

What Tobacco Control Rules Would an Ethically Responsible FDA Implement (If the White House Let It)? – Would a Nicotine-Reduction Rule Pass Muster?

O'Neill Institute Working Paper

Eric N. Lindblom, Senior Scholar

September 27, 2021

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Abstract

The U.S. Food and Drug Administration (FDA) has not yet used its extraordinary tobacco control powers to implemented any substantive tobacco control rules that would sharply reduce the more than 400,000 deaths and other enormous harms and costs caused by smoking and other tobacco use each year. FDA's failure is not entirely its fault. Since 2009, when FDA first received its tobacco control authorities, the agency has never received the support it needs from the White House and the Office of Management and Budget to move any major rules through the federal clearance process successfully. Instead, White House apathy or opposition, alternative priorities, or political concerns have impeded FDA's efforts to put effective new tobacco control rules into effect.

Applying the most directly relevant ethical approaches – utilitarianism, bioethics, and public health ethics – this paper shows that the White House has an irrefutable ethical duty to ensure that FDA quickly uses its extraordinary statutory powers to issue strong, new rules to reduce the unnecessary harms and costs from tobacco use as quickly as possible – so long as those rules are ethically valid and appropriate. The paper then explains how the many complications that arise when trying to develop ethically appropriate policies or regulations because of conflicting ethical goals or perspectives and the subjectivity of values are reduced or eliminated by the Tobacco Control Act's overriding goal of protecting the public health, the enormous ethical harms caused by tobacco use, and the ready availability of a range of effective measures to reduce them. It then shows how FDA could use the paper's ethical framework and guidance to identify, structure, and implement new ethically appropriate rules that would quickly minimize tobacco use health harms and secure other ethical benefits – if FDA finally received the White House support it requires.

The tobacco industry often argues that respect for smokers' rights or individual choice should constrain any efforts to prevent or reduce tobacco use by FDA or other government actors. But the ethical analysis presented here shows that, even if personal autonomy concerns are given as much weight as they could possibly deserve, a range of unprecedented new FDA tobacco control rules, including a rule to minimize nicotine in cigarettes, are not only legally viable and ethically appropriate but also ethically required. Through its analysis, this paper not only provides direct legal and ethical guidance for the White House and FDA but also provides an ethical framework for selecting and evaluating tobacco control proposals or actions at all levels of government in the United States and in other countries, as well.

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Introduction & Background

Smoking and other tobacco use in the United States causes close to half a million deaths each year, while more than 16 million Americans suffer from tobacco-caused disability and disease.² To address this problem, the 2009 U.S. Tobacco Control Act provided the U.S. Food & Drug Administration (FDA) with extraordinary powers to regulate tobacco products and their manufacture, distribution, marketing, and sale, so long as the agency reasonably determines that its regulatory actions are “appropriate for the protection of the public health.”³ To date, however, FDA has not successfully implemented any major substantive rules to reduce the enormous amounts of death, disease, and other harms caused by smoking and other tobacco use. Pursuant to a statutory mandate and court order, FDA did issue a belated rule to require graphic warning labels on cigarette packs in March 2020, after its first attempt was struck down by the courts in 2011. But that final rule has also been legally challenged and is currently on hold as the lawsuit proceeds.⁴ Moreover, while putting graphic warnings on cigarette packs would certainly help toward reduce smoking, it would not sharply reduce smoking or overall tobacco-caused harms.⁵

² See, e.g., Maddy Bolger, *Toll of Tobacco in the United States of America*, Campaign for Tobacco-Free Kids factsheet (May 18, 2021), <https://www.tobaccofreekids.org/assets/factsheets/0072.pdf>.

³ Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 111th Cong. (2009), Section 101 amends the Food, Drug, and Cosmetic Act (FDCA), creating a new Chapter IX with new §§ 900 to 919 [21 U.S.C. 387 et seq.] [hereinafter TCA]. For the Act’s use of the “appropriate” standard for issuing new regulations, see § 906(d)(1)&(3) [21 U.S.C. 387f(d)(1)&(3)], relating to rules to restrict the marketing, sale, and distribution of tobacco products, and § 907(a)(3)&(4) and (c)(2)&(3) [21 U.S.C. 387g(a)(3)&(4) and (c)(2)&(3)], relating to tobacco product standards (rules regulating the tobacco products, themselves).

⁴ See, e.g., *American Academy of Pediatrics v. U.S. FDA*, 330 F.Supp.3d 657 (D. Mass. 2018); FDA, Final Rule, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 8 FEDERAL REGISTER 15638 (March 18, 2020). FDA, “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed,” *Federal Register* [86\(174\): 50854](https://www.federalregister.gov/documents/2021/09/13/86174-50854) (Sept. 13, 2021). In 2016, FDA implemented a major rule to put cigars, pipe tobacco, e-cigarettes, and other non-tobacco nicotine-based products under its tobacco control jurisdiction in 2016, but it was primarily procedural and has had only a minor impact on tobacco use and harms. FDA, *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products* (Deeming Rule), 81 FEDERAL REGISTER 28974 (May 10, 2016) [21 C.F.R. §§ 1100, 1140, 1143]. Separate from rule making, FDA has implemented effective public education campaigns to prevent and reduce youth tobacco use and has taken enforcement actions against retailers and tobacco product manufacturers that violate the Tobacco Control Act. But the public health impacts of those efforts are relatively small compared to the health gains FDA could secure by issuing and enforcing strong new tobacco control rules.

⁵ Research on graphic health warnings in other countries shows that their impact on smoking cessation is marginal, at best. See, e.g., Anh Ngo, *Global Evidence on the Association between Cigarette Graphic Warning Labels and Cigarette Smoking Prevalence and Consumption* 15 Intl Jnl Environmental Research & Public Health 421 (Feb. 28, 2018). In addition, the graphic warnings required in FDA’s rule are considerably less powerful than those in other countries because of FDA’s efforts to try to avoid First Amendment concerns. Perhaps to reduce pressure from a related lawsuit against FDA, in April 2021, FDA announced that it would be issuing a proposed rule to ban menthol as a characterizing flavor in cigarettes (the only characterizing flavor currently allowed other than tobacco) and a proposed rule to ban all characterizing flavors (including menthol) in cigars (which currently have no flavor restrictions). FDA News Release, [FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers](https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-preventing-future-generations-smokers) (April 29, 2021). Public Health Law Center, website page, “African American Tobacco Control Leadership Council et al. v. U.S. Dept. of Human Services et al. (2020),” <https://www.publichealthlawcenter.org/content/african-american-tobacco-control-leadership-council-et-al-v-us-dept-human-services-et-al>, accessed Sept. 15, 2021.

This FDA failure to use its tobacco control authorities as intended to issue rules to protect and improve the public health is not entirely the agency's fault. To implement a major FDA rule requires obtaining formal clearances from the Office of Management and Budget and from any other federal agency whose activities or goals might be significantly affected. Concurrence from the White House Domestic Policy Council, if not the President, is also required; and White House support is critically important for getting any major regulatory action through the process successfully. But FDA's tobacco control efforts received little or no White House support under the Obama Administration or Trump Administrations.⁶

The first public White House support for any possible major FDA tobacco control action since President Obama signed the Tobacco Control Act into law in June 2009 occurred in the fall of 2019, when President Trump and the First Lady publicly expressed support for FDA enforcement efforts to take all flavored e-cigarettes other than tobacco flavored off the market in order to protect kids.⁷ But that support quickly faded in response to political pressures, and FDA's final enforcement policy ended up being directed only at capsule-based e-cigarettes and still allowed menthol flavor, as well as tobacco, and taking no action against the continued sale of disposable e-cigarettes and open-system e-cigarettes with thousands of kid-attracting flavors.⁸ Nothing more was ever said by President Trump about FDA possibly implementing any new substantive rule to protect kids or otherwise reduce smoking-caused death, disease, and other harms; and the head of the White House Domestic Policy Council subsequently expressed considerable hostility toward FDA taking any tobacco-related action at all.⁹

⁶ See, e.g., Katie Thomas & Sheila Kaplan, [E-Cigarettes Went Unchecked in 10 Years of Federal Inaction](#), THE NEW YORK TIMES (Oct. 14, 2019); Emily Baumgaertner, [The FDA tried to ban flavors years before the vaping outbreak – Top Obama officials rejected the plan](#), LOS ANGELES TIMES (Oct. 1, 2019). See, also, Robert M. Califf, et al., [Seven Former FDA Commissioners: The FDA Should Be An Independent Federal Agency](#), 38 HEALTH AFFAIRS 84 (2019); Rick Berke & Sheila Kaplan, [Former FDA chief Margaret Hamburg speaks out about Califf, Cruz, and Congress](#), STAT (March 16, 2016)[“Often, even the White House really was a little bit suspect about what FDA was and what was our value”], <https://www.statnews.com/2016/03/16/margaret-hamburg-fda>. For the Trump Administrations' generally anti-regulation approach, see, e.g., Executive Order 13771, [Reducing Regulation and Controlling Regulatory Costs](#), 82 Fed. Register 9339 (Jan. 30, 2017); Executive Order 13777, [Enforcing the Regulatory Reform Agenda](#), 82 Fed. Register 12285 (Feb. 24, 2017).

⁷ As described, the proposed FDA enforcement action would take all e-cigarettes off the market that had any added flavor other than tobacco, but they could reenter the market if they received a permissive PMTA order from FDA. Sheila Kaplan, [Trump Administration Plans to Ban Flavored E-Cigarettes](#), THE NEW YORK TIMES (Sept. 11, 2019).

⁸ See, e.g., Nathaniel Weixel, [Top Trump official questions FDA tobacco oversight as vaping ban looms](#), THE HILL (Nov. 8, 2019), <https://thehill.com/policy/healthcare/469618-top-white-house-official-questions-fda-tobacco-role-as-vaping-ban-looms>; Kaplan, S, “Teens Find a Big Loophole in the New Flavored Vaping Ban,” [The New York Times](#) (Jan. 31, 2020); Editorial Board, “Opinion: The vaping ban is here, and it's already out of date,” [The Washington Post](#) (Feb. 8, 2020); McDonald, J, “Will Trump Stop the FDA's May 11 Vape Apocalypse?,” [Vaping360](#) (Jan. 20, 2020), <https://vaping360.com/vape-news/87905/will-trump-stop-the-fdas-may-11-vape-apocalypse>, accessed Sept. 15, 2021. FDA, Guidance for Industry, “Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (April 2020)[revision to first edition of the guidance issued in January 2020].

⁹ Weixel, THE HILL (Nov. 8, 2019), *id.*; C-SPAN, [User Clip: Joe Grogan – White House Domestic Policy Council – Discusses e-cigarette regulation](#) (Nov. 8, 2019), <https://www.c-span.org/video/?c4828413/user-clip-joe-grogan-white-house-domestic-policy-council>, accessed Sept. 20, 2021. For the Trump Administrations' generally anti-regulation approach, see, e.g., Executive Order 13771, [Reducing Regulation and Controlling Regulatory Costs](#), 82

This paper considers how FDA could legally use its tobacco control rulemaking powers most ethically and effectively to prevent and reduce smoking and other tobacco use harms and risks – if it finally received the White House support it needs to get its major regulatory actions through the federal clearance procedures promptly. It describes how FDA could choose which rules to implement and, within applicable legal constraints, how FDA could structure them to be most beneficial for the public health and otherwise ethically appropriate. The paper will also apply its ethical analysis to a possible FDA rule to reduce nicotine in cigarettes, as a former Commissioner of FDA and a former Secretary of the U.S. Department of Health and Human Services (HHS) have publicly stated that such a rule was the top priority of FDA and HHS – and such a rule appears to be FDA’s best option for rapidly reducing smoking and overall tobacco use harms.¹⁰

The Papers Ethical Framework

To be most helpful and relevant, the paper’s ethical analysis will apply those ethical perspectives most frequently used to evaluate, guide or critique public health policymaking: utilitarianism,¹¹ bioethics (with its four core principles of beneficence, nonmaleficence, justice, and respecting personal autonomy);¹² and public health ethics.¹³ This approach will also necessarily include

FED. REGISTER 9339 (Jan. 30, 2017); Executive Order 13777, [Enforcing the Regulatory Reform Agenda](#), 82 FED. REGISTER 12285 (Feb. 24, 2017).

¹⁰ Alex M. Azar & Scott Gottlieb, [We cannot let e-cigarettes become an on-ramp for teenage addiction](#), The Washington Post (Oct. 11, 2018). Benjamin J. Apelberg, et al., [Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States](#), 378 New Eng. J. Med. 1725 (2018). See, also, Jennifer Maloney, [“Biden Administration Considering Rule to Cut Nicotine in Cigarettes.”](#) *The Wall Street Journal* (April 29, 2021); Scott Gottlieb & Mitchell Zeller, [A Nicotine-Focused Framework for Public Health](#), 377 New England Jnl Medicine 1111 (Sept. 21, 2017). See, also, *infra* note 69. If FDA does, as promised, issue proposed rules to ban menthol in cigarettes and all flavors in cigars, and then issues a final rule, there would still be a considerably amount of remaining smoking and youth initiation into smoking. Accordingly, a nicotine-reduction rule would still be appropriate, and this paper’s related ethical analysis would still be relevant. See, also, *infra* note 69.

¹¹ Generally seeking “the greatest good [or happiness] for the greatest number.” See, e.g., Afschin Gandjour & Karl W. Lauterbach, [Utilitarian Theories Reconsidered: Common Misconceptions, More Recent Developments, and Health Policy Implications](#), 11 HEALTH CARE ANALYSIS 229 (Sept. 2003); Olivier Bellefleur & Michael Keeling, [Utilitarianism in Public Health](#), Nat’l Collaborating Centre for Healthy Public Policy, Public Health Agency of Canada (Jan. 2016), http://www.nccchp.ca/127/Publications.ccnpps?id_article=1527, accessed Sept. 20, 2021.

¹² For descriptions of bioethics in its original context of medical patient care, see, e.g., Thomas R. McCormick, [Principles of Bioethics](#), Dept. Bioethics and Humanities, School of Medicine, Univ. of Washington, <https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/articles/principles-bioethics>, accessed Sept. 20, 2021; Tom L. Beauchamp & James F. Childress, [PRINCIPLES OF BIOMEDICAL ETHICS](#) (7th Edition 2013). For an application of bioethics to public health and to tobacco control policymaking, see, e.g., Peter Schroeder Bach, et al., [Teaching seven principles for public health ethics: towards a curriculum for a short course on ethics in public health programmes](#), 15 BMC MEDICAL ETHICS 73 (2014) (adding health maximization, efficiency, and proportionality to the four core principles); and Brian J. Fox, [Framing tobacco control efforts within an ethical context](#), 14(Suppl. II) TOBACCO CONTROL ii38 (2005) (adding two procedural principles: transparency and truthfulness). The principles of bioethics also apply directly to protecting human subjects in FDA and FDA-funded research. Nat’l Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [The Belmont report: Ethical principles and guidelines for the protection of human subjects of research](#) (April 18, 1979), www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html, accessed Sept. 20, 2021; [Criteria for IRB approval of research](#), 24 CFR 46.111(a)(1) to (a)(5).

¹³ Public health ethics focuses on the need to improve the public health, ideally while also reducing inequitable health disparities and otherwise promoting justice, followed by a concern for respecting personal autonomy to the

consideration of the ethical goal of reducing inequitable health disparities, the “harm principle,”¹⁴ and the related frequent claims by libertarians and the tobacco industry that personal autonomy (or smoker’s rights) should be given predominant consideration.¹⁵

Reaching any clear conclusions for policy making through ethical analysis can be difficult given that different ethical perspectives often conflict with each other or have conflicting goals, themselves.¹⁶ In the context of public health and tobacco control policy making, a frequent conflict arises when promoting the ethical goal of improving the overall health of the population contradicts or infringes on such ethical goals as respecting personal autonomy; not causing brand-new health or other harms, especially to already vulnerable or disadvantaged groups; or not increasing inequitable health or other disparities between advantaged and disadvantaged groups.

These conflicts arise most clearly and directly when applying a bioethics perspective, with its explicitly articulated and often conflicting core principles of beneficence, non-maleficence, justice, and autonomy.¹⁷ Although public health ethics generally prioritizes broadly beneficial public health gains over reducing inequitable health disparities, with protecting personal autonomy a third-level priority, conflicts can still arise when measures to secure overall public health gains also increase health disparities or seriously infringe on personal autonomy.¹⁸ With its single goal

extent possible and reasonable in this public health context. See, e.g., Ruth Faden & Sirine Shebaya, *Public Health Ethics*, in Edward N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy* (Winter 2016); Ronald Bayer & Amy L. Fairchild, *The Genesis of Public Health Ethics*, 18 *BIOETHICS* 1467 (Nov. 2004); James F. Childress, et al., *Public health ethics: mapping the terrain*, 30 *JNL LAW MED ETHICS* 170 (Summer 2002). See, also, U.S. Centers for Disease Control & Prevention (CDC), *Public Health Ethics*, www.cdc.gov/od/science/integrity/phethics, accessed Sept. 20, 2021; Public Health Leadership Society, *Principles of the Ethical Practice of Public Health*, Version 2.2 (2002); American Public Health Association, *Public Health Code of Ethics* (2019), https://www.apha.org/-/media/files/pdf/membergroups/ethics/code_of_ethics.ashx, accessed Sept. 20, 2021. See, also, James Wilson, *Why It's Time to Stop Worrying About Paternalism in Health Policy*, 4 *PUBLIC HEALTH ETHICS* 269 (Oct. 2011)

¹⁴ “[T]he only purpose for which power can be rightfully exercised over any member of a civilized society, against his (sic) will, is to prevent harm to others.” John S. Mill, *ON LIBERTY* (1869), accessed Sept. 20, 2021, <https://www.utilitarianism.com/ol/one.html>. See, also, Larry O. Gostin & Kieran G. Gostin, *A broader liberty: J.S. Mill, paternalism and the public's health*, 123 *PUBLIC HEALTH* 214 (March 2009).

¹⁵ See, e.g., Jessica Flanigan, *Public Bioethics*, 6 *PUBLIC HEALTH ETHICS* 170 (2013); Elizabeth A. Smith & Ruth E. Malone, *“We will speak as the smoker”*: *the tobacco industry's smokers' rights groups*, 17 *EUR. JNL PUBLIC HEALTH* 306 (2007), National Association of Tobacco Outlets, *About NATO*, <http://www.natocentral.org/about>, accessed Sept. 20, 2021; James E. Katz, *Individual rights advocacy in tobacco control policies: an assessment and recommendation*, 14 *TOBACCO CONTROL* ii31 (2005).

¹⁶ In addition, choosing to use the ethical perspectives of utilitarianism, bioethics, and public health ethics reduces but does not eliminate the fundamental problems and complications caused for ethical analysis by the subjectivity of moral or ethical values, or the subjectivity of what constitutes the “good” or “happiness” of utilitarianism. See, e.g., J. L. Mackie, *The Subjectivity of Values*, chapter 18 in George Sher (ed.), *Ethics: Essential Readings in Moral Theory* (Routledge 2012) at 181; George C. Freeman III, book review, *Liberalism and the Objectivity of Ethics - Beyond Subjective Morality: Ethical Reasoning and Political Philosophy by James S. Fishkin*, 47 *La. L. Rev.* 1235 (1987); Gandjour & Lauterbach (Sept. 2003), *supra* note 11.

¹⁷ *Supra* note 12.

¹⁸ *Supra* note 13. Some possible conflicts and complications are avoided, however, by the fact that lower-income and less-educated persons, and other disadvantaged and vulnerable subpopulations disproportionately smoke and use other tobacco products and suffer disproportionately from tobacco-caused health harms. See, e.g., Jeffrey Drope, et al., *Who's still smoking? Disparities in adult cigarette smoking prevalence in the United States*, 68 *CA CANCER JNL CLINICIANS* 106 (March 2018). Accordingly, any non-targeted, non-discriminatory tobacco control intervention that secures significant, broad-based public health gains, such as FDA tobacco control rules, will almost certainly reduce

of maximizing the overall good for the greatest number, utilitarianism can seem more straightforward or mathematical. But ethical conflicts arise there, too, when securing public health gains also produces negative impacts on other non-health factors contributing to the good or when securing the greatest good conflicts with benefiting the greatest number.¹⁹ To further complicate matters, none of the ethical perspectives provide any clear guidance as to how to resolve any such internal conflicts; nor is it clear how to resolve conflicts between different ethical perspectives.²⁰

As the following analysis hopes to show, these ethical complications and uncertainties can be greatly reduced for FDA tobacco control rulemaking because FDA must operate, and make its ethical decisions, within the legal framework provided by the Tobacco Control Act, the Administrative Procedures Act, and related case law. In addition, FDA can avoid many ethical close calls or uncertainties by focusing its efforts on the many tobacco control rules that will either: (a) produce solid public health gains (and other ethical benefits) without producing any non-trivial ethical harms or risks or would produce such enormous public health gains (and other ethical benefits) that they would overwhelm any possible related ethical harms, thereby making the rules clearly ethically acceptable (under each of the ethical perspectives).

Accordingly, this paper will describe what FDA must, may, and cannot do within that legal framework; show how FDA could most ethically exercise its discretion to interpret the remaining gray areas in the legal standards that govern its actions; describe what ethically ideal FDA tobacco control rules would look like; consider how FDA could use those ideals to guide its rulemaking actions; and then apply that analysis to a possible FDA rule to minimize nicotine levels in cigarettes.²¹

Besides providing ethical guidance for how FDA should use its tobacco control rulemaking authorities, if given the opportunity to do so, the paper's ethical analysis directly supports more robust FDA action and offers an ethical framework that the public health community could use when evaluating and commenting on FDA proposed tobacco control rules or advocating for more aggressive federal action. In this way, the paper also provides an ethical framework for selecting and evaluating tobacco control proposals or actions at other levels of government in the United States, and in other countries, as well.

inequitable tobacco-related health disparities. But see *infra* notes 61-63 and associated text. In addition, tobacco control rules that reduce tobacco-caused death and disability work directly to increase the personal autonomy of those enabled to live longer with less or no disability.

¹⁹ *Supra* note 11.

²⁰ But see Raanan Gillon, [Defending the four principles approach as a good basis for good medical practice and therefore for good medical ethics](#), 41 JNL MEDICAL ETHICS 111 (Jan. 2015) and Beauchamp & Childress (7th Edition 2013), *supra* note 12, at 22-23, presenting conditions that should be met when choosing to infringe one ethical principle when conflicts between principles arise, including providing good reasons, infringement will promote a moral or ethical goal, no ethically preferable alternative is available; infringement is minimized; negative effects from infringement are minimized; and all affected parties are treated impartially.

²¹ See *supra* note 10 and associated text.

What Do the Tobacco Control Act and Other Applicable Laws Say FDA Must, May, and Cannot Do When Issuing Tobacco Control Rules?

The Tobacco Control Act provides FDA with enormous discretion regarding what specific tobacco control rules, if any, it chooses to implement, beyond those few required by the Act, so long as the rules it implements are “appropriate for the protection of the public health” (AFPPH).²² Neither FDA nor any court has yet provided any clarification as to how, exactly, FDA intends to interpret this standard or how it must or could be interpreted and applied. But the plain language of the statute, along with its legislative history, shows that the Tobacco Control Act and its AFPPH standard are directed at two equal, related objectives: (1) protecting the public health; and reducing youth tobacco use. Most directly, the House of Representatives Report on the legislation that became the Tobacco Control Act states that the objectives of the legislation are to provide FDA “with the proper authority over tobacco products in order to protect the public health and to reduce the number of individuals under 18 years of age who use tobacco products.”²³

Consistent with this legislative history, the Act, itself, refers repeatedly to concerns about reducing youth *use* of tobacco products and the need to prevent and reduce youth *use* of tobacco products, but never specifically mentions reducing youth *harms* caused by tobacco use in the context of FDA’s authorities, AFPPH determinations, or other regulatory actions under the Act.²⁴ In regard to protecting the public health, however, the Act clearly means to prevent and reduce overall tobacco-related health harms and risk, with the AFPPH standard concerned with reducing only the

²² *Supra* note 3.

²³ U.S. House of Representatives, Comm. on Energy and Commerce, Family Smoking Prevention and Tobacco Control Act (TCA), H.R. Rep. No. 111-58, pt. 1 (2009) [hereinafter “2009 House Legislative History”] at 14 under “Statement of General Performance Goals and Objectives.” No other goals or objectives are mentioned in that section of the report. *See, also*, the parallel text in the House Report on the same legislation the prior year. Comm. on Energy and Commerce, Family Smoking Prevention and Tobacco Control Act, H.R. Rep. No. 110-762 (2008) at 57.

²⁴ *See, e.g.*, TCA, Sec. 3. Purpose (21 USC § 387 note) at (2), (7); TCA, Sec. 2. Findings (21 USC § 387 note) at (1), (4), (5), (6), (14), (15), (16), (18), (20), (21), (22), (27), (28), (31). All but one of the Act’s references to “youth,” persons under 18 year of age, “children,” “minors,” or “underage” outside of the Findings and Purpose sections of the Act refer to protecting youth from tobacco product marketing or otherwise preventing or reducing youth use, with one reference to protecting children from exposure to secondhand smoke. TCA Sec. 102 (21 USC § 387a-1) at (d)(2)(iii); Sec. 105 (21 USC § 387f-1) at (a)(1); Sec. 913 (21 USC § 387m); Sec. 903 (21 USC § 387c) at (a)(5); Sec. 907 (21 USC § 387g) at (e)(1) and (f)(1); Sec. 102 (21 USC § 387a-1) at (b)(1); Sec. 103(q)(F)(i) and (3); Sec. 105(b)(2); and Sec 201(a) (15 USC § 1333(4)(a)(1)). The one reference to youth harms, as opposed to youth use, does not relate to FDA or the purpose of the TCA but requires the Comptroller General to conduct a study of cross-border trade in tobacco products that includes collecting “data on the health effects (particularly with respect to persons under 18 years of age) resulting from cross border trade.” TCA, Sec. 302. There is also nothing in the Act to suggest that reducing youth use of any particular type of product is more important than reducing youth use of any other type. For example, Findings (14) and (15) refer only to youth smoking, but that appears to reflect the fact that youth smoking was the most prevalent form of youth tobacco use, by far, when the TCA was drafted and signed into law. Similarly, Findings (31) and (32), which pertain to the Final Rule the TCA requires FDA to implement, refer to only youth smoking and youth smokeless tobacco use because those were the only tobacco products that Final Rule applied to; but they also refer to those two very different forms of youth tobacco product use without indicating that reducing one is more important than the other.

health harms and risks to the population *as a whole*.²⁵ Consequently, the health impacts on certain individuals or subpopulations from issuing a rule are not directly relevant to AFPPH determinations, except to the extent they contribute to the overall impact on the public health; and non-health impacts are irrelevant except to the extent they also produce impacts on the public health.²⁶ But subpopulation and non-health impacts, including health harms among youth, could, of course, be quite relevant to any ethical analysis beyond their contribution to the health harms and risks of the population as a whole.²⁷

Accordingly, any FDA determination of whether a potential new tobacco control rule would be AFPPH must not only consider what its impact will be on the public health (i.e., the extent to which it is likely to produce net increases or decreases in overall tobacco-related health harms) but also its impact on the number of persons under 18 who use tobacco products (i.e., the extent to which it is likely to produce net increases or decreases in overall youth use). Fortunately, the vast majority of the rules that FDA might implement either to reduce youth use or to reduce overall public health harms related to tobacco would simultaneously promote the other objective, as well.²⁸

In addition, the Administrative Procedures Act (APA), as incorporated by Section 912 of the Tobacco Control Act, requires that FDA exercise its tobacco control authorities in ways that are “not arbitrary or capricious [or] an abuse of discretion.”²⁹ In general, that standard is quite permissive, requiring agencies to follow the established procedures for taking their regulatory actions, explain how its regulatory actions and related agency choices about how to structure them promote the relevant statutory purposes (e.g., to protect the public health), and consider all relevant available information, including contrary evidence and analysis and alternative ways the regulatory action might be structured, when making their regulatory decisions.³⁰ When an agency

²⁵ TCA § 906(d)(1)&(3) [21 U.S.C. 387f(d)(1)&(3)]; § 907(a)(3)&(4) and (c)(2)&(3) [21 U.S.C. 387g(a)(3)&(4) and (c)(2)&(3)]; Lindblom, Eric N., “[What Is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?](#),” *Food and Drug Law Journal* 74(4): 523-585 (June 2020). The TCA also requires that FDA’s evaluation of whether a tobacco control rule or order is AFPPH must be comprehensive, considering the public health consequences of the impacts on both users and nonusers, including the effects of the regulatory action on initiation, cessation, dual or multi-product use, switching among tobacco products, relapse, non-user exposure, etc. *Id.*

²⁶ Lindblom, *Food & Drug Law Journal* 74(4): 523-585 (June 2020), *id.*

²⁷ The paper I published in 2020 on the AFPPH standard stated, inaccurately, that the TCA’s AFPPH standard gives equal priority to preventing and reducing youth tobacco use and harms as adult use and harms. Lindblom, *Food & Drug Law Journal* 74(4): 523-585 (June 2020), *id.* While that paper’s analysis relating to the AFPPH standard remains accurate – including its finding that the standard does not put a higher priority on preventing or reducing youth tobacco-related health *harms* versus adult or overall tobacco-related *harms* – it did not consider or reflect the TCA legislative history establishing that the Act puts an equal priority on protecting the public health (i.e., preventing and reducing overall tobacco-related health harms) as it does on “reducing the number of individuals under the age of 18 who use tobacco products.” 2009 House Legislative History, *supra note 23*, at 14.

²⁸ *But see infra* note 35.

²⁹ 5 U.S.C. § 706(2)(A); TCA § 912(a)&(b) [21 U.S.C. 387l(a)&(b)].

³⁰ *See, e.g.,* FERC v. ELEC. POWER SUPPLY Ass’n, 136 S. Ct. 760, 782 (2016); U.S. DEP’T OF JUSTICE FED. BUREAU OF PRISONS FED. CORRECTIONAL COMPLEX v. FED. LABOR RELATIONS AUTHORITY, 737 F.3d 779, 785 (D.C. Cir. 2013); NAT’L ASS’N OF HOME BUILDERS v. DEFENDERS OF WILDLIFE, 551 U.S. 644, 658 (2007); ASSOCIATED FISHERIES OF MAINE, INC. v. DALEY, 127 F.3d 104, 110 (1st Cir. 1997).

follows these procedures adequately, the courts may strike down an agency's regulatory decision as "arbitrary or capricious" only if it is irrational, incomprehensible, or clearly wrong.³¹

However, courts have also interpreted the "not arbitrary or capricious" standard to require agencies to structure their regulatory actions to reduce any related costs not necessary to promoting the action's statutory purposes (even when the statute does not mention any concerns about costs).³² Accordingly, these rulings also support a broader FDA duty to make any readily available changes to a tobacco control rule or order, within its scope, that will reduce any other undesirable impacts, comparable to or worse than regulatory costs, without impeding the ability of the rule or order to promote the Tobacco Control Act's core purpose, to reduce health harms and risks to the population as a whole.³³ In this way, the "arbitrary or capricious standard" could require agencies to take at least some readily available steps to make their rules clearly more ethically appropriate or ethically beneficial, so long as making those changes do not interfere with the rule's ability to secure its statutory purposes.

In regard to reducing public health harms and risks, the Act is silent as to whether an FDA tobacco control rule could be AFPPH if it were not only likely to secure a net public health benefit but also created a significant risk of producing a negative net public health impact, instead. It is difficult to imagine any "not arbitrary or capricious" interpretation of the AFPPH standard, that would find a rule "appropriate" if it created a greater risk of producing a negative net public health impact instead of a positive one or was only marginally more likely to create a small positive net impact than create a much larger negative net impact. But neither the Act nor the "not arbitrary or capricious" standard, nor related case law, provides any clear guidance for less clear scenarios (e.g., a 75% chance of a big public health gain with a 25% chance of a smaller but still serious net harm, instead). Accordingly, FDA may develop its own interpretation of how the potential gains and possible risks from a possible tobacco control rule should be weighed against each other for making AFPPH determinations – so long as its interpretation is not arbitrary or capricious.³⁴ But FDA has not yet done so.

³¹ *Id.* For a more comprehensive discussion of existing "arbitrary and capricious" case law relevant to FDA's regulatory actions under the TCA, see Lindblom, *Food & Drug Law Journal* 74(4): 523-585 (June 2020), *supra* note 25.

³² See, e.g., *STATE OF LA., EX REL. GUSTE V. VERITY*, 853 F.2d 322, 331 (5th Cir. 1988); *SOUTH TERMINAL CORP. V. EPA*, 504 F.2d 646, 655-56, 676 (1st Cir. 1974). These cases, along with other available case law on regulatory agencies being "not arbitrary or capricious," do not suggest that regulatory agencies must choose to implement those discretionary regulatory actions that will best promote their statutory objectives or that will do so effectively with minimum related costs, but only that, once they exercise their discretion to choose what regulatory action to develop (or are required to take a regulatory action), the regulatory agencies must take advantage of any available revisions to the action, within its scope, that will reduce its related costs without interfering with its ability to achieve the statutory goals.

³³ Lindblom, Eric N., "[The Tobacco Control Act's PMTA and MRTP Provisions Mean to Protect the USA From Any New Tobacco Products That Will Not Reduce Health Harms – But FDA Isn't Cooperating.](#)" *Journal of Health Care Law & Policy* 23(2): 121-186 (Feb. 2021).. A parallel "not arbitrary or capricious" analysis suggests that agencies may also have a duty to take advantage of readily available ways to structure their regulatory actions so that they promote their statutory purposes more powerfully and effectively, at least when doing that does not significantly or disproportionately increase costs or any equally or more serious undesirable impacts. But there do not appear to be any cases on point one way or the other. *Id.*

³⁴ On the courts' deference to agency decisions for how to interpret the grey areas, ambiguities, and gaps in their authorizing statutes that cannot be clarified through the statutes' text or legislative history, see, e.g., *UTILITY AIR*

Similarly, neither the Tobacco Control Act nor its legislative history provides any guidance as to how FDA should handle conflicts between the Act's objective of reducing overall tobacco-related health harms and its objective of reducing the use of tobacco products by persons under the age of 18. While a rule that was likely to produce a significant reduction in both youth use and overall health harms would clearly be AFPPH and not arbitrary or capricious, as would rules likely to promote either of those objectives without any negative impacts on the other. But guidance for less-clear scenarios are absent here, as well (e.g. if a possible rule would establish large reductions in overall tobacco-related health harms but also substantially increase youth tobacco product use).³⁵ Here, too, FDA has not said anything about how it might try to resolve any such conflicts.

The Tobacco Control Act also provides no guidance as to how FDA is meant to make AFPPH determinations or structure its regulatory actions to be not arbitrary or capricious given the inevitable uncertainties in trying to identify and predict the future health or other relevant impacts from issuing a specific rule or rule variant. In many cases, real world examples of similar interventions in other countries or jurisdictions are sparse or nonexistent, or other relevant research and evidence is inadequate or incomplete or cannot be fully developed. More fundamentally, no matter how much relevant information is available, trying to predict how different members of the tobacco industry will respond to a new rule, such as changes in product development and marketing or new lobbying efforts or legal challenges will always be uncertain and imprecise -- as will efforts to predict how different youth and adult users and nonusers will respond to a new rule and to the industry's related actions.

Here, too, FDA could exercise its discretion to address this gap in the Tobacco Control Act by explaining how it will handle these uncertainty challenges in a reasonable way. Instead, FDA has made its AFPPH decisions to date in an ad-hoc, case-by-case way, without clearly identifying or discussing these uncertainty challenges, without disclosing any formal practices and procedures for handling those uncertainties, and without providing a reasonable explanation and justification for the related practices and procedures it does use to make AFPPH decisions, whether formal or not.³⁶

These gaps in the legal framework provided by the Tobacco Control Act, and the considerable not-yet-exercised discretion given to FDA to determine how to address them, provide a major opportunity for ethical analyses to provide constructive guidance as to:

REGULATORY GROUP V. EPA, 573 U.S. 302, 325 (2014); *U.S. v. BEAN*, 537 U.S. 71, 77 (2002); *CHEVRON, USA V. NRDC*, 467 U.S. 837, 843 (1984).

³⁵ An example might be rule that prompts many smokers to move to less-harmful forms of tobacco use (e.g. minimally harmful e-cigarettes) but, as a side effect, also sharply increases youth use of those less-harmful tobacco products.

³⁶ See, e.g., Lindblom, Eric N., "[The Tobacco Control Act's PMTA and MRTP Provisions Mean to Protect the USA From Any New Tobacco Products That Will Not Reduce Health Harms – But FDA Isn't Cooperating.](#)" *Journal of Health Care Law & Policy* 23(2): 121-186 (Feb. 2021) [on how FDA has not addressed the uncertainty issues adequately in the orders it has issued to date to allow new types of tobacco products on the U.S. market or allow products to be marketed with modified risk tobacco product claims]. For a more general discussion of how FDA could, should, and has handled the uncertainties problem in the context of making AFPPH decisions, see Lindblom, *Food & Drug Law Journal* 74(4): 523-585 (June 2020), *supra* note 24.

- The extent to which FDA should use its extensive tobacco control rulemaking authorities to take more substantive and effective action to realize the Act’s major purpose (to reduce tobacco-related health harms and risks, including youth use) more quickly.
- How FDA should interpret and apply the AFPPH standard in the context of its tobacco control rulemaking.
- Which rules FDA should choose to develop given the many different possible tobacco control rules it could consider, and how it should structure the rules it decides to develop and implement.

The Key Question is Not Whether FDA Should Do More to Reduce Tobacco Use Harms But How It Could Do So Ethically

From any reasonable ethical or moral perspective, there is no excuse for the absence of any substantive FDA tobacco control rules during either the Obama or Trump Administrations.³⁷ Given the enormous health and other harms caused by smoking and other tobacco use, without any offsetting benefits, more aggressive FDA tobacco control action is certainly mandated as ethically necessary and long overdue whether one is following the utilitarian goal of producing the greatest good for the greatest number; the public health ethics’ overriding goal of improving the public health while reducing health disparities and inequities that favor advantaged subpopulations over disadvantaged or vulnerable subpopulations and, to the extent possible, respecting individual autonomy; or the bioethics’ goals of increasing health benefits (beneficence), doing no harm (non-maleficence), ensuring justice, and respecting autonomy.³⁸ No matter how you slice it, the failure of FDA to issue strong substantive rules to quickly reduce smoking and other tobacco use harms is ethically and morally wrong (although it is likely that the Obama and Trump White House

³⁷ In fact, FDA has not even fulfilled its legal obligations under the Tobacco Control Act to issue several substantive tobacco control rules. As mentioned, the TCA required FDA to issue a final rule mandating graphic health warnings on cigarette packs by September 2010. TCA § 201, creating a new 15 U.S.C. 1333(d). FDA issued a final rule in late 2010, but it was struck down by the courts as unconstitutional. Pursuant to a court order, FDA finally issued the statute-required warnings rule in March 2020. *Supra* note 4. The Act also requires FDA to issue a number of other substantive rules that have not yet appeared in proposed or final form, including rules to regulate the sale, distribution, promotion, and marketing of tobacco products not sold in face-to-face exchanges (deadlines passed); to establish good manufacturing practices for tobacco products (no deadline), and to require recordkeeping for tracking and tracing tobacco products from import or manufacture through distribution to retail outlets (no deadline). TCA § 906(d)(4)&(e) [21 U.S.C. 387f(d)(4)&(e)]; § 920(b) [21 U.S.C. 387t(b)]. See, also, § 909(b); § 206, creating new 15 U.S.C. 1333(e). The TCA also required FDA, within 180 days of enactment, to reissue a 1996 FDA final rule relating to cigarettes and smokeless tobacco products, which the courts had struck down in 2000 as beyond FDA’s pre-TCA authorities. TCA § 102 [21 U.S.C. 387a-1]. FDA re-issued that rule but omitted some provisions. FDA, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 75 FEDERAL REGISTER 13225 (March 10, 2010).

³⁸ *Supra* notes 11-13. Even a purely libertarian or individual-rights perspective would have no objection to new FDA tobacco control rules, so long as the rules fully respected individual rights and personal autonomy, and would ethically mandate any tobacco control rules necessary to protect or promote personal autonomy (e.g., by stopping tobacco product users from causing harm to others unable or unwilling to provide consent or preventing tobacco industry actions that mislead consumers). See, e.g., *supra* note 14-15; Janet Hoek, [Informed choice and the nanny state: learning from the tobacco industry](#), 129 PUBLIC HEALTH 1038 (Aug. 2015). More generally, see Carwyn R. Hooper & C. Agule, [Tobacco regulation: autonomy up in smoke?](#), 35 JNL MED ETHICS 365 (June 2009).

Domestic Policy Council, if not the Presidents, themselves, deserve that ethical and moral condemnation, not FDA).³⁹

The only caveat from each of these ethical perspectives is that the ethically required FDA tobacco control rules must be structured not only to reduce tobacco use harms quickly but also to do so consistently with the perspective's broader ethical goals or principles. The key ethical question, then, is: How could FDA develop and structure its tobacco control rules and orders in ethically appropriate ways, consistent with its legal authorities and applicable legal constraints, to reduce tobacco use harms and risks as quickly as possible?

What Would Ethically Ideal FDA Tobacco Control Rules Look Like?

FDA could act consistently with the ethical perspectives being applied here, and largely avoid any related ethical conflicts and uncertainties, if FDA were able to identify and implement AFPPH tobacco control rules that would quickly move toward minimizing tobacco-related health harms and risks, including reducing overall youth use, without causing any significant impacts that would be seen as negative and undesirable by any of the ethical perspectives (or, ideally, producing only additional ethically relevant gains). Such tobacco control rules would be selected and designed to work to reduce the total amount of tobacco-related public health harms as effectively as possible while also following these ethically ideal criteria:

1. Not causing any new health harms to any individuals or subpopulations.
2. Reducing, or at least not increasing, existing health disparities and inequities.
3. Increasing, or at least not reducing, individual autonomy.
4. Reducing, or at least not causing, any other ethically relevant non-health harms or inequitable disparities.
5. Increasing, or at least not reducing, any other ethically relevant benefits.

The fourth and fifth ideal criteria refer to “other ethically relevant” harms or benefits beyond health impacts. Yet bioethics and public health ethics show little concern for any specific, substantive, non-health harms or impacts, beyond their different levels of concern for personal autonomy – except to the extent that those non-health impacts might also have an effect on the public health, individual health, health disparities, or personal autonomy (with the concern over personal autonomy in public health ethics quite weak compared to its public health priority).⁴⁰ Utilitarianism, however, looks well beyond just health, with its focus on producing the greatest *good* for the greatest number being concerned with not only health impacts but any other impacts that have a significant effect on individual people's happiness, pleasure, or overall wellbeing.⁴¹

³⁹ See *supra* notes y and

⁴⁰ *Supra* notes 12-13.

⁴¹ *Supra* note 11. Given the necessity of avoiding death to be able to experience happiness, pleasure, or wellbeing, and the key role of good health, or at least avoiding disability or chronic pain, to be able to secure happiness, pleasure, or wellbeing in various ways, utilitarianism could also be seen as prioritizing major health improvements over certain other non-health harms or benefits.

Accordingly, FDA would have to identify all the non-trivial ethically relevant health and other impacts that different possible rules would or might produce in order to apply these ideal ethical criteria. That could be done through considering parallel or similar real world experiences and relevant available research and other information, with special attention not only to any impacts with public health consequences but also to any impacts that might affect personal autonomy, vulnerable or disadvantaged groups, or related disparities and inequities, or that might otherwise have any significant effects on the happiness or wellbeing of individual people. While doing all that might appear complicated or difficult, it is usually relatively easy to identify the major possible real-world impacts from different specific tobacco control rules based on available research, consultation with relevant experts, logic, and common sense (especially given that rules must be developed through a public notice-and-comment procedure).⁴² Once the possible significant, ethically relevant impacts of a considered rule were identified, FDA would not need to quantify their likelihood or size but would need only to reliably determine whether any of the rule's possible public health or other ethically relevant impacts would or might be negative and non-trivial. If so, the rule would not meet the ideal ethical criteria.

As discussed below, FDA could implement a number of new FDA tobacco control rules that appear to meet the ideal ethical criteria. But implementing them, alone, would not enable FDA to minimize or even sharply reduce tobacco use harms, much less do so quickly. At the same time, applying the ideal ethical criteria would prevent FDA from implementing much more effective tobacco control rules that would certainly be AFPPH and otherwise viable under the Tobacco Control Act. For example, rules to reduce nicotine levels in cigarettes or ban all flavors in smoked tobacco products would all violate the ideal ethical criteria because they would infringe on personal autonomy, at least to some extent, and possibly create at least some brand-new health or other ethically relevant harms. So following the ideal ethical criteria strictly would seriously impede and delay FDA's efforts to achieve the purpose of the Tobacco Control Act, to prevent and reduce tobacco-related harms and improve the public health.

To avoid these impediments -- while still acting ethically and largely avoiding serious ethical conflicts and complications -- FDA could use the ideal ethical criteria to guide, rather than define, its rulemaking efforts under the Tobacco Control Act.

How FDA Could Use the Ideal Ethical Criteria to Guide Its Efforts to Choose, Develop, and Implement Effective, Ethically Appropriate Tobacco Control Rules

To begin reducing tobacco-related harms as quickly as possible in the most ethically appropriate manner, FDA could, first, use the ideal ethical criteria to identify those rules it could issue under its statutory authorities that would be most likely either to secure significant new reductions in tobacco-related public health harms while also reducing youth use (or not increasing it) with no

⁴² FDA is required to develop rules through the APA's notice-and-comment rulemaking process. TCA §§ 906(b); 907(c). In addition, when publishing proposed rules for comment FDA could specifically ask for comments about all possibly significant or relevant harms and benefits the rule might produce, and how any identified harmful impacts might be eliminated.

significant deviations from the ideal ethical criteria (or with such disproportionate and trivial ethically relevant harms that they would certainly be considered negligible and acceptable under any of the ethical perspectives). FDA could then use the ethical criteria to improve the rules by: (1) making all available changes to the rules structure and content that would clearly increase the likelihood and size of the expected public health gains (to the extent that could be done without creating any ethically relevant harms that were not clearly trivial); and then (2) making all available changes that would increase the likelihood and size of any ethically relevant gains or eliminate any risks of producing any ethically relevant harms (to the extent that could be done without reducing the likelihood or size of the net public health gains).

To secure larger and more rapid public health gains, FDA could then use the ideal ethical criteria to identify additional possible rules that would secure disproportionately large public health gains with only relatively small ethically relevant negative impacts (and thereby be most likely to be both AFPPH and ethically appropriate). Then, using the just described process, it would use the ethical criteria to improve them further.⁴³ Going further, FDA could then determine if there were other complementary actions it could readily take under its statutory powers and authorities to maximize the rule's public health gains (without producing ethically relevant harms) and to minimize its ethically relevant harms (without also reducing its public health gains).

Despite all these efforts, it is theoretically possible that the ethically relevant harms caused by a fully developed rule could still be too large, compared to the public health benefits, to make the rule ethically appropriate under one or more of the ethical perspectives. Moreover, in cases where the developed rules were not clearly ethically appropriate, determining when the ratio of the rules' ethical gains to ethical harms were or were not sufficient to make the rule ethically acceptable could raise many of the complications and other difficulties that can occur when trying to evaluate and apply conflicting ethical principles or perspectives, which this analysis has been trying to avoid.

Alternatively, a fully developed rule might appear to be ethically appropriate (e.g., by producing significant public health gains while also reducing youth use, or not increasing it, with no ethically relevant harms or by securing very large public health gains and only very few, very small ethically relevant harms) but might not be AFPPH or ethically acceptable because readily available modifications that would produce additional ethically relevant harms would also disproportionately increase the public health gains. If such additional changes were available and would make the final version of the rule both more AFPPH and more ethically beneficial, overall, FDA should, ethically, implement them, and in especially clear or disproportionate cases might even be required to do so to avoid being "arbitrary or capricious."⁴⁴ But determining whether such changes would make the rule more ethically beneficial, overall, could raise those same

⁴³ In both cases, to ensure compliance with the "not arbitrary or capricious" standard, FDA would also have to take advantage any readily available reasonable steps to revise the rules to reduce its costs that would not also reduce the likelihood or size of the net public health gains they would secure. *Supra* notes 29-33 and associated text. However, such costs are not likely ethically relevant, as they have no direct or significant discernable effect on the health or wellbeing of individual people or subpopulations. In particular, the FDA's tobacco control activities, including any costs of issuing rules, are fully funded through established user fees already levied against the tobacco industry. TCA § 919 [21 U.S.C. 387s]. As discussed more fully below, other economic costs and impacts are unlikely to be ethically relevant, or will be ethically beneficial. *Infra* notes 99-109 and associated text.

⁴⁴ *Supra* notes 29-33 and associated text.

complications and other difficulties inherent in applying inevitably conflicting ethical goals and perspectives.⁴⁵

Fortunately, these ethical and practical challenges are unlikely to appear. Taking some actual rules that FDA might identify and improve through the ethical rule-development process described here will show that these ethical challenges and complications either will not arise or could be readily resolved consistently with the three ethical perspectives because the public health gains (and related ethically relevant gains) from the final rule or the additional rule changes being evaluated would be so disproportionately large compared to the much smaller ethically relevant harms they could produce that the rules or additional modifications would clearly be ethically appropriate.

Moreover, the many tobacco control rule options available to FDA that would likely be both AFPPH and ethically appropriate or acceptable (once FDA takes them through the ethical rule-development process) suggest that FDA could implement a range of constructive new tobacco control rules that would bring tobacco use harms and youth use down to very low levels before ever possibly having to consider implementing any additional rules that would raise more difficult ethical conflicts or complexities. Showing how FDA could use the rule-development process to select and revise some actual rules will also reveal other substantive and procedural challenges and describe how FDA could legally and ethically address them. The remaining barriers would be political and bureaucratic, not legal, practical, or ethical.

Taking Advantage of Readily Available “Ethically Ideal” Rules

Numerous tobacco control rule options available to FDA appear to fit the ideal ethical criteria so closely that they avoid raising any difficult ethical questions. Either they produce no ethically relevant negative impacts or produce only negative deviations from the criteria that are so trivial or disproportionately small compared to the public health and other ethical gains that they must also be ethically appropriate to accept. One possibility would be rules to provide existing tobacco product users with accurate, non-misleading information about tobacco product harms and risks and ways to address them through package inserts or through warnings on packages and in advertising, thereby enabling users and experimenters to make more independent and informed decisions relating to their own tobacco product use and providing assistance to those who choose to try to quit or take other harm-reducing actions.⁴⁶ Other options could prevent tobacco industry

⁴⁵ Given the overriding purpose of the TCA to protect the public health through reducing tobacco-related health harms and risks and reducing youth use, it is likely that FDA would be violating the TCA and also be “arbitrary or capricious” if it revised a proposed rule to secure *smaller* net public health gains in order to reduce ethically relevant harms or increase other ethically relevant benefits, especially if they were non-health harms or benefits – even if an ethical analysis supported such changes. Accordingly, this analysis will not consider that situation. *Id.*

⁴⁶ See, e.g., Adrien Barton, [How Tobacco Health Warnings Can Foster Autonomy](#), 6 PUBLIC HEALTH ETHICS 207 (April 2013); Eric N. Lindblom, et al., [FDA-Required Tobacco Product Inserts & Onserts – and the First Amendment](#), 72 FOOD & DRUG LAW JOURNAL 1 (March 2017); FDA, Proposed Rule, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements* 84 Federal Register 42754 (Aug. 15, 2019). But any information provided to smokers about reducing harms by switching to less-harmful tobacco or nicotine products would have to be carefully designed, and possibly supplemented with other measures, so it does not create any significant risk of prompting smokers who would otherwise quit all use to switch or engage in dual use, instead, or encouraging use of the less-harmful products by otherwise nonusers. See, e.g., Yvette van der Eijk, [Ethics of tobacco harm reduction from a liberal perspective](#), 42 JNL MEDICAL ETHICS 273 (May 2016).

marketing that mislead or manipulate youth or adult consumers by prohibiting certain advertising that reaches youth;⁴⁷ prohibiting terms, colors, or images in ads or labeling or tobacco product sub-branding that inaccurately communicates reduced risk; or allowing ads to have only text and those graphics or images necessary to convey product information to legal adult consumers.⁴⁸

Any such FDA rules that restricted industry advertising or required warnings or information with tobacco products or in their ads would have to do so consistently with First Amendment protections for commercial speech. But FDA could comply with existing First Amendment requirements by designing and testing the required warnings and information and otherwise structuring the rules to ensure that they would help to reduce tobacco use harms, increase consumers understanding about tobacco use harms and risks, leave the tobacco industry with reasonable ways to communicate relevant product information to their legal adult consumers, and not require any warnings or instructions for use that were inaccurate, misleading, or manipulative.⁴⁹ And that First Amendment compliance would also help to ensure that these rules would also fit the ideal ethical criteria, especially in regard to securing significant public health gains without infringing on (and ideally increasing) personal autonomy.⁵⁰

⁴⁷ For example, FDA determined that it was AFPPH to issue an order to allow the new Philip Morris IQOS “heat-not-burn” tobacco product onto the U.S. market, but only if its internet, social media, and other electronic advertising and sales were done only with rigorous age and ID verification to prevent youth exposure to the advertising or access to the sales; and FDA could issue a rule to apply those same kinds of restrictions to all tobacco products. FDA’s decision summary for its order letter presented considerable research and analysis to support this restriction, which would also support extending it to all tobacco product marketing, as well as support a range of other tobacco product advertising restrictions to protect youth. Holman, MR, Director, Office of Science, Center for Tobacco Products, FDA, Marketing Order letter to Philip Morris Products, S.A., FDA Submission Tracking Numbers (STNs): PM0000424-PM0000426, PM0000479 (April 30, 2019); Office of Science, Center for Tobacco Products, FDA, *PMTA Coversheet: Technical Project Lead Review (TPL)* (April 29, 2019) All favorable FDA PMTA orders and underlying decision summaries are available at FDA website, *Premarket Tobacco Product Marketing Orders*, <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>, accessed Sept. 20, 2021.

⁴⁸ There is extensive research and court findings on how the tobacco industry has used and continues to use product characteristics, labeling, and advertising terms and images that mislead consumers in ways that produce inaccurate risk perceptions and increase use or decrease cessation. *See, e.g.*, Lauren K. Lempert & Stanton Glantz, *Packaging colour research by tobacco companies: the pack as a product characteristic* 26 *Tobacco Control* 307 (May 2017); Meghan Moran, et al., “*Beyond 'Natural': Cigarette Ad Tactics that Mislead about Relative Risk*,” 4 *Tobacco Regulatory Science* 3 (Sept. 2018); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 535 (6th Cir. 2011).

⁴⁹ *See e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *R.J. Reynolds Tobacco v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012); *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2011); *See, also*, the First Amendment analyses in Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 *Food and Drug L. J.* 57 (2015); Eric N. Lindblom et al., *FDA-Required Tobacco Product Inserts & Onsets – and the First Amendment*, 72 *Food & Drug L. J.* 1 (2017).

⁵⁰ If the instructions for use or warnings provided information about how some tobacco products are less harmful than others, that could prompt some users of the more-harmful products who would otherwise quit to switch or engage in dual use with the less-harmful products, instead, or could prompt some youth or adults who would not otherwise use any tobacco product to become users of the reduced-risk product. These risks could be avoided by not including any such relative-risk information in any warnings or other messaging unless it had been rigorously tested to ensure that it would not mislead users or nonusers and would encourage health-improving choices (without prompting an health-harming responses).

These rule options would also be consistent with protecting and improving personal autonomy, as they would prohibit only misleading tobacco product characteristics, labeling, and advertising; restrict only those advertising characteristics unnecessary for providing product information to consumers; or prevent advertising that directly reaches youth (who are not legal customers). There also does not appear to be any risk that any of these possible rules would produce any brand-new health or non-health harms, much less any of a size or character to be of ethical significance.⁵¹

Rules to make tobacco products less harmful might be another option for following the ethical ideal. There is considerable skepticism as to whether conventional cigarettes could be made significantly less harmful, largely because making inhaled, burned tobacco markedly less harmful is difficult.⁵² But prohibiting harmful or potentially harmful flavorings and other unnecessary additives to e-cigarette liquids could make e-cigarette use less harmful, and certain harmful ingredients necessary for the e-cigarettes operation might also be prohibited when viable, less-harmful options were available. It also appears that there are ways to make smokeless tobacco products less harmful by setting limits on certain harmful constituents.⁵³

However, such harm-reducing measures might also backfire and increase youth use and overall harms if any otherwise non-using youth and adults were willing to try and use the tobacco products because of the reduced-risk measures, or if some users who would otherwise quit would switch to the reduced-harm products, instead – and such harm-increasing behaviors would be even more likely if the harm or risk reductions in response to the rules prompted youth and adults to perceive them as considerably less harmful than they actually were.⁵⁴ In addition, reducing product harmfulness might be characterized as infringing on personal autonomy if the required changes made the products unpalatable or significantly less attractive to users (e.g., by prohibiting popular but harm-increasing flavors that could not be directly replaced with alternatives). Nevertheless, FDA might be able to develop some rules to reduce the harmfulness of certain tobacco products that would follow the ethical ideal if the final rule: (a) reduced harms in ways that did not also

⁵¹ This conclusion assumes that increasing costs or other burdens on tobacco industry members, or reducing their sales or profits, are not harms of ethical significance in this context. Raising costs on tobacco industry members could also better promote the purposes of the TCA to the extent that they prompted industry members to increase tobacco product prices, which can prevent and reduce tobacco use. *See, e.g.*, U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, *The health consequences of smoking – 50 years of progress: a report of the Surgeon General* (2014) at 322-37. But that could also raise ethical issues relating to increased financial burdens on the low-income households of smokers or other tobacco product users who do not quit or cutback despite the price increases. This issue is considered below. *See infra* notes 104-110 and associated text.

⁵² *See, e.g.*, Michael Givel, [In search of the less hazardous cigarette](#), 41 INT'L JNL HEALTH SERVICES 77 (2011).

⁵³ *See, e.g.*, FDA, *Tobacco Product Standard for N-nitrosornicotine Level in Finished Smokeless Tobacco Products*, 82 Federal Register 8004 (January 23, 2017).

⁵⁴ Such risks would be dampened somewhat by the TCA provisions that prohibit the labeling or marketing of tobacco products with reduced-risk or reduced-exposure claims unless the manufacture first obtains a permissive MRTP order from FDA and that make it illegal for tobacco businesses to make any express or implied communication to consumers that FDA has, through its regulation of a tobacco product, approved it, deemed it safe or less harmful, or endorsed it for consumer use. TCA § 911 [21 U.S.C. 387k]; § 103(b)(13), creating a new 21 U.S.C. 331 (tt). But there would still be considerable press and other media coverage of any rule implemented to make tobacco products less harmful, as well as ongoing related communications about the rule through social media and the like.

make the products less attractive to existing users; (b) placed restrictions on the reduced-harm products' labeling, marketing, and sale that would ensure that their reduced harmfulness would not attract any otherwise non-using youth or adults to use the products or otherwise encourage any new harm-increasing uses of the product; and (c) still made the product readily available to existing users and others whose use of the product would reduce their tobacco-related health harms and risks.⁵⁵

Rules to prevent tobacco-related behaviors by individual users that seriously interfere with the individual rights or personal autonomy of others might also satisfy the ideal ethical criteria. For example, prohibiting the use of smoked tobacco products in certain enclosed areas where children or nonconsenting adults are present might fit these ideal criteria by protecting both the health and personal autonomy of the youth and nonconsenting adults).⁵⁶ But FDA does not appear to have any direct authority to prohibit smoking in any locations. However, FDA does have authority to require labeling on smoked tobacco products stating something like “Not authorized for use in any enclosed locations where children are present” or “To avoid harming others do not use this product when near any other people.”⁵⁷

Some tobacco control initiatives that de-normalize smoking – such as ad campaigns that explicitly or implicitly vilify or denigrate smokers or smoking – have been ethically critiqued because they can alienate, shame, or stigmatize smokers, thereby reducing their general wellbeing.⁵⁸ Such efforts can also interfere with concepts of justice or equity by having a disproportionate negative effect on disadvantaged or marginalized subpopulations, and can prompt policymakers and others to have less respect for the stigmatized smokers' individual autonomy or human rights.⁵⁹ But none of these new harms appear to occur here, as none of the previously described possibly ethically ideal rules would target or mention any specific subpopulations, vilify or criticize smokers, or link smoking or other tobacco use to any disadvantaged or marginalized groups. FDA could further address these ethical concerns about smoker shame or stigmatization by designing and testing any required warnings and provided information to ensure that they did not increase shame or

⁵⁵ Because of these complications and substantive challenges, FDA might choose not to consider any rules to reduce the harmfulness of any specific tobacco products. But FDA must confront parallel issues and challenges whenever it considers applications to allow new tobacco products on the market or to allow certain tobacco products to be marketed with reduced-risk or reduced-exposure claims. TCA §§ 910, 911 [21 U.S.C. 387j, 387k]. On how FDA might address these challenges, see Lindblom, Eric N., “[How Would an Ethically Responsible FDA Evaluate PMTA and MRTP Applications and Issue Related Orders?](#),” *Food and Drug Law Journal* 75(1): 1-38 (August 2020).

⁵⁶ See, e.g., Katz (2005), *supra* note 15; Thaddeus Mason Pope, [Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations](#), 61 UNIVERSITY OF PITTSBURGH LAW REVIEW 419 (2000).

⁵⁷ TCA § 906(d) [21 U.S.C. 387f(d)].

⁵⁸ See, e.g., Kristin Voigt, [Smoking and Social Justice](#), 3 PUBLIC HEALTH ETHICS 91 (2010); Bryan P. Thomas & Lawrence O. Gostin, [Tobacco Endgame Strategies: Challenges in Ethics and Law](#), 22 TOBACCO CONTROL i55 (2013); Jessica Flanigan, [Double Standards and Arguments for Tobacco Regulation](#), 42 JNL MEDICAL ETHICS 305 (2016); Lynn T. Kozlowski, [Younger individuals and their human right to harm reduction information should be considered in determining ethically appropriate public health actions](#), NICOTINE & TOBACCO RESEARCH (Epub April 3, 2019). More generally, see, e.g., Andrew Courtwright, [Stigmatization and Public Health Ethics](#), 27 BIOETHICS 74 (2013); Ronald Bayer, [Stigma and the ethics of public health: Not can we but should we](#), 67 SOC. SCIENCE & MEDICINE 463 (2008). For an ethical defense of tolerating stigma in some public health interventions, see Andrew Courtwright, [Stigmatization and public health ethics](#), 27 BIOETHICS 74 (Feb. 2013).

⁵⁹ *Id.*

alienation among smokers and did not further stigmatize smokers or otherwise make nonusers view smokers less favorably.

Common sense indicates that all of the previously described ethically ideal rule possibilities would also be highly likely to produce at least some public health gains by providing useful information to consumers, reducing tobacco product marketing that is misleading or reaches youth, or reducing youth access to tobacco products. But FDA would have to design and evaluate the rules carefully to ensure that they would be highly likely to produce at least some public health gains with no significant risk of creating any non-trivial new health or other harms or increasing youth use.⁶⁰

If FDA confirmed that a rule would not create any significant risk of creating any new health harms, that would also ensure that the rule would not create any significant new health harms or risks to any disadvantaged or vulnerable subpopulations. Nevertheless, it would still be possible for such a rule to increase health disparities if it benefited advantaged subpopulations more than it benefited disadvantaged or vulnerable subpopulations. For example, there is evidence that less-educated or less literate consumers could be less likely to understand product warnings or consumer information and less likely respond in ways that improve their health compared to other consumers.⁶¹ FDA could minimize this risk by designing the warnings or instructions so that they could be readily understood, at least to some extent, by all consumers, regardless of education, literacy, or primary language.⁶² If that were done, it is likely that any minimal increase in health disparities still caused by the warnings or instructions would, at worst, be only marginal, if not trivial.⁶³ Any such impacts would also likely be ethically acceptable under each of the ethical perspectives as the less educated and less literate subpopulation would still experience significant health improvements, their personal autonomy would be increased by receiving useful warnings and information, overall public health and personal autonomy would also be improved, and there would be no other significant ethically relevant harms caused by the rule.

⁶⁰ How FDA could do that in a reasonable, “not arbitrary or capricious” way is discussed below in the more complex and difficult context of possible AFPPH rules that also create significant ethically relevant impacts. *Infra* text preceding and associated with note 74-78.

⁶¹ See, e.g., Sarah Hill, et al., [Impact of tobacco control interventions on socioeconomic inequalities in smoking: review of the evidence](#), 23 TOBACCO CONTROL e89 (Nov. 2014); Tamara Brown, [Equity impact of population-level interventions and policies to reduce smoking in adults: a systematic review](#), 138 DRUG & ALCOHOL DEPENDENCE 7 (May 2014); Theo Lorenc, et al., [What types of interventions generate inequalities? Evidence from systematic reviews](#), 67 JNL EPIDEMIOLOGY & COMMUNITY HEALTH 190 (Feb. 2013); Jeff Niederdeppe, et al., [Socioeconomic variation in recall and perceived effectiveness of campaign advertisements to promote smoking cessation](#), 72 SOCIAL SCIENCE MEDICINE 773 (March 2011).

⁶² For example, FDA could use images as well as text and could require that warnings or instructions delivered with tobacco products periodically appear in languages other than English common among consumers and that warnings in ads be in the same language as the ads. Going further, FDA could make any readily available revisions to the warnings or information that related research or testing indicated would increase beneficial impacts on disadvantaged or vulnerable subpopulations without reducing the benefits to the more advantaged subpopulations by even more.

⁶³ See, e.g., Takahiro Tabauchi, et al., [Tobacco Control Measures to Reduce Socioeconomic Inequality in Smoking: The Necessity, Time-Course Perspective, and Future Implications](#) 28 JNL EPIDEMIOLOGY (April 2018) (“all tobacco control measures may have the potential to reduce smoking inequality, if they continue for a long term, covering and reaching all socioeconomic subgroups”).

Other than carefully designing and testing the warnings or information required to be provided to consumers, there do not appear to be any other readily available ways to revise those rules, within their scope, either to increase the rules' public health gains (with or without creating or increasing ethically relevant harms) or to increase the rules' other ethically relevant benefits or reduce their ethically relevant harms (without reducing public health gains). With any rules to minimize youth exposure to tobacco product advertising, however, FDA would need to include all readily available measures to minimize that exposure that would be consistent with the First Amendment, and the efforts to ensure compliance with the First Amendment would also help to ensure that the restrictions would not create any new ethically relevant harms (e.g., by impeding the delivery of useful product information to consumers). Similarly, with any rules to prevent or reduce the use of misleading or potentially misleading text, images, or other content in tobacco product labeling or advertising, FDA would also have to take advantage of all readily available measures to do so that would not violate the First Amendment, while also ensuring compliance.⁶⁴

Having to put these rules through the APA's notice-and-process rulemaking procedures would also help to ensure that all ethically appropriate revisions to the rules were made, as interested parties would likely suggest numerous ways the rule might be revised to increase public health or other gains or to prevent or reduce any related harms or costs (whether they were ethically relevant or not). As an extra precaution, FDA could expressly ask for comments that would identify any missed opportunities to revise the rules, within their scope, to secure even larger public health gains (ideally without producing any serious non-health harms) or to reduce any harms or costs from the rules (without reducing their public health gains).⁶⁵

Although quickly implementing all rules that directly follow the ideal ethical criteria would accelerate tobacco control gains considerably, they would not quickly minimize tobacco-related health harms. When done well, warnings on tobacco product labels and ads and providing information via product inserts or onserts can directly and significantly increase knowledge, improve risk perceptions, and increase desires or intentions to quit only among a portion of all

⁶⁴ To help ensure constitutional and ethical compliance, any such FDA rules should include a procedure whereby businesses would be given exceptions to any of the rules' advertising or other communication restrictions if they provided convincing evidence to FDA that the exception was necessary to provide accurate, non-misleading product information to legal adult customers or would provide such information to legal consumers without creating any significant risk of increasing tobacco use or harms among youth. *Supra* note 49 and associated text. Whether FDA has an ethical duty to include advertising and other commercial speech restrictions and requirements in these rules that are in the gray areas of constitutionality under evolving First Amendment law is beyond the scope of this paper. But to avoid potential delays in securing the most powerful available declines in tobacco harms from any rules that include restrictions or requirements that raise First Amendment issues, FDA should also include in those rule some safety-net or back-up provisions in those rules that would easily pass constitutional muster and would remain in place or be activated if any of the stronger provisions in the rule were struck down by the courts.

⁶⁵ *Supra* note 42. Once a proposed rule is issued for public comment, the regulatory agency may not make any changes to the proposed rule in the implemented final version unless they are a "logical outgrowth" from the proposed rule (e.g., not outside the scope of the proposed rule as described in the notice of proposed rulemaking and the proposed rule, itself). *See, e.g.*, *Environmental Defense Center v. E.P.A.*, 344 F.3d 832, 851 (9th Cir., 2003); *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 642 (1979) (cert. denied, *Costle v. EPA*, 444 U.S. 1096 (1980)). Similarly, the previously cited cases finding that regulatory agencies, prior to issuing a final rule, must make any readily available changes which would reduce their costs without reducing their ability to achieve statutory objectives do not in any way indicate that the regulatory agency might also have a legal duty to reduce costs by issuing an entirely different less-costly but equally or more effective rule, instead. *STATE OF LA.*, 853 F.2d 322 (5th Cir. 1988), *SOUTH TERMINAL*, 504 F.2d 646 (1st Cir. 1974), *supra* note 32.

users, and their impacts on actually prompting those addicted users to quit all use are less profound.⁶⁶ Preventing advertising that reaches youth (while leaving the industry with ways to continue reaching adult consumers) would help reduce the number of youth who become new tobacco users, but would have a less powerful impact on reducing the vast amount of all tobacco use that is done by existing adults users. Also restricting the characteristics of all still-permitted tobacco product advertising to prevent the use of words, phrases, colors, or images that mislead consumers would directly dampen tobacco use among adults, as well. But even if the rules were made as strict and comprehensive as the First Amendment allows, they still could not be as effective as the complete bans on tobacco product advertising that many other countries have, and those bans have not quickly cut adult smoking rates in half or otherwise dramatically reduced smoking and other tobacco use, much less minimized it.⁶⁷ Similarly, prohibiting certain tobacco product and packaging colors, images, words, or other characteristics that attract or mislead consumers would also help dampen tobacco use, but would not reduce it quickly or sharply.⁶⁸

Accordingly, to honor the purpose of the Tobacco Control Act and fulfill the ethical duty to minimize tobacco use deaths and harms as quickly as possible, FDA would need to supplement the implementation of the rules that closely follow the ethical ideal with other AFPPH tobacco control rules it can identify and develop that would also be ethically appropriate, despite creating some ethically relevant harms or risks.

Identifying and Developing Additional Rules to Reduce Tobacco-Related Harms as Quickly and Ethically as Possible

The most powerful tobacco control rules that FDA has said it is considering are rules to reduce nicotine to non-addicting levels in cigarettes and possibly other smoked tobacco products; to ban menthol in cigarettes (the only non-tobacco flavor still allowed for cigarettes); and to ban flavors in cigars (which currently have no flavor restrictions).⁶⁹ Although they would all secure significant

⁶⁶ See, e.g., Victoria Lambert, et al., [Exploring the impact of efficacy messages on cessation-related outcomes using Ecological Momentary Assessment](#), 16 TOBACCO INDUCED DISEASES 44 (Sept. 2018); James F. Thrasher, et al., [Cigarette package inserts can promote efficacy beliefs and sustained smoking cessation attempts: A longitudinal assessment of an innovative policy in Canada](#), 88 PREVENTIVE MEDICINE 59 (July 2016); David T. Levy, et al., [The Impact of Implementing Tobacco Control Policies: The 2017 Tobacco Control Policy Scorecard](#), 24 JNL PUBLIC HEALTH MANAGEMENT & PRACTICE 448 (Jan. 2018); Seth M. Noar, et al., [The Impact of Strengthening Cigarette Pack Warnings: Systematic Review of Longitudinal Observational Studies](#), 164 SOCIAL SCIENCE & MEDICINE 118 (Sept. 2016); Steven J. Hoffman & Charlie Tan, [Overview of systematic reviews on the health-related effects of government tobacco control policies](#), 15 BMC PUBLIC HEALTH 744 (Aug. 2015).

⁶⁷ See, e.g., Levy (Jan. 2018) and Hoffman & Tan (Aug. 2015), *id*; Wilm Quentin, et al., [Advertising bans as a means of tobacco control policy: a systematic literature review of time-series analyses](#), 52 INT'L JNL PUBLIC HEALTH 295 (2007).

⁶⁸ See, e.g., [A systematic review of smoker and non-smoker perceptions of visually unappealing cigarette sticks](#), 16 TOBACCO INDUCED DISEASES 02 (Jan. 2018); Aaron Drovandi, et al., [A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes](#), 8 SYSTEMATIC REVIEWS 25 (Jan. 2019).

⁶⁹ FDA News Release, [FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers](#) (April 29, 2021). Jennifer Maloney, ["Biden Administration Considering Rule to Cut Nicotine in Cigarettes," The Wall Street Journal](#) (April 29, 2021). FDA, website, "Comprehensive Plan for Tobacco and Nicotine Regulation" ("last updated 07/31/2019"), <https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation> (accessed Sept. 20, 2021). Alex M. Azar & Scott Gottlieb, [We cannot let e-cigarettes become an on-ramp for teenage addiction](#), *The Washington Post* (Oct. 11, 2018). Scott

public health gains, these rules would directly infringe on personal autonomy, at least to some extent, by reducing the existing range of legal tobacco product choices available to adult consumers. It is also possible that these rules might create other ethically relevant harms or risks, perhaps by prompting the development of an illicit market offering illegal versions of the newly prohibited or restricted tobacco products to any former users willing and able to buy them.

There do not seem to be any obviously more powerful tobacco control rule options available to FDA under its statutory authorities, much less any that would also produce smaller ethically relevant harms.⁷⁰ But there are other viable options with similar or weaker tobacco control potential that FDA could also consider, such as rules to restrict the sale of smoked or all tobacco products to adult-only locations;⁷¹ ban existing filters on smoked tobacco products;⁷² or prohibit or restrict sweeteners or other additives to smoked or all tobacco products that make them more

Gottlieb & Mitchell Zeller, [A Nicotine-Focused Framework for Public Health](#), 377 *New England Jnl Medicine* 1111 (Sept. 21, 2017). FDA, News Release, “FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death” ([July 27, 2017](#)); Gottlieb, S. [FDA Commissioner], Speech, “Protecting American Families: Comprehensive Approach to Nicotine and Tobacco” ([July 28, 2017](#)). FDA, Special Announcement, “FDA Seeks Public Comment on a Potential Product Standard to Lower Nicotine in Cigarettes to a Minimally or Non-Addictive Level” (March 15, 2018), accessed Sept. 15, 2021, <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-seeks-public-comment-potential-product-standard-lower-nicotine-cigarettes-minimally-or-non>. FDA, Advance Notice of Proposed Rulemaking, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, *Federal Register* [83\(52\): 11818](#) (March 16, 2018). FDA, Advance Notice of Proposed Rulemaking, Regulation of Flavors in Tobacco Products,” *Federal Register* [83\(55\): 12294](#) (March 21, 2018). See, also, HHS/FDA, “Tobacco Product Standard for Characterizing Flavors in Cigars,” RIN: 0910-AI28, in the federal Unified Agenda of Regulatory and Deregulatory Actions, Spring 2021 [listing “08/00/2021” as date for proposed rule], <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202104&RIN=0910-AI28>. The Spring 2021 Unified Agenda has no listing for an FDA proposed nicotine-reduction rule; but it had been listed on the Unified Agenda previously, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0910-AH86> (Spring 2019). Unified Agenda items accessed Sept. 20, 2021.

⁷⁰ The TCA specifically prohibits any FDA rules that would prohibit tobacco product sales except through medical prescriptions or authorizations; prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlet; establish a minimum age of sale of tobacco products greater than 18; or ban all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products. TCA § 906(d)(3) [21 U.S.C. 387f(d)]; § 907(d)(3) [21 U.S.C. 387g(d)(3)]. In addition, the TCA does not provide FDA with any authority to establish or increase taxes on tobacco products, prohibit smoking or other tobacco use in certain locations, or provide cessation drugs or other cessation treatment assistance to individual users (as opposed to running public health campaigns or requiring cessation information to be provided along with tobacco products).

⁷¹ See, e.g., Jennifer M. Polinski, et al., [Impact of CVS Pharmacy's Discontinuance of Tobacco Sales on Cigarette Purchasing](#) (2012-2014), 107 *AM. JNL. PUBLIC HEALTH* 556 (April 2017); Laura J. Finan, et al., [Tobacco outlet density and adolescents' cigarette smoking: a meta-analysis](#), 28 *TOBACCO CONTROL* 27 (Jan. 2019).

⁷² See, e.g., Jeffrey S. Stein, et al., [Effects of Filter Ventilation on Behavioral Economic Demand for Cigarettes: A Preliminary Investigation](#), 20 *NICOTINE & TOBACCO RESEARCH* 1278 (Oct. 2018); Min-Ae Song, et al., [Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma](#), *JNL NAT'L CANCER INST* (Epub Dec. 1, 2017); Richard J. O'Connor, et al., [Filter presence and tipping paper color influence consumer perceptions of cigarettes](#), *BMC PUBLIC HEALTH* (Epub. Dec. 22, 2015); [The intractable cigarette 'filter problem.'](#) 20(Suppl 1) *TOBACCO CONTROL* i10 (May 2011). See, also, Thomas E. Novotny, et al., [Tobacco and cigarette butt consumption in humans and animals](#), 20(Suppl 1) *TOBACCO CONTROL* i17 (May 2011); Javad Torkashvand, et al., [Littered cigarette butt as a well-known hazardous waste: A comprehensive systematic review](#), *JNL HAZARDOUS MATERIALS* (Epub Sept. 19, 2019).

palatable or appealing.⁷³ These additional options could also be seen as reducing personal autonomy (e.g., by removing certain tobacco product options currently available to adult consumers) and might also produce other ethically relevant harms or risks (e.g., if they prompted illicit sales of non-compliant products).

Given the enormous amount of ongoing tobacco use harms and the ethical need to reduce them as quickly as possible, FDA would, ideally, implement as many of these possible additional new AFPPH rules as possible that could also easily qualify as ethically appropriate – at least after FDA worked to make them approximate the ideal ethical criteria by taking advantage of any available means to maximize their public health gains while minimizing their ethically relevant harms and securing any other available ethical gains (without reducing their public health benefits).⁷⁴

As a first step, FDA would need to identify the public health and other ethically relevant impacts from each of the possible rules and how they might be changed by any readily available revisions. Doing that would be complicated by the previously described uncertainties that inevitable arise when trying to identify or quantify the relevant impacts of a possible rule, given the difficulties in predicting how the industry will respond or how different relevant subpopulations of youth and adult consumers might respond to the rule and the industry’s responses. However, FDA could legally and ethically handle these complications by exercising its discretion to rely on any reasonable “not arbitrary or capricious” method for identifying and estimating the future relevant impacts of the various rules it might choose, revise, and implement.

For example, FDA might reasonably determine that using estimated impacts on reduced mortality, increases in life years, or increases in quality adjusted life years (QALYs) were valid proxies for quantifying a rule’s future health impacts, both among the population as a whole and among different subpopulations, such as youth, adults, users, nonusers, or certain disadvantaged vs

⁷³ It is clear from the TCA and its legislative history that FDA has strong legal authority to issue a rule to restrict the amount of nicotine in cigarettes (or any other tobacco products) to non-actionable or non-addicting levels (so long as it does not require yields of zero nicotine), and that such a rule would not constitute a TCA-prohibited de facto ban of all cigarettes, cigars, or little cigars. Micah L. Berman, et al., [Anticipating Industry Arguments: The US Food and Drug Administration’s Authority to Reduce Nicotine Levels in Cigarettes](#), 133 PUBLIC HEALTH REP. 502 (July-Aug. 2018). But it is possible that the courts would strike down an FDA rule to eliminate all or some additives in certain tobacco products as a prohibited de facto ban if it made the products so unpalatable that they could not be consumed.

⁷⁴ More realistically, FDA ethically needs to develop and implement any ethically appropriate AFPPH rule that the powers that be will support or at least allow, even if other rules might be even better for the public health, produce smaller ethically relevant harms, or have better ethically relevant benefits to harms ratios. Even in an ideal world where FDA could implement any and all ethically appropriate AFPPH rules and were able to implement many simultaneously or consecutively, the public health and other ethically relevant impacts of the rules could change considerably if they were implemented after certain others. For example, a rule to make smoked tobacco products less appealing by prohibiting filters or banning flavors would have a much larger public health impact and different impacts on personal autonomy if implemented first, by itself, compared to being implemented only after a prior rule that minimized nicotine levels in all smoked tobacco products (when they might not even be needed if the nicotine rule works well). Accordingly, FDA’s analyses and evaluations of the public health and other ethically relevant impacts of its rule options, and its related revisions to the rules to improve those impacts, will have to take into account other rulemaking, as well as any major new non-FDA federal, and possibly state/local, tobacco-related changes to laws or regulations.

advantaged groups.⁷⁵ Then FDA could determine that it was reasonable to project those impacts through using relevant experts' worst-case, best-case, and most-likely-case estimates (based on available research, data, and other evidence) relating to the major factors creating such mortality or life-year impacts, such as the extent to which the rule would prompt different harm-increasing or harm-reducing behavior changes among different subpopulations (including considerations of different ways the industry might react to the rule to influence consumer behaviors), or what the mortality or life-year gains or losses would be among different subpopulations and overall from the different behavior changes. FDA could develop these evidence-based expert estimates by having its own tobacco control experts or relevant outside experts review available relevant data, research, and analysis before developing consensus worst, best, and most-likely case estimates. Or estimated ranges of relevant health impacts and probabilities could be developed through more formal and detailed modeling, with formal expert elicitations or other reasonable procedures used to develop any of the model's needed inputs which had uncertain values that could not otherwise be reasonably quantified.⁷⁶

Consultations with relevant experts could also identify the major ethically relevant non-health harms and risks that the various rules might produce. Quantifying estimated possible impacts on personal autonomy, happiness, or overall wellbeing or other non-health impacts would be more difficult, compared to estimating mortality, life-year, or QALY impacts.⁷⁷ Nevertheless, FDA could still reasonably use the procedures outlined here at least to estimate the numbers of people in different relevant subpopulations who might have their personal autonomy affected or have their non-health happiness or wellbeing affected in various identified and described positive or negative ways under best-case, worst-case, and most-likely case scenarios.⁷⁸

Such procedures to identify and estimate the impacts of the rule options on the public health, the health of relevant subpopulations, and other ethically relevant impacts would provide FDA with sufficient information it needs to evaluate which rules to develop and how to revise them ethically before implementation. As these procedures and their impact estimates would confirm, numerous different rule options available to FDA would produce declines in smoking or overall tobacco use harms that would be massive compared to any new ethically relevant harms and risks they would produce (even under the most pessimistic or worst-case scenarios), especially after FDA took all readily available steps to approximate the ideal ethical criteria as closely as possible. By implementing these tobacco control rules (along with those that do not produce any non-trivial

⁷⁵ See, e.g., John La Puma J & Edward F. Lawlor, [Quality-Adjusted Life-Years: Ethical Implications for Physicians and Policymakers](#), JAMA 263(21):2917-21 (1990); Yves Arrighi et al., [To count or not to count deaths: reranking effects in health distribution evaluation](#), 24 Health Economics 193 (Feb. 2015).

⁷⁶ See, e.g., M. Granger Morgan, [Use \(and abuse\) of expert elicitation in support of decision making for public policy](#), 111 PROC. NAT. ACAD. SCI. USA 7176 (2014); Benjamin J. Apelberg, et al., [Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States](#), 378 NEW ENG. J. MED. 1725 (2018); David T. Levy et al., [Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States](#), 101 AM. J. PUB. HEALTH 1236 (2011).

⁷⁷ But see, e.g., Steven J. Firth, [The Quality Adjusted Life Year: A Total-Utility Perspective](#), 27 Cambridge Quarterly Healthcare Ethics 284 (April 2018).

⁷⁸ Given the many more promising rule options available, FDA could promote its goal of improving the public health with as few ethical negatives or complications as possible by simply rejecting any possible rules where the most pessimistic expert estimates indicated possible negative net public health impacts or suggested the possibility of only small public health gains with significant ethically relevant harms.

ethically relevant harms) FDA could largely or completely avoid the difficult and complicated ethical issues that would arise when evaluating rules with smaller public health gains and larger ethically relevant losses to determine whether their ethical benefits outweigh their ethical harms.

Nevertheless, FDA could still face significant ethical challenges in its efforts to implement any revisions to the rules, or complementary actions, that would increase its public health gains without *disproportionately* increasing its ethically relevant harms and risks. Disproportionately could be interpreted and applied quite differently among or within the different ethical perspectives. But here, too, the ethical complications could be largely or completely avoided if the available changes would all produce reasonably estimated public health gains (perhaps with other ethical benefits) that were obviously much more ethically beneficial than any related new or increased ethically harmful impacts – and FDA could simply reject any revisions that created any ethical close calls.

To see how this could play out in a possible real-world example, this analysis will consider an FDA rule to reduce nicotine levels in cigarettes and possibly other smoked tobacco products, which FDA and HHS (FDA’s parent department) once said was FDA’s and the Department’s top tobacco control priority.⁷⁹ A nicotine-reduction rule also appears to be one of the most powerful tobacco control rules FDA could implement.⁸⁰ Following the ideal ethical criteria, this analysis will consider how FDA might:

1. Take advantage of any readily available means to increase the likelihood and size of the net public health gains from the rule without disproportionately:
 - (a) Causing any new health harms to any individuals or subpopulations
 - (b) Increasing inequitable health disparities
 - (c) Infringing on personal autonomy
 - (d) Causing any other ethically relevant harms or disparities
2. Take advantage of any readily available measures that would not reduce the net public health gains from the rule but would reduce or reverse the likelihood or size of any possible:
 - (a) New health harms to any individuals or subpopulations
 - (b) Increased inequitable health disparities
 - (c) Infringements on personal autonomy
 - (d) Other ethically relevant non-health harms or inequitable disparities
3. Evaluate whether the final rule is not only AFPPH (under any possible, legally viable interpretation of the standard) but also ethically acceptable or appropriate.

⁷⁹ *Supra* note 10.

⁸⁰ See, e.g., Apelberg, et al. (2018), *supra* note 76; Eric N. Lindblom, [Filling in the Blanks on Reducing Tobacco Product Addictiveness in the FTC Partial Guidelines for Articles 9 & 10](#), O’NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW WORKING PAPER NO. 1 (Nov. 2014), https://oneill.law.georgetown.edu/wp-content/uploads/2014/11/Oneill_Institute_Working_Paper_Article_9_and_10_Guidelines_V2.pdf (last visited Sept. 20, 2021). David T. Levy et al., [Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States](#), 101 Am. J. Pub. Health 1236 (2011). Christopher J. Cadham, et al., [“The actual and anticipated effects of a menthol cigarette ban: a scoping review,”](#) *BMC Public Health* 20(1): 1055 (July 2020). See, also, *supra* note 10.

Ethics and an FDA Rule to Reduce Nicotine in Cigarettes and Other Smoked Tobacco Products

After the implementation of a rule reducing the amount of nicotine in cigarettes to non-actionable or non-addicting levels, smokers could no longer satisfy their addiction and related cravings through smoking cigarettes and would, consequently, quit all tobacco-nicotine use or switch to some other way of obtaining the nicotine their addictions demanded. To reduce all smoking and ensure that smokers did not simply switch to other smoked tobacco products, which would not secure any significant public health gains, the nicotine rule must apply not only to cigarettes but to any smoked tobacco product that could be used as a cigarette or smoking substitute.⁸¹ To ensure that smokers would not be able to compensate for the reduced nicotine levels and secure the nicotine their addiction craves by inhaling more deeply or smoking more, the rule would have to reduce the amount of nicotine permitted in the subject tobacco products all at once, with no phasing in, and require such low levels that it would be impossible for any quantity of the products to deliver addiction creating or sustaining levels no matter how often or intensely they were smoked.⁸²

The Tobacco Control Act provisions requiring manufacturers to obtain prior FDA approval before introducing any new or substantially changed tobacco products onto the U.S. market should prevent the tobacco industry from modifying their minimal-nicotine smoked tobacco products with new ingredients so that they are still physically addictive.⁸³ But FDA could further protect against such strategies by using a comprehensive definition of nicotine in its rule (e.g., including nicotine analogues; prohibiting synthetic nicotine in any tobacco products; and prohibiting any other additives intended, expected, or likely to make the tobacco products more physically addictive. Going further, FDA could permit manufacturers of existing smoked tobacco products to make only those changes necessary to bring the products into compliance and require the manufacturers to show that any related changes to any non-nicotine ingredients or constituents of the product would not increase its physical addictiveness.

Predicting the future impacts of such a rule are difficult because no other country or jurisdiction has yet implemented such a rule. But actual results are likely to be more powerful than those found

⁸¹ Smoked tobacco products which might not serve as viable direct alternatives to cigarettes include expensive, premium cigars; other cigars too harsh for active inhaling; and perhaps hookah or other pipe tobacco if it could not be inhaled deeply when smoked or could not be rolled into cigarettes. But some experts in the FDA-supported modeling study predicted that some cigarette smokers would switch to using water pipes or hookah if hookah tobacco was not subject to the nicotine-reduction rule. Apelberg, et al. (2018), *supra* note 76. Excluding any smoked tobacco products would also reduce public health gains by failing to prompt users of those products to quit all use or switch to less-harmful tobacco-nicotine products, and by enabling smokers of the subject smoked tobacco products to switch completely or partly to smoking the exempted products.

⁸² See, e.g., Dorothy Hatsukami, et al., [*Effect of Immediate vs Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure: A Randomized Clinical Trial*](#), 320 JAMA 880 (Sept. 2018); Dorothy Hatsukami, et al., [*Compensatory smoking from gradual and immediate reduction in cigarette nicotine content*](#), 24 CANCER EPIDEMIOLOGICAL BIOMARKERS PREVENTION 472 (Feb. 2015); Lindblom, O'Neill Inst. Working Paper (Nov. 2014), *supra* note 80. Under the TCA, FDA can reduce nicotine levels in tobacco products to the lowest levels it determines are AFPPH, but FDA cannot issue a rule requiring the reduction of nicotine *yields* to zero. TCA § 907(d)(3)(B) [21 USC 387g(d)(3)(B)].

⁸³ TCA § 910 [21 U.S.C. 387j].

in empirical studies with samples of smokers given only reduced-nicotine cigarettes, which were necessary conducted in today's world where legal full-nicotine cigarettes were still readily available and used by some of the study smokers to escape the studies' restrictions.⁸⁴ An FDA-developed expert-elicitation modeling study has estimated that a rule which reduced nicotine levels to such non-actionable levels in all cigarettes and all other smoked tobacco products highly likely to serve as cigarette substitutes would, over 45 years, prevent 700,000 to 4.3 million deaths, producing a gain of 31.6 to 183 million life years, with related estimates of reduced initiation, increased cessation, dual use, and the like.⁸⁵ Additional expert-elicitation estimates and modeling could supplement and refine those estimates, and identify and estimate the other ethically relevant impacts FDA should consider.⁸⁶

The main factors the FDA modeling study considered that could reduce the nicotine rule's public health gains were smokers switching to illicit full-nicotine cigarettes or switching to non-smoked legal tobacco products (e.g., e-cigarettes or smokeless tobacco or IQOS) instead of quitting all use.⁸⁷ Other significant possibilities include e-cigarettes turning out to be more harmful or less harm-reducing than expected to those smokers who switch to them, or delayed smoking cessation or increased initiation because smokers, youth, and others believe that the new minimal-nicotine cigarettes and other smoked tobacco products are substantially less harmful or risky than the prior full-nicotine versions.⁸⁸

Smoking reductions and related health gains from a nicotine rule could also be delayed or reduced if some smokers responded by continuing to smoke the minimal-nicotine cigarettes while still satisfying their addictions either by also using some other legal products to deliver the nicotine needed to satisfy their addiction (e.g., e-cigarettes, IQOS, smokeless tobacco, or medicinal nicotine

⁸⁴ See, e.g., Hatsukami (Sept. 2018) and Hatsukami (Feb. 2015) *supra* note 82; Eric C. Donny, et al., [Randomized Trial of Reduced-Nicotine Standards for Cigarettes](#), 373 NEW ENGLAND JNL MEDICINE 1340 (Oct. 2015).

⁸⁵ Apelberg, et al. (2018), *supra* note 76. The published study did not report on any explanations from the experts as to why they came up with such wide ranges of possible positive impacts. While that might have been helpful for further analysis, the key finding here is that all the projected health results were positive and substantial, and there was no finding of any likelihood of a negative public health impact of any size.

⁸⁶ New expert-based procedures could also be used to provide more up-to-date estimates of the same consumer behavior and public health impacts the existing FDA-supported modeling study provided, based on the continually growing body of relevant research and other information, or based on the perspectives of additional or different relevant experts to confirm the prior study or provide a stronger foundation for the estimates. But the absence of any estimated negative estimates and the consistently large estimates of beneficial impacts from the study already done by FDA indicate that it may already provide sufficient estimates to enable FDA to move forward without being "arbitrary or capricious."

⁸⁷ FDA allowed Phillip Morris IQOS "heat-not-burn" tobacco-based cigarette substitute onto the U.S. market by issuing a permissive PMTA order for several IQOS products in April 2019. Holman, FDA Marketing Order (April 30, 2019), *supra* note 47. Although FDA has determined that IQOS fits the legal definition of "cigarette" in the TCA, it presumably would not be included in any rule to reduce nicotine in conventional cigarettes as FDA found that allowing it on the U.S. market was AFPPH explicitly because it would serve as a less-harmful smoking alternative.

⁸⁸ Such beliefs are quite possible because many believe that nicotine is the major carcinogen or harm-causing ingredient in cigarettes and other smoked tobacco products. See, e.g., M. Justin Byron, et al., [Public misperception that very low nicotine cigarettes are less carcinogenic](#), 27 TOBACCO CONTROL 712 (Nov. 2018); Melissa Mercincavage, et al., [Examining Risk Perceptions Among Daily Smokers Naïve to Reduced Nicotine Content Cigarettes](#), 21 NICOTINE & TOB. RESEARCH 985 (July 2019).

gum or patches) or by somehow adding nicotine into the minimal-nicotine cigarettes. But any smokers who tried these strategies, especially those with low incomes, might not be able to tolerate or sustain the considerable added expense, time, and inconvenience and, at some point, move on to more affordable and beneficial options, such as using only legal nicotine-delivery products or quitting all use.⁸⁹

Because of a range of practical difficulties and the continued legal availability of alternative ways smokers could continue inhaling nicotine, it is also unlikely that any large-scale illicit trade in full-nicotine cigarettes would emerge to reduce the public health gains of the nicotine-reduction rule to any great extent.⁹⁰

Following the ethically directed rulemaking procedures outlined in this paper – and guided by related expert consultations or elicitations – FDA would also implement a range of readily available rule modifications and complementary actions to reduce these possible threats to the nicotine rule’s public health gains (without creating any disproportionately large new or increased ethically relevant harms). Such actions would likely include the following:

- To prevent the emergence of any significant illicit trade: (a) prohibit the distribution and sale of commercial cigarette-making machines and non-nicotine-reduced tobacco, filters, and cigarette and cigar papers or other wrapper in larger-than-consumer-use quantities to anyone other than exporters or cigarette and other tobacco product manufacturers registered with FDA or the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB);⁹¹ and (b) require age and ID verification and other anti-illicit-trade measures for all subject tobacco product sales over the

⁸⁹ Another smoker strategy to continue smoking full-nicotine products might be to purchase large amounts of the full-nicotine versions before the rule goes into effect, but that would only temporarily delay its full beneficial impact, primarily among higher-income smokers. FDA could also prevent such consumer stockpiling by putting limits on maximum purchases that would go into effect well before the effective date of the nicotine-reduction provisions in the rule (e.g., no individual sales transaction including more than one carton of cigarettes or \$25 worth of smoked tobacco products). Stockpiling by manufacturers, distributors, and retailers would presumably be prevented by FDA’s standard procedure of implementing consecutive deadlines for the legal manufacture, distribution, and retail sale of any full-nicotine versions of the smoked tobacco products, regardless of the amount of full-nicotine products in the different businesses’ inventories. *See, e.g.,* FDA, Proposed Rule, *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements* 84 Federal Register 42754 (Aug. 15, 2019) at 42785.

⁹⁰ As the FDA study notes, a major report on illicit trade in tobacco products by the National Research Council and the Institute of Medicine found that although a strong conclusion cannot be drawn, limited evidence suggests that regulations modifying cigarettes are unlikely to produce substantial demand for illicit unmodified products. Peter Reuter, et al., National Research Council, [Understanding the U.S. illicit tobacco market: characteristics, policy context, and lessons from international experiences](#) (National Academies Press, 2015) at Summary-6, 8-18. *See, also,* Eric N. Lindblom., [Illicit Trade Poses No Threat to an FDA Rule to Minimize Nicotine in Smoked Tobacco Products](#), 109 AM. JNL. PUBLIC HEALTH 960 (July 2019); Tammy O. Teng, et al., [The AMA proposal to mandate nicotine reduction in cigarettes: a simulation of the population health impacts](#), 40 PREV. MEDICINE 170 (Feb. 2005).

⁹¹ FDA’s could likely restrict the sale of commercial cigarette-making machines and smoked tobacco product components pursuant to its authorities to regulate the manufacture and distribution of tobacco products and to take action relating to any illicit trade in tobacco products. TCA § 906(e)(1) [21 U.S.C. 387f(e)(1)]; Title III. Alternatively, these restrictions could be implemented through legislation. *See, e.g.,* Sec. 202 of H.R. 729, 115th Congress.

Internet or via mail order (as the federal PACT Act already does for cigarettes and smokeless tobacco products).⁹²

- To prevent commercial efforts to encourage and assist smoker efforts to add nicotine into minimal-nicotine cigarettes or cigars or to convert smokeless tobacco products into smokable full-nicotine products, prohibit the sale to consumers of any nicotine or nicotine-addition systems, roll-your-own kits, smokeless-conversion packets, and the like that are intended or expected to be used for such purposes.⁹³
- To encourage the most health-improving consumer responses to the rule, include requirements in the rule that all subject products must contain warnings on their labels or information in product inserts to inform consumers that the most effective way to reduce health harms and risks is to quit all tobacco use, or never start, and that reduced-nicotine cigarettes and the like are *not* significantly less harmful than full-nicotine versions – and reinforce this product-based messaging with targeted FDA public education campaigns directed at smokers and smoking-vulnerable youth.⁹⁴

⁹² Prevent All Cigarette Trafficking Act of 2009 (Pub L No. 111-154). For additional possible FDA measures to prevent and reduce any illicit trade, see Kurt M. Ribisl, et al., *Strategies to Reduce Illicit Trade of Regular Nicotine Tobacco Products After Introduction of a Low-Nicotine Tobacco Product Standard*, 109 AM. JNL. PUBLIC HEALTH 1007 (July 2019); Lindblom, *AJPH* 109(7): 960 (July 2019), *supra* note 90. FDA could also reduce illicit trade risks by not applying the rule to all smoked tobacco products that might be used as cigarette substitutes, thereby providing smokers with additional attractive legal alternatives to seeking out illicit full-nicotine cigarettes. But any such exemptions would sharply reduce the rule's public health gains.

⁹³ FDA's authority over "tobacco products" includes authorities to regulate nicotine (when sold for non-therapeutic purposes) as well as all tobacco product "accessories," which FDA could reasonably interpret to include any modification kits, RYO materials, and the like. TCA § 101(a), creating new 21 U.S.C. 321(rr). If required by our ethical process and related expert evaluations of the public health and ethical risks, FDA could establish additional barriers to commercial assistance to consumers making their own full-nicotine smoked tobacco products by prohibiting any existing smokeless tobacco products that could readily be ignited or smoked and by requiring minimum moisture levels for moist-snuff smokeless (consistent with their conventional use) to make drying and smoking it more difficult. By preventing the appearance and for-profit marketing of new commercial products that would make it easier for consumers to make their own full-nicotine tobacco products to smoke, these restrictions could be seen as reducing personal autonomy. But they would simply be a logical extension of the rule's core purpose of making nicotine-delivering smoked tobacco products illegal; and the overall personal autonomy impacts of the rule, as modified, are fully discussed below. *Infra* notes 116-141 and associated text. In addition, preventing the emergence of new commercial choices with related gains to personal autonomy is often seen as less ethically harmful than restricting existing choices, although either type of restriction can be justified if the other ethical gains from the action are much larger. See, e.g., Luc Bovens, [Don't Mess With My Smokes: Cigarettes and Freedom](#), 16 AM. JNL. BIOETHICS 15 (July 2016); Andreas T. Schmidt, [Withdrawing Versus Withholding Freedoms: Nudging and the Case of Tobacco Control](#), 16 AM. JNL. BIOETHICS 3 (2016).

⁹⁴ As discussed above, any such messaging should also be designed and tested to prevent stigmatizing smokers and to ensure they work as effectively as possible to encourage health-improving consumer behaviors and discourage health-harming consumer behaviors. *Supra* notes 61-63 and associated text. To further discourage any use of the reduced-nicotine smoked tobacco products and otherwise encourage total cessation of all tobacco-nicotine use over switching to less harmful tobacco products. FDA could also use the ethical criteria and procedures outlined here to consider concurrently prohibiting all flavors in all smoked tobacco products (if FDA has not done so already), prohibiting all or some flavors in all non-smoked tobacco products and restricting all tobacco product sales to adult-only sales outlets. To prevent tobacco industry efforts to encourage smokers to switch to other tobacco products instead of quitting all use, FDA could also consider implementing additional requirements and restrictions relating to the labeling and advertising of tobacco products (consistently with the First Amendment) that FDA had not already implemented, especially any that fit within the ideal ethical criteria, as discussed above. *Supra* notes 46-50 and associated text.

- To produce the largest possible health gains from smokers switching entirely to e-cigarettes instead of quitting all use, ensure that no e-cigarettes are allowed to stay on or enter the U.S. market unless they have been designed and manufactured to minimize contamination, eliminate harmful or potentially harmful additives or ingredients unnecessary for their operation, and otherwise make them as minimally harmful and risky as possible.⁹⁵

While FDA would need to use available resources and expertise to confirm it, neither the nicotine-reduction rule nor any of these extra provisions and FDA activities appear to cause a serious risk of producing any significant new underlying health harms or increasing health disparities. Given the enormous harms caused by legal smoking, it is unlikely that smoker switching to illicit cigarettes would create any significant new harms, especially as most illicit cigarettes would likely be cigarettes diverted from other legal markets. New health harms might occur if the rule prompted the emergence of illicit markets that were also quite violent; but that seems unlikely given the very low levels of violence in U.S. illicit cigarette markets to date.⁹⁶ Moreover, the risk of any substantial illicit trade emerging, whether violent or not, appears quite small to begin with, and including the extra anti-illicit-trade provisions in the rule would reduce the risk even further.⁹⁷

⁹⁵ FDA could take these e-cigarette actions through rulemaking, PMTA orders, and enforcement against e-cigarettes on the market without PMTA orders. FDA might further increase the public health gains from its nicotine-minimization rule if it also minimized nicotine in all e-cigarettes and “heat-not-burn” products or in all tobacco-nicotine products. That would prevent experimenting youth and adult nonusers from becoming addicted regardless of which products they might try, and would prompt many current users of those non-smoked products to quit. Expanding the nicotine-minimization rule to reach some or all non-smoked tobacco-nicotine products would also make it more difficult or impossible for smokers to switch to other still-legal tobacco products to continue feeding their nicotine addictions, thereby further increasing total quitting. But reducing or eliminating the legal non-smoked options for obtaining nicotine through non-medical products would also have a stronger negative impact on personal autonomy and could raise possible fairness concerns. Minimizing nicotine not only in smoked tobacco products but in e-cigarettes and heat-not-burn products, would also leave smokers with no legal way to buy products that would enable them to continue inhaling nicotine into their lungs, which could make the possible emergence of a sizeable new illicit trade in full-nicotine cigarettes more likely. Nevertheless, research-based expert projections might determine that the increased public health gains would be so much larger than any new or increased ethically relevant harms that expanding any future nicotine-minimization rule to reach some or all non-smoked tobacco-nicotine products would still be ethically appropriate. However, such an expansion of the nicotine-reduction rule would also enormously increase the breadth and ferocity of opposition from the tobacco industry, as it would negatively impact even more products and companies, and much more sharply reduce the industry’s future tobacco product sales and profits. While not ethically relevant, that increased opposition – along with likely opposition to the rule as being too radical or going too far, too fast from members of Congress, the media, and the public – might prompt FDA to focus just on smoked tobacco products for strategic purposes even if FDA determined it would more powerfully benefit the public health and be even more ethically appropriate to reach additional tobacco-nicotine products, as well.

⁹⁶ See, e.g., National Research Council, UNDERSTANDING THE U.S. ILLICIT TOBACCO MARKET (2015) *supra* note 90 at Summary-2 [“the people involved in all segments of the distribution process of the illicit tobacco trade generally do not have serious criminal records, and the illicit tobacco market is not associated with violence. Although many claims have been made regarding the relationship between the illicit tobacco trade and terrorism, the link between the U.S. illicit tobacco market and terrorism appears to be minor, and there is also no systematic evidence of sustained links between the global illicit tobacco trade and terrorism”].

⁹⁷ *Supra* note 90. In the context of a proposed menthol flavored cigarette ban, concerns have been raised by commentators supported by the big cigarette companies that the ban could increase violent police enforcement against illicit sellers that might be racially biased (due to African-American smokers being more likely to smoke menthol cigarettes than white smokers). See, e.g., Hannah Knowles & Laurie McGinley, *Stung by inaction on menthol cigarettes*, THE WASHINGTON POST (Nov. 3, 2019). But local police do not enforce FDA rules, and the neither a menthol-ban or nicotine-reduction rule would place any restrictions or requirements on individual

The tobacco industry has attacked an FDA nicotine-reduction rule by claiming that it could have a damaging impact on the economy (e.g., by reducing retail sales revenues from smoked tobacco products or shrinking related employment).⁹⁸ If such negative economic impacts actually occurred, they could have a negative effect on health or create other ethically relevant impacts. However, some portion of the reduced expenditures on smoked tobacco products caused by the rule would simply switch to purchases of alternative tobacco-nicotine products, which are often already manufactured or sold by the same businesses, often with inputs from the same underlying businesses or farms.⁹⁹ Moreover, even when a smoker quits all use, the money he or she used to spend on cigarettes or other smoked tobacco products does not disappear. The money stays in the economy and is either spent on other, alternative goods and services or saved or invested – which is much more economically and socially beneficial, and more helpful to individual households, than the prior spending just on cigarettes and other smoked tobacco products. In particular, cigarette and other tobacco product manufacturing is quite capital intensive; so shifting consumer spending to other goods and services will increase rather than decrease overall employment.¹⁰⁰ Smoking declines will also reduce government, private sector, and smoking-caused household health care and other costs (e.g., tobacco smoke and fire damage), freeing up additional funds for more productive uses.¹⁰¹ By increasing worker health and on-the-job fitness and by reducing premature worker disability and death, the smoking declines will also directly increase worker health and productivity, thereby further strengthening the economy.¹⁰²

consumers. While any persons or criminal organizations able to obtain full-nicotine or full-menthol cigarettes for illegal street sales after such rules were implemented, their vulnerability to enforcement would be no different than what currently applies to any street sales of cigarettes (which are all illegal under federal, state, and local trafficking, tax, and licensing laws). In addition, this critique of a menthol ban also fails to mention that more white people smoke menthol than African Americans (despite the latter being more likely to smoke menthol if they smoke). See, also, Cristine D. Delnevo, et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, 22 NICOTINE & TOBACCO RESEARCH 10 (Oct. 8, 2020). In any case, the nicotine-reduction rule would apply to all or virtually all smoked tobacco products, rather than just to those disproportionately used by any specific disadvantaged or vulnerable subpopulation; so this same kind of critique does not apply.

⁹⁸ See, e.g., Jose Luis Murillo, Altria Client Services, Inc., Comments submitted on behalf of Philip Morris USA, Inc. et al. (July 16, 2018), Docket No. FDA-2017-N-6189, Advanced Notice of Proposed Rulemaking on Tobacco Product Standard for Nicotine Level of Certain Tobacco Products, <https://www.regulations.gov/document?D=FDA-2017-N-6189-7074>.

⁹⁹ For example, the largest cigarette company in the United States, Philip Morris USA, is a subsidiary of Altria, which owns 35% of Juul, the largest e-cigarette company, and Altria and Philip Morris also control the sale of IQOS in the United States. Reynolds American, the second biggest cigarette company, also sells Vuse, the e-cigarette brand with the second largest market share from non-online retail outlets. Similarly, retail outlets that sell smoked tobacco products typically sell e-cigarettes and smokeless tobacco products, as well. In addition, a reduced demand for tobacco for smoked tobacco products could be partially offset by an increased demand for tobacco or tobacco-derived nicotine for the non-smoked products some smokers would switch to using.

¹⁰⁰ See, e.g., Kenneth E. Warner, *The economics of tobacco: myths and realities*, 9 TOBACCO CONTROL 78 (2000).

¹⁰¹ See, e.g., Laura Bach, *Toll of Tobacco in the United States of America*, Campaign for Tobacco-Free Kids factsheet (Feb. 12, 2019), <https://www.tobaccofreekids.org/assets/factsheets/0072.pdf>; Anne Boonn, Campaign for Tobacco-Free Kids Factsheet, *Responses to Misleading and Inaccurate Tobacco Company Arguments Against State Cigarette Tax Increases* (Dec. 21, 2018) at myths VII, XIV, www.tobaccofreekids.org/fact-sheets/tobacco-control-policies/tobacco-taxes, accessed Sept. 20, 2021.

¹⁰² *Id.*; Michael T. Halpern, et al., *Impact of smoking status on workplace absenteeism and productivity*, 10 TOBACCO CONTROL 233 (Sept. 2001); Christine L. Baker, et al., *Benefits of quitting smoking on work productivity and activity*

Accordingly, the nicotine-reduction rule should produce a strong, beneficial impact on employment, the private sector, government, and the economy, which should also benefit the public health and otherwise improve overall wellbeing. But as these beneficial economic changes occur, some individual tobacco and tobacco-related firms (which could include businesses that treat smoking-caused disease) will inevitably suffer economic harms linked directly to the ethically desired smoking declines secured by the rule. Those economic business harms, by themselves, are not directly relevant to our ethical perspectives, which focus on impacts on people, certain subpopulations, or the population as a whole. But they could be ethically relevant if some owners and employees of these tobacco-related businesses will likely experience reduced income, lost employment, or other economic dislocations, at least temporarily, possibly with consequences to their health or overall wellbeing.¹⁰³ From a strictly utilitarian or net-public-health-impact perspective, any new harms of this type would not matter to the extent that they were offset by the wellbeing or health gains experienced by those who would benefit from the funds previously spent on smoked tobacco products being spent elsewhere, instead. Accordingly, these possible individual harms might be ethically acceptable as necessary byproducts of the inevitable churning and reconfiguring that occurs in response to any major policy or market intervention (and directly parallel similar ongoing dislocations and readjustments that continually occur in any dynamic economy). To be more ethically cautious, however, such restructuring harms could be ethically accepted and ignored only if they were inevitable and unavoidable byproducts of securing the rule's much larger public health gains, would not harm anyone because of their belonging to any ethically relevant disadvantaged or vulnerable subpopulations, and would not cause any serious and sustained new harms to any other persons who could be readily identified and would also ethically merit new government action to address their harms.

Another possible ethical issue could occur if the regulatory compliance costs to the tobacco businesses subject to the nicotine reduction rule were large enough to force the businesses to increase the prices they charge consumers for their minimal-nicotine smoked tobacco products by large enough amounts to cause ethically relevant harms. For example, cigarette tax increases have been criticized for requiring those addicted low-income smokers who cannot or do not quit, reduce their consumption, or switch to lower-priced products to spend more for the cigarettes their addictions crave, possibly reducing the amount of income available to pay for household necessities.¹⁰⁴ However, only marginal manufacturer price increases of a few cents per pack would raise hundreds of millions of dollars, making it unlikely that compliance costs relating to any tobacco product regulation would require large enough price increases to be noticed by consumers

[impairment in the United States, the European Union and China](#), 71 INT'L JNL CLINICAL PRACTICE e12900 (Jan. 2017).

¹⁰³ Any economic harms to owners and higher-level employees of tobacco-product businesses who had freely and intentionally engaged in illegal or unethical practices to maximize tobacco product sales for personal and business gains deserve no ethical consideration here (especially if they continue to do so); but tobacco-related business owners and employees with ethically clean hands could also be economically harmed, which could raise some ethical issues.

¹⁰⁴ See, e.g., Eric A. Feldman, *The Bioethics of Tobacco*, in Vardit Ravitsky, et al. (eds), PENN CENTER GUIDE TO BIOETHICS (Springer Publishing Co. 2009) at Chapter 53, pages 621-30; Bryan P. Thomas & Lawrence O. Gostin, [Tobacco Endgame Strategies: Challenges in Ethics and Law](#), 22 TOBACCO CONTROL i55 (2013).

or cause possible ethically relevant economic or other harms.¹⁰⁵ In addition, the increased costs incurred by smokers who exercise their personal autonomy to choose to continue buying and smoking minimal-nicotine cigarettes (or other smoked tobacco products), free from any pressures from addiction, is not an ethically relevant individual harm.¹⁰⁶

It could be ethically relevant, however, if lower-income smokers who could not or did not want to quit all use in response to the nicotine-reduction rule could only obtain legal alternative nicotine-delivery products by substantially increasing their tobacco-nicotine-related expenditures.¹⁰⁷ Fortunately, some or all of the cost for nicotine replacement therapies (e.g., nicotine gum or patches) are covered for at least some period of time by private health insurance, Medicaid, or other programs; and, although e-cigarettes tend to be more expensive than cigarettes per use, alternative tobacco products are sometimes available at comparable or lower prices than cigarettes, especially in states with average or above-average cigarette tax rates but lower taxes or no taxes on e-cigarettes or certain other smoking alternatives.¹⁰⁸ Although the initial cost of buying an e-cigarette or IQOS device can be quite high compared to the price of a pack of cigarettes, the long-term costs from just buying replacement e-liquid or e-liquid pods are similar or lower (and sellers might offer installment plans for the initial purchase).¹⁰⁹ It is also likely that the prices of alternative nicotine-delivery products would decline in response to the nicotine-reduction rule as their manufacturers and sellers would compete aggressively for the former smokers' business. Even if some smokers who switched to alternative products did still experience increased product-purchase costs, they would also enjoy reduced household healthcare costs (from the harm reductions from switching) and other smoking-caused cost reductions (e.g., for repairs or cleaning costs caused by smoking or related burns or fires).¹¹⁰

¹⁰⁵ In 2020, more than 11 billion cigarette packs were sold in the United States; so, a price increase of only five cents per pack would raise more than half a billion dollars. Alcohol and Tobacco Tax and Trade Bureau (TTB), [Statistical Report – Tobacco Products, Reporting Period: December 2020](#) (March 24, 2021).

¹⁰⁶ It is also questionable whether the increased costs to smokers who choose to find and buy higher-priced illegal full-nicotine cigarettes raises any ethical concerns, at least when lower-cost legal nicotine-delivery products are readily available to satisfy their addictions.

¹⁰⁷ See, e.g., Thomas & Gostin (2013), *supra* note 104 (if government reduces nicotine in cigarettes it has a duty to make tobacco cessation therapies accessible and affordable). Despite the problem of increased tobacco product prices possibly straining the budgets of households with ongoing users, a U.S. Centers for Disease Control & Prevention (CDC) Best Practices User Guide relating to increasing health equity recommends tobacco product price increases because they typically work to reduce existing health disparities by reducing tobacco use among disadvantaged subpopulations. CDC, *Best Practices User Guide: Health Equity in Tobacco Prevention and Control* (2015), www.cdc.gov/tobacco/stateandcommunity/best-practices-health-equity/index.htm, accessed Sept. 20, 2021.

¹⁰⁸ See, e.g., Kai-Wen Cheng et al., “Costs of vaping: evidence from ITC Four Country Smoking and Vaping Survey,” *Tobacco Control* **30(1)**: 94 (February 2021); Tingting Yao et al., “The impact of e-cigarette and cigarette prices on e-cigarette and cigarette sales in California,” *Preventive Medicine Reports* **20**:101244 (Dec. 2020); Alex C. Liber et al., “Combustible cigarettes cost less to use than e-cigarettes: global evidence and tax policy implications,” *Tobacco Control* **26(2)**: 158 (March 2016). A number of vaping websites offer price analyses showing vaping costs significantly lower than smoking costs, especially over time. See, e.g., RuthlessVapor.com at <https://www.ruthlessvapor.com/blogs/ruthless-e-liquid/vaping-vs-smoking-cost>; Vapesimple.com (UK) at <https://www.vape-simple.com/blogs/news/the-cost-of-smoking-vs-vaping>, accessed Sept. 20, 2021.

¹⁰⁹ *Id.*; John Reid Blackwell, *Altria starts first U.S. sales of iQOS heat not burn product in Atlanta market*, RICHMOND TIMES DISPATCH (Oct. 4, 2019).

¹¹⁰ See, e.g., Adam McCann, *The Real Cost of Smoking by State*, WalletHub (Jan. 9, 2019), available at <https://wallethub.com/edu/the-financial-cost-of-smoking-by-state/9520>, accessed Sept. 20, 2021. Even if lower-income smokers who switched or engaged in dual use experienced significant increased product costs, their

To further improve the situation, and secure larger health gains, FDA could run public education campaigns encouraging smokers to quit all use and providing cessation assistance tips along with information on how to secure additional cessation assistance.¹¹¹

Similarly, any reduced utilitarian pleasure or happiness among smokers no longer legally able to obtain nicotine-delivering smoked tobacco products can be discounted or eliminated as an ethical concern because the temporary negative emotional and physical impacts from quitting all use or the inconvenience and possible negative emotional impacts from switching to less-harmful alternative nicotine-delivering products would be dwarfed by the smokers' future health gains and pain reductions, among other benefits.¹¹² The availability of nicotine-delivering e-cigarettes and "heat-not-burn" tobacco products, which many smokers have already found quite attractive and enjoyable to use, would also offer smokers a way to avoid some of the more serious negative emotional and physical impacts that total quitting might entail (although their larger longer-term physical and emotional benefits would also be reduced).

The only clearly remaining ethically relevant harm from the nicotine rule is its negative impacts on personal autonomy from making full-nicotine smoked tobacco products no longer legally available to adult consumers.¹¹³

Nicotine Reduction and Personal Autonomy

Possible conflicts with personal autonomy often dominate analyses of the ethical propriety of government tobacco control or other public health interventions.¹¹⁴ The tobacco industry also

increased expenditures would still be much smaller on a per-capita basis than those enjoyed by the lower-income smokers who quit all use (who would no longer spend anything on tobacco-nicotine products). In addition, the higher prices would prompt even more lower-income smokers to quit all use (and secure the much larger cost savings) – making it highly likely that the overall impact would be a substantial net decrease in tobacco-related costs among affected low-income households.

¹¹¹ FDA could also take steps, under its authorities over therapeutic drugs, to make it possible for manufacturers to secure FDA approvals more quickly and easily for nicotine-replacement therapies that could be used as long-term harm-reducing alternatives to smoking. See, e.g., American Academy of Pediatrics, et al., *Comments submitted to Docket No. FDA-2019-D-0297, Draft Guidance, Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products: Guidance for Industry* (April 23, 2019) accessed Sept. 20, 2021, <https://www.regulations.gov/document?D=FDA-2019-D-0297-0009>.

¹¹² See, e.g., Terry F. Pechacek, et al., [*Reassessing the importance of 'lost pleasure' associated with smoking cessation: implications for social welfare and policy*](#), 27 TOBACCO CONTROL e143 (Oct. 2018).

¹¹³ As federal and state laws already prohibit sales of tobacco products to persons under 18 or, in some states, 21 – with some state and local laws also prohibiting purchases or possession of tobacco products by minors – an FDA rule minimizing nicotine in smoked tobacco products could not negatively impact the personal autonomy of those under the applicable minimum age by reducing their legal commercial choices.

¹¹⁴ See, e.g., Ronald Bayer & Amy L. Fairchild, [*The Genesis of Public Health Ethics*](#), 18 BIOETHICS 1467 (Nov. 2004); James E. Katz, [*Individual rights advocacy in tobacco control policies: an assessment and recommendation*](#), 14 TOBACCO CONTROL ii31 (2005); Jessica Flanigan, [*Double Standards and Arguments for Tobacco Regulation*](#), 42 JNL MEDICAL ETHICS 305 (2016); Bovens (July 2016), *supra* note 93; Carwyn R. Hooper & C. Agule, [*Tobacco regulation: autonomy up in smoke?*](#), 35 Jnl Med Ethics 365 (June 2009); Darren Shickle, [*The ethics of public health practice: balancing private and public interest within tobacco policy*](#), 91 BRITISH MED. BULL. 7 (2009); P.E. Griffiths & C. West, [*A balanced intervention ladder: promoting autonomy through public health action*](#), 129 PUBLIC HEALTH 1092 (Aug. 2015).

frequently raises personal autonomy and “smokers’ rights” claims to oppose tobacco control efforts, and has done so to oppose an FDA nicotine reduction rule.¹¹⁵ But any infringement on personal autonomy from a nicotine-reduction rule would be quite small, given that the rule would apply only to tobacco industry businesses and would not legally prohibit any actions by consumers or establish any penalties for smokers or other human beings.¹¹⁶ After the rule’s implementation, adult smokers could still purchase legally manufactured and sold minimal-nicotine smoked tobacco products or, to continue inhaling nicotine into their lungs, could legally purchase e-cigarettes or IQOS. They could also grow their own full-nicotine tobacco for rolling their own full-nicotine cigarettes.¹¹⁷

In addition, the ability to be able to purchase commercially provided full-nicotine smoked tobacco products is neither a constitutional or otherwise legal or fundamental right.¹¹⁸ Restricting tobacco product options does not restrict political speech, religious freedom, or any other valued liberty or core freedom necessary to preserve the ethical independence or integrity of individual people or enable them to exercise their core beliefs and values.¹¹⁹

As the harm principle makes clear, any asserted ethical objection to a government policy that reduces or hinders individual choice disappears if the exercise of that choice harms others or if the intervention is necessary to prevent harms to others.¹²⁰ Yet smoking causes direct harms to others by exposing those who do not or cannot consent to secondhand or thirdhand smoke exposure, smoking-harmed pregnancies and offspring, smoking-caused fires, and pollution and poisonings from cigarette butts. By reducing smoking effectively, the nicotine rule would reduce these harms to others; and more direct government action to stop smokers from smoking in ways that cause these harms would be much more intrusive to personal autonomy.¹²¹ Even if people smoked only

¹¹⁵ See, e.g., *supra* note 15; *supra* note 98.

¹¹⁶ The TCA does not authorize FDA to place requirements or restrictions directly on tobacco product consumers, much less establish penalties or take enforcement action against consumers.

¹¹⁷ If any smoked tobacco products were excluded from the rule because their cost, the harshness of their smoke, or other characteristics made them unlikely to serve as viable, direct cigarette-smoking alternatives, their availability would further reduce the rule’s negative impacts on consumer choice and any related negative impacts on personal autonomy. *But see supra* note 81. *See, also, supra* note 81.

¹¹⁸ See, e.g., W. Kent Davis, Answering Justice Ginsburg’s Charge That the Constitution is “Skimpy” in Comparison to Our International Neighbors: A Comparison of Fundamental Rights in American and Foreign Law, 39 S. TEXAS L. REV. 951 (Fall 1998). It is possible, however, that taking away a previously legally available commercial product is more ethically damaging to personal autonomy than not allowing its commercial sale in the first place. Bovens (July 2016), *supra* note 93. *But see* Schmidt, *Withdrawing Versus Withholding Freedoms* (2016), *supra* note 93.

¹¹⁹ See, e.g., Stephanie R. Morain & Janet Malek, [Minimum Age of Sale for Tobacco Products and Electronic Cigarettes: Ethical Acceptability of US “Tobacco 21 Laws,”](#) 107 AM. JNL. PUBLIC HEALTH 1401 (Sept. 2017) (citing Ronald Dworkin, Justice for Hedgehogs (Harvard Univ. Press 2011)). *See, also,* Yvette van der Eijk & Gerard Porter, [Human rights and ethical considerations for a tobacco-free generation,](#) 24 TOBACCO CONTROL 238 (May 2015) (reporting on England court ruling that smoking is not sufficiently close to the integrity of identify, the development of personality, or the ability to establish and develop relationships with others to merit protection under European Union Convention on Human Rights).

¹²⁰ “[T]he only purpose for which power can be rightfully exercised over any member of a civilized society, against his (sic) will, is to prevent harm to others.” Mill, ON LIBERTY (1869), *supra* note 14.

¹²¹ See, e.g., Jill A. Jarvie & Ruth E. Malone, [Children’s Secondhand Smoke Exposure in Private Homes and Cars: An Ethical Analysis,](#) 98 AM. JNL. PUBLIC HEALTH 2140 (Dec. 2008). In any case, FDA has no authority to place

in ways that avoided such direct harms to others, their smoking would still hurt other people through such things as deforestation from tobacco farming, reducing the productivity of the nation's workforce, the costs of treating the smoking-caused health harms of smokers who are poor or under insured, shifting lower-income household's expenditures away from necessities to pay for smoked tobacco products and other smoking-caused costs, similarly increasing and misallocating government spending, and pulling economic goods and services away from more productive uses.

There also does not appear to be any way to prevent smoking-related harms to others as effectively as a well-designed nicotine-reduction rule would, except through measures that would restrict individual choice even more, such as banning all smoked tobacco products or penalizing people for smoking or possessing smokable tobacco products (which FDA has no authority to implement). Even if stronger, less-infringing tobacco control options were available, FDA would need to implement them alongside an FDA nicotine-reduction rule (not as substitutes) in order to fulfill its statutory purpose and ethical duty to prevent tobacco-related harms to others as quickly as possible.

Personal autonomy concerns are also reduced by the fact that the vast majority of smokers first experiment with smoking during the immaturity of youth or before their brains are fully developed and become more resistant to nicotine-induced changes, or before the minimum legal age for tobacco product sales.¹²² Such smoking experimentation is also directly encouraged and increased by tobacco industry advertising and other marketing, which is frequently misleading and never fully communicates the products' risks and harms to consumers.¹²³ Those industry efforts can be seen as directly interfering with the personal autonomy of consumers and are often designed to do so.¹²⁴ For these and other reasons, the vast majority of experimenters and initiators and many current smokers are not fully informed of smoking harms and risks or have cognitive biases that

restrictions on individual smokers' behavior, such as prohibiting or penalizing smoking in homes or cars when children are present, throwing cigarette butts into waterways or forests, smoking in bed, or smoking during pregnancy. Nor do there appear to be any other actions FDA could take specifically to prevent such smoking harms to others.

¹²² See, e.g., Jennifer Cantrell, et al., [Patterns in first and daily cigarette initiation among youth and young adults from 2002 to 2015](#), PLOS ONE e0200827 (2018); Saida R. Sharapova, et al., [Age of tobacco use initiation and association with current use and nicotine dependence among US middle and high school students, 2014-2016](#), TOBACCO CONTROL (Epub Nov. 29, 2018); Dana Zeid, et al., [Differential Effects of Nicotine Exposure on the Hippocampus Across Lifespan](#), 16 CURRENT NEUROPHARMACOLOGY 388 (May 2018); Menglu Yuan, et al., [Nicotine and the adolescent brain](#), 593 JNL PHYSIOLOGY 3397 (Aug. 15, 2015); Sarah J. Cross, et al., [Sex dependent effects of nicotine on the developing brain](#), 95 JNL NEUROSCIENCE RESEARCH 422 (Jan. 2, 2017); David M. Lydon, et al., [Adolescent Brain Maturation and Smoking: What We Know and Where We're Headed](#), 45 NEUROSCIENCE & BIOBEHAVIORAL REVIEWS 323 (Sept. 2014).

¹²³ See, e.g., John P. Pierce, et al., [Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study](#), 172 JAMA PEDIATRICS 444 (May 2018); Matthijs Morgenstern, et al., [From never to daily smoking in 30 months: the predictive value of tobacco and non-tobacco advertising exposure](#), 3 BMJ OPEN e002907 (June 11, 2013); Sandy J. Slater, et al., [The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake](#), 161 JAMA PEDIATRICS 440 (May 2007); Janet Hoek, [Informed choice and the nanny state: learning from the tobacco industry](#), 129 PUBLIC HEALTH 1038 (Aug. 2015). See, also, Manuela F. Pinto, [To Know or Better Not to: Agnotology and the Social Construction of Ignorance in Commercially Driven Research](#), 30 SCIENCE & TECHNOLOGY STUDIES 53 (2017) (describing tobacco industry strategies to subvert research and otherwise produce or maintain ignorance about smoking harms).

¹²⁴ See, e.g., Tony Cutler & David Nye, [Subjects and accomplices: regulation and the ethics of cigarette advertising](#), 27 INT'L JNL HEALTH SERVICES 329 (1997).

interfere with their ability to understand or appreciate the harms and risks.¹²⁵ Few, if any, smokers first experiment with or begin smoking because of a desire to become addicted. Yet the rapid addictive powers of tobacco smoking quickly convert many experimenters or early users into long-term addicted smokers, regardless of their initial intentions.¹²⁶ Other external factors also come into play to promote experimentation and initiation into regular, addicted use, such as birth-determined differences in brain chemistry or structure; the smoking practices of one's family, friends, or peers; or the smoking-related norms in one's household or community.¹²⁷ As a result, initiation into smoking and continued smoking rarely occur through an adult making the kind of rational, independent, and informed choices that suggest the exercise of true personal autonomy.¹²⁸ Not surprisingly, the vast majority of smokers wish that they never started, regret that they did, or otherwise want to quit, and many try but cannot readily do so because of their addiction.¹²⁹ There is also substantial support for a nicotine-reduction rule or law among smokers.¹³⁰

Accordingly, the nicotine-reduction rule would increase personal autonomy by enabling consumers not already under the addictive power of smoked tobacco products to make a more autonomous choice as to whether to become regular users, without addiction subverting their decision, if they decide to experiment or if they are prompted to do so by industry marketing, peer pressure, or other autonomy-reducing factors. The rule would also prevent many youths from having their personal autonomy as adults constrained by becoming addicted before reaching adulthood. The rule would also increase the personal autonomy of some existing smokers by helping those who truly desire to quit smoking to do so and by helping those who want to make a decision about smoking free from addiction to do so.¹³¹ It also would not interfere with the personal autonomy of any who consented to the rule and its restrictions.¹³² Indeed, the rule's reduction in

¹²⁵ See, e.g., Hoek (Aug. 2015), *supra* note 123.

¹²⁶ See, e.g., Martin J. Jarvis, [Why people smoke](#), 328 *BMJ* 277 (Jan. 2004); Lucy Popova & Bonnie L. Halpern-Feisher, [A Longitudinal Study of Adolescents' Optimistic Bias about Risks and Benefits of Cigarette Smoking](#), 40 *AM. JNL. HEALTH BEHAVIOR* 341 (May 2016); Ovide F. Pomerleau, et al., [Why some people smoke and others do not: new perspectives](#), 61 *JNL CONSULTING & CLINICAL PSYCHOLOGY* 723 (Oct. 1993).

¹²⁷ See, e.g., Kristin Voigt, [Smoking and Social Justice](#), 3 *Public Health Ethics* 91 (July 2010). See, also, Cheryl Heaton & Kathleen Nelson, [Reversal of Misfortune: Viewing Tobacco as a Social Justice Issue](#), 94 *AM. JNL PUBLIC HEALTH* 186 (Feb. 2004).

¹²⁸ For similar analyses in an ethical context, see, e.g., Alec Rajczi, [Liberalism and Public Health Ethics](#), 30 *Bioethics* 96 (Feb. 2016); Voigt (July 2010), *id* (also noting that the more likely and horrible the personal consequences are to the decision makers, the higher the standard must be for determining whether the decision is truly voluntary so that any interference would conflict with liberty or personal autonomy). See, also, Rebecca J. Gray, et al., [A qualitative analysis of 'informed choice' among young adult smokers](#), 25 *TOBACCO CONTROL* 46 (Jan. 2016); Neil Levy, [Autonomy and Addiction](#), 36 *CANADIAN JNL PHILOSOPHY* 427 (July 2005).

¹²⁹ See, e.g., Stephen Babb et al., [Quitting Smoking Among Adults—United States, 2000–2015](#), 52 *MORBIDITY & MORTALITY WEEKLY REP.* 1457 (2017); G Fong, et al., [The near-universal experience of regret among smokers in four countries: findings from the International Tobacco Control Policy Evaluation Survey](#), 6(Suppl 3) *NICOTINE & TOBACCO RESEARCH* S341 (Dec. 2004); Pechacek, et al., *supra* note 112.

¹³⁰ See, e.g., Rachel L Denlinger-Apte, [Correlates of support for a nicotine-reduction policy in smokers with 6-week exposure to very low nicotine cigarettes](#), 28 *TOBACCO CONTROL* 352 (2019); Jennifer L. Pearson, et al., [Public Support for Mandated Nicotine Reduction in Cigarettes](#), 103 *Am. Jnl. Public Health* 562 (March 2013).

¹³¹ See, also, Hooper & Agule, (June 2009), *supra* note 114.

¹³² There is also an argument that those who do not actively consent to certain government infringements on their personal autonomy have already implicitly and indirectly done so through their participation in our representative system of government and its related decision-making procedures, at least if the process creating the infringement –

product choices would likely interfere with the personal autonomy of only those nonuser adults who would otherwise freely choose to become *nicotine-addicted* tobacco smokers and the minority of current adult smokers who, if not compelled by their addiction, would still otherwise freely choose to continue smoking addicting smoked tobacco products.¹³³

At the same time, the nicotine-reduction rule would protect or increase the personal autonomy and individual rights of smokers, otherwise smokers, exposed nonusers, and others in range of additional ways. Most directly, it would reduce harmful exposures to secondhand tobacco smoke among not freely consenting adults or among children lacking the maturity or understanding to provide such consent or the power to withhold it. It would also enable many smokers and otherwise initiators to exercise their overall personal autonomy longer and more effectively by preventing or delaying their death or serious disability from smoking. Reducing smoking and its harms would also directly promote what some see as a human right to health or even a related right to tobacco control, or to protection against the rights violations caused by tobacco companies, while also promoting and protecting the human rights of children to grow up healthy, or at least free from preventable harms, and be able realize their full potential.¹³⁴

Because of all these ways that the nicotine-minimization rule would protect, restore, or increase personal autonomy, its overall net impact on personal autonomy could actually be positive. But even if the personal autonomy gains from the nicotine rule did not outweigh the personal autonomy harms, the other ethically relevant benefits from a nicotine-reduction rule would be enormously larger than any net ethically relevant harms from reducing personal autonomy (or causing any other negative ethical impacts). As already mentioned, the FDA-supported modeling study estimated that over time the rule would prevent 2.2 to 11.2 million tobacco-related deaths, gaining 31.6 to 183 million additional life years.¹³⁵ By reducing smoking-caused disease, disability, and other health harms, the rule would also directly improve the quality of the life years of many more people, while also reducing smoking-caused government, private sector, and household costs and otherwise strengthening the economy, which would produce additional improvements to personal and overall health and wellbeing. Even on an individual basis, smokers who quit generally

like the federal notice-and-comment rulemaking process – is required not to violate certain important individual rights; must be non-arbitrary, fair and transparent; must permit and consider alternative views and amendments and explains related choices; and, even if it complies with all applicable laws, could still be struck down or changed by the elected representatives. *See, e.g.,* Bovens (2016) and Schmidt (2016), *supra* note 93.

¹³³ This analysis will not explore whether any such independent choices to become *addicted* smokers or to continue *addictive* smoking might still be so “self-centered, pig-headed, impulsive, random, ignorant, out of control and regrettable or unacceptable” or otherwise deficient that they would not be worthy of ethical respect in tobacco control policy making. James Wilson, [Is respect for autonomy defensible?](#), 33 *Jnl Medical Ethics* 353 (June 2007) (quoting Onora O’Neill, *Autonomy and trust in bioethics* (Cambridge University Press, 2002)).

¹³⁴ *See, e.g.,* Yvette van der Eijk & Gerard Porter, [Human rights and ethical considerations for a tobacco-free generation](#), 24 *TOBACCO CONTROL* 238 (May 2015); Carolyn Dresler, et al., *Human rights-based approach to tobacco control*, 21 *TOBACCO CONTROL* 208 (March 2012); David Reubi, [Making a human right to tobacco control: expert and advocacy networks, framing and the right to health](#), 7(Suppl 2) *GLOBAL PUBLIC HEALTH* S176 (2012); Brigit Toebes, [The human rights responsibilities of multinational tobacco companies](#), 14(Suppl 2) *TOBACCO CONTROL* ii14 (2005); Brigit Toebes, et al., [A missing voice: the human rights of children to a tobacco-free environment](#), 27 *TOBACCO CONTROL* 3 (Jan. 2018). The assertion of these human rights to tobacco control and the like often reference the Universal Declaration of Human Rights and the International Covenant on Civil and Political Rights (which the United States has signed and ratified) and the International Covenant on Economic, Social, and Cultural Rights and the Convention on the Rights of the Child (which the U.S. has signed but not ratified). As these international agreements and conventions indicate, the related rights can also exist independently as ethically supported individual or human rights, regardless of the documents or which countries have signed.

¹³⁵ Apelberg, et al. (2018), *supra* note 76.

report being happier.¹³⁶ Given that lower-income and less-educated persons make up a disproportionate portion of the smoking population and suffer disproportionately from smoking-caused health harms, the broad smoking declines and related health gains secured by the nicotine rule would also reduce existing health disparities. Against these massive ethically relevant gains, any possible net infringements on personal autonomy from no longer allowing businesses to make full-nicotine smoked tobacco products legally available to adult consumers would certainly be ethically acceptable.¹³⁷

Nevertheless, following our ethical procedures FDA would still be obligated to implement any readily available rule revisions or complementary measures that could reduce any related harms or risks to personal autonomy that would not also reduce the nicotine rule's public health gains.¹³⁸ But any change to enable adult smokers to continue have some way to obtain full-nicotine smoked tobacco products legally would inevitably prompt some to do so, thereby reducing the public health gains from the original rule, making it less AFPPH and less ethically appropriate. Moreover, even if the Tobacco Control Act and the Administrative Procedures Act legally permitted FDA to reduce the public health gains of a rule in order to secure non-health, ethically relevant gains, there do not appear to be any available revisions to the nicotine rule to reduce its infringements on personal autonomy in ways that would make the described nicotine-minimization rule more ethically appropriate. For example, revising the rule to require manufacturers only to produce and market minimal-nicotine smoked tobacco products, without also prohibiting the marketing of full-nicotine smoked tobacco products, could not conceivably produce even a substantial fraction of the smoking cessation and related health gains from the original nicotine-minimization rule.¹³⁹

Another option might be to prohibit the sale of only completed full-nicotine smoked products but still allow the sale to consumers of full-nicotine tobacco so that they could roll their own full-nicotine cigarettes. But the current marketing of convenient "roll-your-own" machinery and cigarette components enable smokers to quickly and easily make cigarettes identical to commercially sold versions, and smokers have shown a considerable interest and ability to turn to

¹³⁶ See, e.g., Pechacek, et al., *supra* note 112.

¹³⁷ For a similar ethical analysis and conclusion supporting a complete ban of all cigarettes, see Kalle Grill & Kristin Voigt, [The case for banning cigarettes](#), 42 JNL MEDICAL ETHICS 293 (May 2016). See, also, Eric N. Lindblom, [Are There Any Ethical Barriers to Effective Antismoking Measures?](#), 107 *Am. Jnl. Public Health* 1364 (September 2017). For a contrary view, see Flanigan (2016), *supra* note 114. More generally, see Larry O. Gostin & Kieran G. Gostin, [A broader liberty: J.S. Mill, paternalism and the public's health](#), 123 PUBLIC HEALTH 214 (March 2009) (ethically justifying hard paternalism over the harm principle in the context of population-based public health interventions); James Wilson, [Why It's Time to Stop Worrying About Paternalism in Health Policy](#), 4 PUBLIC HEALTH ETHICS 269 (Oct. 2011) (presenting four principles to guide government public health policies, which appear to justify a nicotine-reduction rule); and Alec Rajczi, [Liberalism and Public Health Ethics](#), 30 Bioethics 96 (Feb. 2016) (proposing that honoring liberalism and its priority for liberty does not actually rule out or interfere with strong, population-based anti-smoking or other public health interventions).

¹³⁸ In bioethics, a similar approach has been referred to as using an "intervention ladder" with the policy options that are more intrusive to personal autonomy (the highest rungs of the ladder) requiring the strongest justifications, with a presumption for using the "least restrictive alternative" (e.g., the lowest rung on the ladder) that will produce the desired health results. See, e.g., Nuffield Council on Bioethics, [PUBLIC HEALTH: ETHICAL ISSUES](#) (2007).

¹³⁹ Studies that provide smokers with low-nicotine cigarettes, for example, often have their findings subverted to some extent by the smokers violating the study protocols and smoking the full-nicotine cigarettes that remain legally available from non-study source. *Supra* note 82. While the gains from this alternative approach might be increased by also restricting the sale of the full-nicotine versions to adult-only sales outlets or sharply restricting their marketing, the new final rule would still secure much small public health gains than version allowing no full-nicotine sales of cigarettes or smoked-tobacco products.

such products to reduce their smoking costs, especially in response to cigarette tax and price increases.¹⁴⁰ Consequently, allowing the sale of full-nicotine tobacco to consumers as part of a nicotine-reduction rule would dramatically reduce related smoking declines and health gains – and also make the illicit production of full-nicotine cigarettes for illegal resale much more likely, which would further reduce quitting or switching to less harmful alternative products.¹⁴¹

Following this analysis, it does not appear to be any serious practical, analytical, or ethical difficulties would impede any effort by FDA to apply the ideal ethical criteria to guide and produce the most AFPPH and ethically appropriate nicotine-reduction rule possible, while fully complying with the Tobacco Control Act and the “not arbitrary or capricious” standard.

Moreover, FDA’s development of the rule through the required notice-and-comment rulemaking would work effectively to help identify and include any additional ethically appropriate refinements that FDA might have been missed, especially if FDA explicitly requests interested parties to submit comments regarding any specific ways that the rule might be improved, within its scope, to increase its public health gains (ideally without creating any new or increased harms or other undesirable impacts) or to reduce any related harms or undesirable impacts or increase any related benefits (ideally without reducing the expected net public health gains).

By Itself, Minimizing Nicotine in Smoked Tobacco Products is Not Ethically Adequate

Even after modifying the nicotine-reduction rule to maximize public health gains and make it as ethically appropriate as possible, it still would not minimize tobacco use harms, much less do so as quickly as possible. Given its authorities under the Tobacco Control Act, FDA could still take additional ethical actions to reduce tobacco harms more quickly. Following the same ethical procedures and analysis provided here for the nicotine-reduction rule, FDA could readily identify and develop other rules to help reduce tobacco-related public health harms more rapidly – and would be ethically required to do so.¹⁴²

For just one example, it would be ethically appropriate for FDA to include a provision in the nicotine-reduction rule from the start that would prohibit the sale of tobacco products in any

¹⁴⁰ See, e.g., Michael A. Tynan et al., [Continued implications of taxing roll-your-own tobacco as pipe tobacco in the USA](#), 24 Tobacco Control e125 (June 2015).

¹⁴¹ To reduce these problems, but secure smaller personal autonomy gains, the rule could prohibit the sale of all roll-your-own machinery and components other than personal-use amounts of full-nicotine tobacco and single-sheet packs of paper for hand rolling (e.g., no sales to consumers of cigarette tubes with filters that could be quickly filled with tobacco through hand-held or even more sophisticated mechanisms or machines). But some smokers would still shift to making hand-rolled full-nicotine cigarettes instead of quitting or switching, and the permitted production, distribution, and sale of full-nicotine tobacco for consumer hand-rolling would open the door to illegal efforts to divert it to more organized, higher volume production of illicit full-nicotine cigarettes for black market sales.

¹⁴² For these same reasons, there would be no ethical requirement for FDA to try to find an alternative to issuing the nicotine-reduction rule that would secure similar public health gains but be less restrictive in terms of infringing personal autonomy or causing other ethically relevant harms. Even if such an alternative rule existed, the ethical goal of reducing tobacco use harms as quickly as possible (in ethically appropriate ways) would require that FDA issue both rules, along with any other ethically acceptable AFPPH rules that could help to accelerate tobacco-related public health gains.

physical locations that permit youth to enter or from websites that permit youth to access them. That would certainly prevent tobacco product sales to youth much more effectively than the current system. It would also reduce overall tobacco use, while also promoting personal autonomy, by preventing unplanned or impulse tobacco product purchases by users trying to quit or cutback or by former users when they go to grocery stores, convenience stores, or any other stores accessible both to adults and youth to buy other products.¹⁴³ It would also make planned tobacco product purchases somewhat less convenient, which would further increase the number of smokers who would respond to the nicotine rule by quitting all use instead of switching, while also helping to prompt more quitting by users of non-smoked tobacco products. Moreover, stores blocked by these provisions from selling tobacco products would also be much less likely to display tobacco product advertising, which would help to further reduce adult and youth use; and even if they still displayed such advertising it could no longer prompt unplanned or impulse buys.¹⁴⁴

To further reduce unplanned purchases and use, FDA could also include a provision to prohibit tobacco product sales in any locations where alcohol or state-legalized cannabis are consumed, given that intoxication could prompt impulse purchases and use and impedes the ability of consumers to make rational choices consistent with their personal autonomy.¹⁴⁵

Limiting tobacco product sales to adult-only sales outlets that do not allow alcohol or cannabis consumption would also greatly simplify FDA's oversight and enforcement activities relating to the sale of tobacco products and to its enforcement of the new rule. Any locations found to be selling tobacco products that were youth accessible or allowed alcohol or cannabis consumption would clearly be illegal, eliminating the need for FDA to do any further investigations to identify less-obvious violations, such as actual sales to youth or sales to possible youths without checking ID (which make up a large portion of FDA's current enforcement efforts). Similarly, FDA could shut down street sales of tobacco products or tobacco-product sales in any other youth accessible location without having to determine whether the smoked tobacco products they were selling were actually illegal full-nicotine versions. Moreover, the adult-only requirement would likely substantially reduce the number of bricks-and-mortar sales outlets offering tobacco products,

¹⁴³ See, e.g., Lisa Wood, et al., [Unplanned purchasing of tobacco products: Beyond point of sale display](#), HEALTH PROMOTION JNL AUSTRALIA (Epub. May 18, 2019); Eben J. Clattenburg, et al., [Unplanned cigarette purchases and tobacco point of sale advertising: a potential barrier to smoking cessation](#), 22 TOBACCO CONTROL 376 (Nov. 2013); O.B.J. Carter et al., [The effect of retail cigarette pack displays on unplanned purchases: results from immediate postpurchase interviews](#), 18 TOBACCO CONTROL 218 (June 2009).

¹⁴⁴ See, e.g., Clattenburg et al. (Nov. 2013), *id.* If FDA prohibited tobacco product sales in locations that permitted youth to enter, that would also reduce the First Amendment rights of any stores that permit youth to advertise tobacco products, as any tobacco product advertising restriction that applied to those businesses would not be interfering with their ability to communicate relevant information about the products they sell to legal adult customers. See e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); and the First Amendment analysis in Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 Food and Drug L. J. 57 (2015). Accordingly, FDA should supplement any rule prohibiting tobacco product sales in youth-accessible locations or locations where alcohol or state-legalized cannabis is consumed to also prohibit any publicly visible tobacco product ads at those locations.

¹⁴⁵ The TCA specifically prohibits any FDA rules that would prohibit the sale of any tobacco product in face-to-face transactions by “a specific category” of retail outlet. TCA § 906(d)(3)(A)(i) [21 U.S.C. 387f(d) (3)(A)(i)]. But there is nothing in the Act or its legislative history to suggest that “specific category of retail outlet” would include all locations that allow youth to enter or any locations where alcoholic beverages or state-legalized cannabis are consumed. Accordingly, FDA could reasonably and legally interpret and apply that phrase as prohibiting FDA from banning tobacco product sales only in any specific types of retail outlets, such as in all pharmacies, convenience stores, or grocery stores.

thereby reducing the number FDA would need to inspect or otherwise monitor for other types of violations, such as illegally selling full-nicotine cigarettes or other non-FDA-compliant tobacco products.

At the same time, there does not appear to be any way that these location restrictions would cause any underlying new health harms or health disparity increases. Nor would it seriously infringe on personal autonomy to require those adults wanting to purchase tobacco products to go to the adult-only stores that sell them (rather than continue being able to buy them from any of the currently existing sales outlets), especially as some might consent to the restriction, either to protect themselves making unplanned or addiction-prompted purchases or to protect against youth use.

There also do not appear to be any other serious negative impacts, ethically relevant or not, from adding these sales restrictions into the nicotine-reduction rule. Any stores or websites that already secure the lion's share of their sales revenues and profits from tobacco products would not likely be hurt by converting into an adult-only sales outlets, especially as they would likely receive some of the tobacco product business of non-adult-only tobacco-selling stores that do not convert. Those stores that stop selling tobacco products in response to these provisions could suffer some economic losses if they previously received a significant portion of their revenues and profits from tobacco product sales. As discussed above, however, those economic harms to businesses would not be ethically relevant (or relevant under the Tobacco Control Act) unless they also translated into significant harms to the health, happiness, or overall wellbeing of individual owners or employees. Moreover, any such harms that might occur would be only temporary, necessary side effects from securing the much larger public health gains from the sales restrictions; part of the ongoing dislocations and restructuring that occur as our economy continues to evolve and, with luck or good policies, improve. They would also be offset by the economic and related health and wellbeing gains others would experience as any money no longer spent in some of the current tobacco product selling outlets would be spent elsewhere, instead.¹⁴⁶

As with the core nicotine rule, itself, any new ethically relevant harms these sales restrictions might create would pale in significance when contrasted with the additional public health and other ethical gains they would secure. This example shows how FDA could make the nicotine rule, or any other rule, much more beneficial for the public health and more ethically appropriate by taking a broader, more creative and constructive approach to how it develops and refines its tobacco control rules. Rather than defining their scope narrowly by their core mechanism (e.g., reducing nicotine levels in cigarettes), FDA needs to see and treat each rule as a vehicle that can include any revisions or additions that will directly promote the rule's core public health purpose (e.g., to reduce smoking) or help it do so in a more ethically appropriate way. But even if it issued a fortified, extra-effective nicotine-reduction rule, FDA would still need to implement additional rules and take other related actions to pursue the ethical goal of reducing tobacco use harms as quickly as possible in an ethically appropriate manner.

Conclusion

Ethical analysis, both generally and in the context of government policymaking, is a complicated often inconclusive enterprise, frustrated by the subjectivity of moral or ethical values, conflicts

¹⁴⁶ See *supra* note 103 and related text.

between different adopted ethical perspectives or goals, and difficulties in identifying and predicting ethically relevant impacts. It is absolutely clear, however, that each of the major ethical perspectives most commonly applied to public health policymaking mandates much more aggressive rulemaking by FDA to use its extensive tobacco control authorities and resources to reduce the massive amounts of unnecessary death, disability, and disease and other harms caused by tobacco use – so long as those rules are also structured to be ethically appropriate or acceptable. Moreover, we have seen that FDA could (if allowed by the White House and OMB) act consistently with those ethical perspectives to develop and implement numerous new tobacco control rules that would be both AFPPH and clearly ethically appropriate, while largely or completely avoiding any serious ethical complications or conflicts.

That can be done because the Tobacco Control Act and other applicable laws require that FDA honor the Act's overriding goal of producing net public health gains (by reducing tobacco-related health harms and risks to the population as a whole). That statutory requirement make all other health goals secondary and subservient to the ethical goal of improving the public health, and all non-health ethically relevant goals subservient to the health-related ethical goals. In addition, the ready availability of effective tobacco control rules to reduce the massive ethically relevant harms caused by smoking and other tobacco use without any risk of producing a negative public health impact make it relatively easy for FDA to develop a range of new tobacco control rules that are not only AFPPH but will clearly produce public health gains and other ethically relevant benefits that will dwarf any ethically relevant harms they might also produce. To be ethically appropriate, however, FDA must also ensure that the rules are not producing any unnecessary ethically relevant harms or risks or failing to secure any available additional ethically relevant benefits. As we have seen, FDA could do that, within the constraints of the Tobacco Control Act and related laws, by taking advantage of all readily available modifications or additions to the rules that would clearly increase their net public health gains (and other related ethical benefits) to a much greater extent than they might produce any new ethically relevant harms; and by then taking advantage of any readily available modifications or additions that will reduce any ethically relevant harms or risks from the rules (or produce new ethically relevant benefits) without reducing the likelihood or size of their net public health gains.

Identifying different ethical gains and losses and evaluating them against each other can be difficult. But the ethical procedures described here greatly simplify that challenge by requiring FDA, for the most part, to determine only whether specific rules or changes or modifications to them do or do not create public health and other ethical gains that are clearly much larger than any possible ethical harms or risks they might cause under any possible application of the ethical perspectives. To further help with those efforts, this analysis has shown that the ethical perspectives, working within the health-directed constraints of the Tobacco Control Act and from related law, produce the following hierarchy of secondary ethical goals to follow the overriding goal of securing the largest possible net public health gains: (a) reducing any underlying new health harms or risks to individuals or subpopulations; (b) preventing any increase to inequitable health disparities (or reducing them); (c) avoiding any serious infringements on personal autonomy (or increasing personal autonomy); and (d) reducing any ethically relevant non-health harms (or securing additional ethically relevant benefits).

Moreover, as shown, there are numerous, legally viable ways that FDA can use its own expertise supplemented by outside experts (including ethicists) to develop reasonable evidence-based

estimates of the future public health and ethically relevant subpopulation health impacts from any particular rule (perhaps using prevented deaths, or increased life years or QALYs as a proxy), including worst-case, best-case, and most-likely scenarios. Using the same kinds of procedures FDA could also readily identify the ethically relevant non-health impacts, develop estimated ranges of the numbers of persons likely to be affected negatively or positively in those ethically relevant ways, and secure other insights into the severity of any such ethically relevant harms and risks versus the benefits from any such ethically relevant gains. Taken together, these efforts should provide all the information FDA would need to determine whether the overall public health and other ethically relevant gains from a rule or possible modifications or additions to it would clearly overwhelm and justify any possible related ethical harms.

Fortunately, FDA has considerable resources, staffing, and access to relevant outside experts to follow these procedures and develop and implement the most ethically appropriate, legally viable AFPPH rules that will quickly reduce the horrible toll of death, disability, disease and other health and non-health harms caused by smoking and other tobacco use.

Once smoking is reduced to very low levels and other tobacco use harms are sharply curtailed, the ethical challenges for additional FDA tobacco control rulemaking might become considerably more complex and difficult. But, for now, the ethical path forward for strong, new FDA tobacco control rulemaking seems quite clear and relatively easy to travel. The major obstacles continue to be political. But perhaps this ethics-based analysis will provide some new ammunition in the battle to reduce those political obstacles – or at least provide useful ethical guidance for more constructive FDA tobacco control action if and when there is a White House and OMB that actually allows and supports FDA efforts to use its extraordinary tobacco control powers and authorities to protect the public health as effectively as possible. More immediately, FDA could begin to use these ethical guidelines and procedures to revise and improve any draft proposed rules it has under development and to select and draft other proposed rules that it could quickly issue when an opportunity arises or when FDA or its public health allies create one.¹⁴⁷

¹⁴⁷ FDA could also use this same kind of ethical analysis to guide and improve its evaluations of PMTA and MRTP applications and its development of any related orders allowing the marketing of the products. Lindblom, EN, “How Would an Ethically Responsible FDA Evaluate PMTA and MRTP Applications and Issue Related Orders?,” *Food and Drug Law Journal* [75\(1\): 1-38](#) (August 2020). Lindblom, EN, “The Tobacco Control Act’s PMTA and MRTP Provisions Mean to Protect the USA From Any New Tobacco Products That Will Not Reduce Health Harms – But FDA Isn’t Cooperating,” *Journal of Health Care Law & Policy* [23\(2\): 121-186](#) (Feb. 2021). But PMTA and MRTP orders raise much more difficult ethical issues and complications because the marketing of any new tobacco product, with or without modified-risk claims, unlike any strong tobacco control rules FDA might implement, will almost certainly create a significant risk of producing a negative net public health impact. Unlike with rules and revisions to them, FDA cannot rely on the expected public health gains from PMTA or MRTP orders clearly being much larger than any possible ethically relevant harms to simplify its ethical evaluations and choices. *See, e.g.,* Lindblom, *Food and Drug Law Journal* 75(1): 1-38 (August 2020), *id.*