likely (and possibly designed) to mislead the public in that they combine tobacco and e-cigarette use.[71]

Potential changes in DHHS policies

In July 2017, FDA Commissioner Scott Gottlieb announced new policies that could affect the e-cigarette market:

> I've pledged a deep commitment to taking aggressive steps to address the epidemic of addiction to opioids. I view our opportunity to confront addiction to nicotine with the same obligation. I'll pursue efforts to reduce addiction to nicotine with the same vigor.[72]

Accordingly, the FDA has postponed the premarket approval deadline to August 8, 2022, so the space may be created for e-cigarettes to survive.[73] However, this appears to be only a temporary reprieve. Besides the postponement, Gottlieb ratified the FDA's Deeming Rule, elevated the regulation of nicotine to the same status as opioids,[74] and attacked nicotine delivery[75] per se in order to significantly reduce the legally permissible nicotine content.[76] This is likely to limit the potential future market space for e-cigarettes.

STATE AND LOCAL REGULATORY POLICIES

The police powers enjoyed by the states under the U.S. Constitution clearly include matters of public health and safety, and states that regulate e-cigarettes do so based on these powers. Public health is therefore the rationale for regulating the sale and use of tobacco, and these regulations increasingly are being extended to e-cigarettes.

The Public Health Law Center, an advocacy organization opposed to both smoking and vaping, reports that as of September 15, 2016, 12 states plus the District of Columbia had established sale and use restrictions on vaping similar or identical to those for tobacco cigarettes.[77] In some jurisdictions, restrictions applied only to e-cigarettes that contain nicotine derived from tobacco, but as a practical matter, any use restriction applies irrespective of the presence of nicotine or its source.[78]

A common justification offered for use regulation is that e-cigarettes may lead teens to smoke, but the evidence that supports this hypothesis is limited.[79] Even if this rationale is assumed to be valid, ten of the 13 jurisdictions that regulate e-cigarettes as tobacco also permit the sale and unregulated use of marijuana—a Federal Schedule I controlled substance.[80] California, which has one of the most lenient state laws with respect to marijuana, restricts access to e-cigarettes to those 21 years of age and older because e-cigarettes are regulated as tobacco products.[81]

New legislation may be necessary to define vaping as smoking, at least for criminal sanctions. A New York City court recently ruled against the government's prosecution of a vaper for alleged violation of New York State smoking restrictions because the law defined smoking as "the burning of a lighted cigar, cigarette, pipe or any other matter or substance which contains tobacco."[82] The court dismissed the

70. See *E-Cigarette Use among Youth and Young Adults*. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf. Among other things, Hayward's ordinance required seller of e-cigarettes "to obtain annually a $400 tobacco retailer license that covers the cost of an annual inspection for compliance with federal, state, local, tribal, and territorial tobacco control laws" (p. 224). It also bans new vaping lounges from operating in the city—a provision much more restrictive than requirements imposed on new tobacco sellers. Further, it protects incumbents by prohibiting new tobacco sellers from opening up within 500 feet of an existing tobacco seller.

71. See, e.g., Ahmed Jamal, "Tobacco Use among Middle and High School Students — United States, 2011–2016," *Morbidity and Mortality Weekly Report* 66:23 (June 16, 2017): 597-603. https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w.

72. Scott Gottlieb, "Protecting American Families: Comprehensive Approach to Nicotine and Tobacco," Office of the Commissioner of the U.S. Food and Drug Administration, July 28, 2017. https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm.

73. 82 Fed. Reg. 153 (August 10 2017), 37459-61. The e-cigarette industry is less sanguine about the practical utility of this delay. See Steve Birr, "FDA Gives Vaping Industry Breathing Room on Costly Product Reviews," *The Daily Vaper*, July 28, 2017. http://dailyvaper.com/2017/07/28/surprise-fda-announcement-pushes-off-date-for-reviewing-vaping-products. Birr quotes the general counsel of Nicopure Labs: "[T]he [D]eeming [R]ule as a whole still does not change and it still does not take into consideration the harm reduction potential of e-cigarettes. The grandfather date stays the same, and we still cannot launch new products or improve on existing ones to keep up with advances in technology."

74. Gottlieb. https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm.

75. Ibid.

76. Ibid.

77. The 12 State jurisdictions are California, Colorado, District of Columbia, Hawaii, Indiana, Maine, Minnesota, North Carolina, Pennsylvania, South Dakota, Utah, West Virginia, Wyoming.

See, e.g., "U.S. E-Cigarette Regulations - 50 State Review (2016)," Public Health Law Center, Mitchell Hamline School of Law, 2016. http://www.publichealthlawcenter.org/sites/default/files/E-Cigarette-Legal-Landscape-50-State-Review-November-2016.pdf; and "U.S. E-Cigarette Regulations - Washington DC," Public Health Law Center, Mitchell Hamline School of Law, 2017. http://www.publichealthlawcenter.org/resources/e-cigarette-regulations-washington-dc.

78. It is unclear what public health argument might be crafted that scientifically distinguishes between tobacco and non-tobacco sources of nicotine.

79. See, e.g., Jamal, 597-603. https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w.

80. Of the jurisdictions listed above, only Indiana, South Dakota and West Virginia have not enacted statutes that ostensibly provide for legalized medical use only. See, e.g., "Legal Information by State & Federal Law," Americans for Safe Access, 2017. http://www.safeaccessnow.org/state_and_federal_law.

81. "Clearing the Air on California's New Tobacco, E-Cigarette Law," *Sacramento Bee*, June 9, 2016. http://www.sacbee.com/news/state/california/article82815702.html.

82. *People v. Thomas*, (Criminal Court of the City of New York, Kings County, 2016), Slip Op 26033 (Feb. 5, 2016), p. 6. https://law.justia.com/cases/new-york/other-courts/2016/2016-ny-slip-op-26033.html.

case, noting that "[a]n electronic cigarette neither burns nor contains tobacco."[83] Whether other states have succeeded in defining vaping as smoking requires additional research, but in all likelihood they will do so.

CONSUMER RISK PERCEPTIONS

There is persuasive empirical evidence that smokers and nonsmokers alike have exaggerated perceptions of the risks from both smoking[84] and e-cigarettes.[85] This leads some smokers to quit who otherwise would not and fewer smokers to switch to e-cigarettes. The net effect of exaggerated risk perceptions is difficult to discern. Smokers' perceptions of the efficacy of approved NRTs adds additional uncertainty, particularly given empirical evidence that NRTs are less effective than advertised and e-cigarettes are at least as effective as NRTs as smoking cessation tools, despite not being legally recognized as NRTs.

The FDA Deeming Rule sustains these exaggerated risk perceptions, and possibly intensifies them by signaling that e-cigarettes must be as risky as tobacco. To legally convey truthful risk information to consumers, manufacturers of e-cigarettes and related products must first obtain permission from the FDA pursuant to TCA § 911(g), which includes specific risk-based standards that e-cigarettes likely would be able to traverse if the FDA's determinations were based on scientific evidence alone.[86] The agency's discretion appears to be expansive, however, which makes the result of an application unpredictable.[87] Recent applications have been denied on the grounds that risk was not zero or biologically infeasible.[88] Accordingly, to open regulatory space for e-cigarettes, even if only temporarily, Commissioner Gottlieb must revise the FDA's criteria for evaluating § 911 petitions so that lower (and not just zero) risk products can be approved.

THE POLITICALLY CHARGED NATURE OF RELEVANT SCIENTIFIC RESEARCH

Objective review and analysis are hampered because the scholarly literature is frequently mixed with and sometimes wholly subsumed within an anti-tobacco public health agenda. This was true when the market consisted of only tobacco cigarettes and it remains so with the entry of e-cigarettes. This conflation of science and policy has resulted in both the politicization of science and the "scientization" of policy. The politicization of science is generally understood to occur when policy preferences invade the domain of science by demanding policy-preferred research outcomes. While accusations of politicization typically are leveled against agency officials, tobacco research is so politicized that it no longer attracts notice. Moreover, the science of tobacco has been substantially politicized by scientists themselves. Some scientific journals are devoted to the policy mission of smoking control, and it is impossible for any policy mission not to affect science.

By contrast, the "scientization" of policy is poorly understood and rarely recognized. It arises when science (the study of what is) invades the domain of policymaking (what ought to be). It can be detected when scientists or policymakers assert that science can and should resolve policy disputes instead of informing policy debate. Like politicization, scientization is widely embedded both in academia and in federal and state regulatory agencies. Agency scientists often desire to influence policy, and agency officials often prefer not to be held responsible for policy choices they have been delegated to make.

E-cigarettes have contributed an important change to the scientific environment. Though unwaveringly anti-tobacco, the public health community is now split. The majority appears to consider e-cigarettes the same as tobacco, while a minority considers e-cigarettes a valuable tool to reduce public health risks from smoking. The majority promotes research that attests to the dangers of e-cigarettes and advocates their regulation under identical terms as tobacco.[89] The minority promotes research that attests to the relative safety of e-cigarettes compared to tobacco, and advocates their promotion for health risk reduction.[90] These perspectives are irreconcilable, and they signal that all scholarly literature on

83. Ibid.

84. W. Kip Viscusi, "Do Smokers Underestimate Risks?", *Journal of Political Economy* 98:6 (1990), 1253-69. https://www.jstor.org/stable/2937757?seq=1 - page_scan_tab_contents; W. Kip Viscusi, "Risk Beliefs and Preferences for E-Cigarettes," American Journal of Health Economics 2:2 (May 1, 2016), 213-40. https://law.vanderbilt.edu/phd/faculty/w-kip-viscusi/347_Risk_Beliefs_and_Preferences_for_E_cigarettes.pdf.

85. Marc T. Kiviniemi and Lynn T. Kozlowski, "Deficiencies in Public Understanding About Tobacco Harm Reduction: Results from a United States National Survey," *Harm Reduction Journal* 12:1 (2015), 2. http://dx.doi.org/10.1186/s12954-015-0055-0.

86. TCS § 911 (Modified Risk Tobacco Products), subsection (g) (Marketing), 123 Stat. 1814-1816 https://www.gpo.gov/fdsys/pkg/STATUTE-123/pdf/STATUTE-123-Pg1776.pdf#page=11.

87. A manufacturer seeking an FDA order approving a "modified risk product" must demonstrate that the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" and "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products" (TCA § 911(g)(1)(A)-(B)). The FDA's discretion to consider nonscientific factors in making its determinations is substantial. TCA § 911(g)(3) generally requires the FDA to make a scientific determination based on an applicant's submission, but it appears to also allow the FDA to take account of nonscientific policy considerations ("The determination ... shall be based on (A) the *scientific evidence* submitted by the applicant; and (B) scientific evidence and *other information* that is made available to the Secretary" [emphasis added]).

88. "Modified Risk Tobacco Products: Summary of MRTP Application Actions." https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533753.htm.

89. See, e.g., Arch G. Mainous, Rebecca J. Tanner et al., "Health Considerations in Regulation and Taxation of Electronic Cigarettes," *The Journal of the American Board of Family Medicine* 28:6 (November-December 2015), 802-06. http://www.jabfm.org/content/28/6/802.full.

90. See, e.g., Daniella Saitta et al., "Achieving Appropriate Regulations for Electronic Cigarettes," *Therapeutic Advances in Chronic Disease*, 5:2 (2014), 50-61. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3926346/pdf/10.1177_2040622314521271.pdf.

tobacco and e-cigarettes should be subjected to the strictest scrutiny for error and bias.

EXPECTED COST-SAVINGS FROM SWITCHING TO E-CIGARETTES

The following section summarizes the results of the analysis estimating state-level cost-savings to Medicaid expected to result from non-aged, non-disabled adults enrolled in Medicaid who are everyday smokers. Nonsmokers and occasional smokers are excluded, as are the aged and disabled for whom smoking-related medical care costs are especially difficult to estimate.

Specific Methodology

These estimates consist of several parts. First, current and future smoking prevalence was estimated by state for the general population, taking age, sex, race and ethnicity, and educational attainment into account. Each of these demographic variables correlates with smoking prevalence, and interstate differences are substantial. There is persuasive evidence that smoking prevalence is higher for Medicaid enrollees than for the general public, but no reliable public data was available to capture state-level differences. In lieu of such data, state-level smoking prevalence rates for 18 to 24-year olds with less than a 12th grade education was used as a proxy, which enables the analysis to capture demographic differences at the state level.

Second, state-level Medicaid expenditures on smoking-related illness were estimated. These estimates are fraught with uncertainty because of two types of classification challenges. One involves distinguishing between smoking-related and other medical care expenses. Even expenditures on medical conditions known to be caused by smoking (e.g., lung cancer) cannot be assumed to be smoking-related because these conditions have other causes. Classification becomes more challenging as the causal nexus from smoking to health effect weakens, or as other causes dominate.

Third, estimates were derived for the temporal reduction in smoking-related expenditures per program participant who switched to e-cigarettes. These reductions would not occur immediately. Rather, they would be delayed in accordance with the expected biological lags associated with reduced health effects subsequent to smoking cessation. Based on the official literature, it is assumed that switching from tobacco to e-cigarettes results in the same reductions in morbidity and further, that medical care expenditures by Medicaid decline 5% per year for the first 15 years after switching and remain constant thereafter. Cost savings to Medicaid are assumed to terminate after 25 years; subsequent cost savings are assumed to be captured by Medicare.

Given this 25-year time horizon, the analysis must confront two key dynamic effects. One is the longstanding historic increase in per-capita medical care costs, which is expected to continue at an inflation-adjusted rate of 2.8% per year. The other effect is the time-value of money, which puts a lower value on cost-savings in later years. While the "correct" rate of discount for future cost savings is unknown, the market interest rate on long-term federal bonds is about 2.6%. These effects operate in opposite directions. Given uncertainties in forecasting both phenomena, it is assumed that the rate of increase in medical care costs equals the discount rate. This allows cost savings to be totaled without adjustments for rising costs or the time-value of money.

Fourth, cost-savings per Medicaid enrollee who switches are multiplied by the estimated number of enrollees who switch. Ideally, switching behavior could be estimated from empirical evidence. However, the available evidence of voluntary switching comes from experimental studies of e-cigarette products rather than real-world conditions. There is persuasive evidence that the propensity to switch is at least as great as the cessation rates obtained in studies of nicotine replacement therapies. But NRT studies are handicapped by a different and more challenging objective – the elimination of nicotine. Moreover, there is persuasive research that indicates that statistically significant reductions in tobacco cigarette use purportedly resulting from NRTs may not be reliable.

Because of these uncertainties and controversies, rates of voluntary switching behavior are not estimated. Instead, a standardized switch cohort is devised that consists of 1% of adult Medicaid enrollees who smoke from each state (and the District of Columbia), disaggregated by demographic group. This percentage was chosen to provide a noncontroversial building block from which estimates could later be constructed for specified changes in the market share of e-cigarettes and/or policy changes that would make e-cigarettes relatively more attractive than tobacco ones.[91]

Results

Cost-savings over 25 years per Medicaid enrollee who switches from tobacco to e-cigarettes (Table 1) range from about $11,000 in Arkansas to $41,000 in Montana. Cost-savings in the median jurisdiction are about $24,000.[92]

Table 2 reports 25-year present value cost-savings for the standardized switch cohort by state and demographic group. Total cost-savings are about $2.8 billion and are concentrated in a handful of states; three of the 51 jurisdictions—Califor-

91. The complete estimation procedure is provided in the online Appendix, along with intermediate results.

92. Cost-savings are reported with two significant figures to reflect data uncertainties and to deter inferences of excess precision.

TABLE I: ESTIMATED COST-SAVINGS TO MEDICAID FROM THE STANDARDIZED SWITCH COHORT, BY STATE

State	Cost Savings ($K)
AK	$31
AL	$20
AR	$11
AZ	$32
CA	$18
CO	$18
CT	$31
DC	$24
DE	$37
FL	$17
GA	$30
HI	$27
IA	$17
ID	$23
IL	$17
IN	$24
KS	$20
KY	$24
LA	$17
MA	$18
MD	$31
ME	$17
MI	$20
MN	$27
MO	$20
MS	$19

State	Cost Savings ($K)
MT	$41
NC	$24
ND	$28
NE	$26
NH	$24
NJ	$25
NM	$20
NV	$13
NY	$29
OH	$19
OK	$18
OR	$31
PA	$21
RI	$33
SC	$20
SD	$20
TN	$25
TX	$26
UT	$36
VA	$34
VT	$28
WA	$36
WI	$18
WV	$12
WY	$21
Median	$24

nia, New York, and Ohio—capture 26% of the total ($870 million)

Even though women have a lower smoking prevalence than men, they comprise a much larger fraction of adult Medicaid enrollees. Thus, women in the standardized switch cohort contribute 61% of total cost-savings. Blacks and Hispanics contribute 23% and 16% of total savings, respectively. These ratios reflect proportional representation in the standardized switch cohort, so they would be different if the inherent propensity to switch differs by sex, race or Hispanic ethnicity, or if a state successfully targeted a particular demographic group with a switching campaign.

If the 1% standardized cohort switched in a given year, it seems plausible that similarly sized cohorts would switch in subsequent years. This could occur with or without market changes or policy intervention because, for example, members of the index cohort could motivate others to switch by example. The cost-savings for a 10-year series of 1% standardized switch cohorts would be 10 times the savings estimated here, or about $28 billion nationwide. Similar calculations can be performed for larger standardized cohorts, though care must be taken to account for countervailing financial effects.

STRENGTHS AND LIMITATIONS OF THIS ANALYSIS

All empirical studies have strengths and limitations and it is the duty of responsible analysts to acknowledge them.

Cost-savings estimates presented here are affected by significant uncertainties. Some of these uncertainties are

TABLE 2: COST-SAVINGS FOR THE STANDARDIZED SWITCH COHORT, BY STATE AND DEMOGRAPHIC GROUP

State	Male not Black not Hispanic	Male Black not Hispanic	Male not Black Hispanic	Female not Black not Hispanic	Female Black not Hispanic	Female not Black Hispanic	Total
AK	$3,800,000	$280,000	$120,000	$3,900,000	$290,000	$130,000	$8,500,000
AL	$6,000,000	$3,500,000	$260,000	$8,200,000	$4,600,000	$350,000	$23,000,000
AR	$10,000,000	$3,600,000	$1,100,000	$12,000,000	$4,300,000	$1,400,000	$32,000,000
AZ	$14,000,000	$2,200,000	$9,400,000	$14,000,000	$2,200,000	$9,600,000	$51,000,000
CA	$90,000,000	$18,000,000	$75,000,000	$120,000,000	$24,000,000	$100,000,000	$430,000,000
CO	$15,000,000	$1,600,000	$7,100,000	$17,000,000	$1,800,000	$8,300,000	$51,000,000
CT	$8,300,000	$4,100,000	$2,900,000	$8,800,000	$4,500,000	$3,200,000	$32,000,000
DC	$780,000	$5,400,000	$47,000	$750,000	$5,300,000	$45,000	$12,000,000
DE	$2,500,000	$2,000,000	$390,000	$2,800,000	$2,200,000	$440,000	$10,000,000
FL	$32,000,000	$18,000,000	$11,000,000	$35,000,000	$19,000,000	$12,000,000	$130,000,000
GA	$9,100,000	$8,600,000	$47,000	$10,000,000	$10,000,000	$56,000	$38,000,000
HI	$6,500,000	$120,000	$340,000	$5,900,000	$110,000	$320,000	$13,000,000
IA	$11,000,000	$710,000	$570,000	$11,000,000	$810,000	$670,000	$25,000,000
ID	$3,000,000	$2,900	$12,000	$2,700,000	$2,900	$12,000	$5,800,000
IL	$28,000,000	$21,000,000	$8,800,000	$42,000,000	$25,000,000	$11,000,000	$130,000,000
IN	$21,000,000	$5,800,000	$1,900,000	$23,000,000	$6,700,000	$2,200,000	$60,000,000
KS	$4,500,000	$1,000,000	$900,000	$5,000,000	$1,200,000	$1,000,000	$14,000,000
KY	$23,000,000	$3,500,000	$620,000	$25,000,000	$3,800,000	$700,000	$57,000,000
LA	$12,000,000	$14,000,000	$290,000	$15,000,000	$17,000,000	$370,000	$59,000,000
MA	$30,000,000	$2,900,000	$1,400,000	$30,000,000	$2,900,000	$1,400,000	$68,000,000
MD	$9,800,000	$11,000,000	$1,000,000	$11,000,000	$12,000,000	$1,100,000	$46,000,000
ME	$7,100,000	$230,000	$69,000	$7,200,000	$240,000	$72,000	$15,000,000
MI	$42,000,000	$20,000,000	$2,200,000	$47,000,000	$22,000,000	$2,500,000	$130,000,000
MN	$14,000,000	$3,700,000	$1,100,000	$17,000,000	$4,400,000	$1,400,000	$41,000,000
MO	$10,000,000	$3,700,000	$440,000	$12,000,000	$4,400,000	$540,000	$32,000,000
MS	$4,000,000	$5,500,000	$72,000	$5,000,000	$6,900,000	$92,000	$22,000,000
MT	$5,200,000	$50,000	$140,000	$5,500,000	$54,000	$160,000	$11,000,000
NC	$13,000,000	$9,200,000	$1,300,000	$15,000,000	$11,000,000	$1,600,000	$51,000,000
ND	$1,800,000	$100,000	$59,000	$2,100,000	$130,000	$72,000	$4,300,000
NE	$2,300,000	$430,000	$380,000	$2,500,000	$470,000	$430,000	$6,500,000
NH	$3,200,000	$91,000	$140,000	$3,400,000	$97,000	$160,000	$7,100,000
NJ	$16,000,000	$7,900,000	$3,400,000	$18,000,000	$8,900,000	$3,900,000	$59,000,000
NM	$6,700,000	$320,000	$7,000,000	$7,600,000	$360,000	$8,200,000	$30,000,000
NV	$6,300,000	$2,300,000	$2,900,000	$6,900,000	$2,600,000	$3,300,000	$24,000,000
NY	$67,000,000	$41,000,000	$22,000,000	$71,000,000	$43,000,000	$24,000,000	$270,000,000
OH	$55,000,000	$23,000,000	$1,600,000	$62,000,000	$26,000,000	$1,800,000	$170,000,000
OK	$8,700,000	$1,600,000	$1,300,000	$9,900,000	$1,800,000	$1,500,000	$25,000,000
OR	$17,000,000	$950,000	$3,900,000	$18,000,000	$1,000,000	$4,300,000	$45,000,000

State	Male not Black not Hispanic	Male Black not Hispanic	Male not Black Hispanic	Female not Black not Hispanic	Female Black not Hispanic	Female not Black Hispanic	Total
PA	$39,000,000	$15,000,000	$4,500,000	$45,000,000	$18,000,000	$5,400,000	$130,000,000
RI	$4,700,000	$430,000	$740,000	$5,100,000	$470,000	$840,000	$12,000,000
SC	$7,300,000	$6,900,000	$200,000	$9,200,000	$8,700,000	$260,000	$33,000,000
SD	$1,500,000	$76,000	$50,000	$1,600,000	$82,000	$55,000	$3,400,000
TN	$25,000,000	$11,000,000	$1,100,000	$29,000,000	$13,000,000	$1,400,000	$81,000,000
TX	$16,000,000	$7,000,000	$15,000,000	$17,000,000	$7,600,000	$17,000,000	$79,000,000
UT	$1,700,000	$67,000	$380,000	$1,800,000	$69,000	$410,000	$4,400,000
VA	$7,300,000	$4,400,000	$650,000	$6,700,000	$5,000,000	$770,000	$25,000,000
VT	$3,700,000	$63,000	$16,000	$4,500,000	$62,000	$16,000	$8,300,000
WA	$26,000,000	$2,100,000	$4,200,000	$30,000,000	$2,500,000	$5,100,000	$70,000,000
WI	$16,000,000	$3,600,000	$1,400,000	$19,000,000	$4,300,000	$1,700,000	$46,000,000
WV	$17,000,000	$940,000	—	$18,000,000	$1,000,000	—	$37,000,000
WY	$830,000	$20,000	$110,000	$3,900,000	$290,000	$130,000	$2,000,000
Median	$9,800,000	$3,500,000	$900,000	$11,000,000	$3,800,000	$1,000,000	$32,000,000
Sum	$790,000,000	$300,000,000	$200,000,000	$900,000,000	$340,000,000	$240,000,000	$2,800,000,000

Smoking prevalence from de novo model; see the Appendix, Section 3 for more information.

All Hispanics are assumed to be not Black; see the Appendix, Section 4 for more information.

Estimates are reported with 2 significant figures.

"Total" = total savings by state/territory.

"Median" = median state/territory.

"Sum" = US total by demographic group.

"Standardized Switch Cohort" = 1% of everyday smokier adult Medicaid enrollees in each demographic category assumed to permanently switch to vaping.

"—" = cell size too small to reliably estimate.

controlled by the creation of a standardized switch cohort, but this simplification should not be inferred as a prediction of what a switching program could or would achieve. Estimates are constructed from surveys on smoking prevalence that cannot be extrapolated to future years without uncertainty. Medicaid enrollment data is extremely precise but they appear to have serious quality deficiencies that undermine its reliability. This is especially problematic with respect to the assignment of enrollees to race and ethnicity categories, which have different rates of smoking prevalence and it is an unresolvable source of potential error unless and until the Medicaid data are validated.

Cost-savings estimates are reported with two significant figures to reflect data uncertainties and to discourage readers from inferring excess precision. No analysis has been performed to determine the true precision of these estimates. All estimates are believed to be reasonable and are provided without intentional bias either for or against tobacco or e-cigarettes. Nonetheless, these estimates should always be characterized as illustrative rather than definitive.

The analysis also does not consider medical care expenditures that might arise due to health risks caused by e-cigarettes. This exclusion appears to have negligible significance. While there is growing literature that purports to show the existence of potential health risks from various e-cigarette ingredients, these reports are generally speculative. Further, there is no reported evidence that health care providers are making nontrivial expenditures to manage health risks from e-cigarettes.

Accordingly, this analysis has four key limitations. First, it assumes that FDA's Deeming Rule does not result in significant changes in supply or demand for e-cigarettes in the short run or drives e-cigarettes off the market. Because these outcomes are not unlikely, the assumption of no change in e-cigarette markets is functionally equivalent to assuming that the Deeming Rule is rescinded by the FDA or is overturned and vacated as a result of ongoing litigation. This is clearly an extreme assumption. However, if it is instead assumed that the Deeming Rule is upheld, only perfunctory analysis is required to conclude that cost-savings to Medicaid

from switching will be negligible and short-lived. A product driven off the market by regulation cannot be expected to reduce Medicaid expenditures on smoking-related illness. If the Deeming Rule is neither rescinded by the FDA nor upheld in court, Medicaid expenditures on smoking-related illness can be expected to rise. Many current vapers will return to tobacco cigarettes or if they have never smoked, choose to smoke for the first time.

Second, there are uncertainties in the Behavioral Risk Factor Surveillance System (BRFSS) survey data on which smoking prevalence rates are based. Each prevalence rate reported by BRFSS includes confidence intervals that are not accounted for in this analysis. The width of the confidence interval is greater the smaller the subset of persons in the survey frame is and thus a more complete analysis would propagate these uncertainties into estimated smoking prevalence rates, and then into estimated cost savings. This is not done here because confidence intervals do not exist for certain key assumptions for which uncertainty is likely greater in magnitude, and the propagation of small uncertainties while leaving large uncertainties alone would be misleading.

Third, the BRFSS data may have serious data quality limitations that are known but not widely reported.[93] For example, results are reported as if each state sample is representative and there are no nonresponse biases. These assumptions are problematic. An earlier edition of the BRFSS has been shown to underrepresent racial and ethnic minorities, and those who are younger or have lower income.[94] Smoking prevalence has been reported to be significantly higher for lesbian, gay and bisexual individuals,[95] and refusal to self-identify sexual orientation in the BFRSS appears to be higher among minorities.[96] All surveys that rely on self-reporting, as BRFSS does, have a suite of data quality concerns, especially when the respondent belongs to a rare group or the subject concerns activities that may be disapproved of, such as smoking. State data on adult Medicaid enrollees have known limitations and quality problems because states do not collect data on some key factors, like educational attainment and appear to inaccurately record other key factors, like race and ethnicity.

Fourth, there is substantial uncertainty about the proportion of health care expenditures that are properly attributable to cigarette smoking. Numerous estimates are available, but each depends on myriad assumptions,[97] and small differences in assumptions about causality may have large effects on estimated expenditures attributable to smoking. Estimates of this fraction in the literature appear to vary within a fairly narrow band (< 2x), but this may reflect characteristics of the underlying data and common modeling assumptions that scholars rely upon to derive their estimates. Further, the methodology for determining which expenditures to characterize as smoking-related requires substantial professional judgment and may be subject to investigator bias. A default assumption of 10% is used here, but the extent to which it under- or overstates the true (but unknown) percentage cannot be ascertained. This limitation is not debilitating, however, because alternative assumptions are easily incorporated into the model.

Cost-savings estimates in this analysis are limited to state Medicaid programs. Switching would result in additional reductions in public expenditures on smoking-related medical care as switchers transitioned from Medicaid to Medicare. On the other hand, switching would lead to greater longevity, which would increase Social Security payouts and expenditures for state and local defined-benefit pensions. More immediately, switching from tobacco to e-cigarettes reduces government revenue from tobacco taxes. These revenue declines could be significant. Given that the federal share of New York's[98] Medicaid expenditures is about 55%, it is unclear whether it would lose more in tax revenue (currently $4.35/pack; $5.85/pack in New York City) than it gains from reduced Medicaid expenditures.[99]

Finally, this analysis does not account for any medical care expenditures related to or caused by nicotine dependency. The public health establishment is adamant that nicotine poses health risks of its own.[100] However, there is scant evidence that nicotine dependency results in substantial medi-

93. Government websites that make these data easily accessible and promote them as reliable do not acknowledge these data quality concerns. Considerable effort is required to locate data quality disclosure statements.

94. Karen L. Schneider, Melissa A. Clark et al., "Evaluating the Impact of Non-Response Bias in the Behavioral Risk Factor Surveillance System (BRFSS)," *Journal of Epidemiology and Community Health* 66:4 (2012), 290-95. http://jech.bmj.com/content/66/4/290. Other sampling biases that have not been investigated also may exist.

95. "Lesbian, Gay, Bisexual, and Transgender Persons and Tobacco Use," Centers for Disease Control and Prevention, 2017. https://www.cdc.gov/tobacco/disparities/lgbt/index.htm.

96. Hyun-Jun Kim and Karen I. Fredriksen-Goldsen, "Nonresponse to a Question on Self-Identified Sexual Orientation in a Public Health Survey and Its Relationship to Race and Ethnicity," *American Journal of Public Health* 103:1 (2013), 67-69. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518335.

97. See, e.g., "Smoking-Attributable Mortality, Morbidity, and Economic Costs (Sammec); Smoking-Attributable Mortality (Sam) Glossary and Methods," Centers for Disease Control and Prevention, 2017. https://chronicdata.cdc.gov/Health-Consequences-and-Costs/Smoking-Attributable-Mortality-Morbidity-and-Econo/w47j-r23n.

98. New York is the jurisdiction with the greatest estimated cost savings from switching.

99. "State Health Facts: Federal and State Share of Medicaid Spending," The Henry J. Kaiser Family Foundation, 2017. https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending/?currentTimeframe=0&sortModel=%7B"colId":"Location","sort":"asc"%7D. Note: It is also not clear how cost savings would be shared between state and federal governments.

100. See, e.g., *The Health Consequences of Smoking—50 Years of Progress*. https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf. This report acknowledges that nicotine "has some modest cognition-enhancing effects in adult smokers during withdrawal" (p. 125) and may benefit persons with attention-related deficits. The report does not refuse to acknowledge these effects as benefits, however, they are not supported by randomized controlled trials to demonstrate safety and efficacy This is a standard that nicotine could never meet even if consumers are unambiguously willing to pay for the biochemical effects in question.

cal care expenditures. The stated purpose of NRT is smoking cessation. One explanation for its limited effectiveness is the low doses of nicotine in NRT products. Smokers who seek to reduce health risks from smoking but not necessarily wean themselves off nicotine are likely to abandon NRTs.

However, the analysis also has three key strengths. First, it utilizes the best-available, state-level survey data on smoking prevalence and uses them as the foundation for estimating cost savings, taking account of interstate differences and important demographic factors. Failing to control for these differences would render cost-savings estimates inaccurate and unreliable.

Second, each assumption for a key variable for which reliable data or estimates are not available can be easily changed to account for alternative perspectives, or replaced with reliable data or estimates as they become available. While the results reported depend upon these assumptions, the modeling technology does not.

Third, the development of a standardized switch cohort enables the results to be used as building blocks for national or state-level estimates of the effects of specific market phenomena or public policies. For example, if e-cigarettes become more popular, or public policies that impede e-cigarette innovation, marketing or use are relaxed, cost-savings can be estimated for switch rates that are multiples of the standardized cohort. Additional, more focused analysis is needed to provide objective estimates of cost-savings from specific public policy innovations.

Finally, this analysis provides a way to estimate cost-savings to Medicare or private insurers that results from switching behavior. Nothing about the analytic methodology is specific to the Medicaid program. Modifications would be needed to accurately reflect alternative third-party payers, but the structure of the model need not be changed at all.

ABOUT THE AUTHOR

Dr. Richard B. Belzer is an independent consultant in regulation, risk, economics and information quality. Previously he was a visiting professor of public policy at Washington University in St. Louis (1998-2001) and staff economist in the Office of Information and Regulatory Affairs in the Office of Management and Budget (1988-1998). He received his Ph.D. in public policy from Harvard University, Master's in Public Policy (MPP) from the John F. Kennedy School of Government (now Harvard Kennedy School), and MS and BS degrees in agricultural economics from the University of California at Davis.

He is a regular contributor to scholarly professions through peer review and volunteer service. He was twice elected Treasurer of the Society for Risk Analysis, and was elected Secretary-Treasurer or Treasurer of the Society for Benefit-Cost Analysis four times. He has earned multiple awards for exemplary performance while at OMB. He was also given the SRA's Outstanding Service Award and the SBCA's Richard O. Zerbe, Jr. Distinguished Service Award. He also served as a named Fellow of the Cecil and Ida Green Center for the Study of Science and Society. In 2017, Dr. Belzer completed a two-year term as a Member of the U.S. Environmental Protection Agency's Science Advisory Board Panel on Economy-wide Modeling.

In addition to regulatory consulting, he conducts original research in a number of areas, often involving collaboration with toxicologists, epidemiologists and engineers, and he has served as an expert witness.