TRADING PUBLIC NUISANCE FOR PRODUCT SAFETY: REVIVING THE OFFICE OF TECHNOLOGY ASSESSMENT

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ABSTRACT

Tobacco, lead paint, prescription opioids, and electronic cigarettes (e-cigarettes), once revered as innovative products, are now regarded as public nuisances. These public health epidemics share a similar history that has time and again repeated itself. In a sentence, the industry markets products with unanticipated long-term safety risks, combats or discredits emerging evidence of harm associated with the product, evades liability in personal injury or products liability lawsuits, and finally accepts responsibility when government officials file public nuisance lawsuits. While public nuisance lawsuits successfully respond to public nuisance products, this last resort, resource-intensive, backward-looking intervention fails public health. History does not have to repeat itself again. This Note proposes a technology assessment solution to break the epidemic cycle of public nuisance products at the first phase: revive the Office of Technology Assessment in the United States Patent and Trademark Office to proactively, cost-effectively, and preventively monitor long-term safety risks of consumer products.

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INTRODUCTION

History has a way of repeating itself. In 1964, the Advisory Committee to the U.S. Surgeon General officially and definitively concluded cigarette smoking is a health hazard to American citizens.[1] Today, smoking-related diseases still affect more than sixteen million Americans.[2]

Over two decades ago, the Centers for Disease Control and Prevention (CDC) declared "elevated blood lead levels . . . the

1. *History of the Surgeon General's Reports on Smoking and Health*, *Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/sgr/history/ (Nov. 15, 2019); *see also Achievements in Public Health, 1900–1999: Tobacco Use – United States, 1900–1999*, CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WKLY. REP. fig.1 (Nov. 5, 1999) [hereinafter *U.S. Tobacco Use 1900–1999*], https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a2.htm#fig1 (plotting per capita cigarette consumption throughout the twentieth century, in relation to significant public health events).

2. *Fast Facts*, *Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION [hereinafter *Fast Facts*], https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm (May 21, 2020).

first non-infectious condition to be notifiable[3] at the national level."[4] From 1999–2010, 1.2 million American children were affected by elevated blood lead levels.[5]

In 2017, the Acting Secretary for the Department of Health and Human Services declared the national opioid crisis a public health emergency.[6] In 2018, 47,600 people died from prescription opioid overdose.[7]

Recently, the Surgeon General recognized youth electronic cigarette (e-cigarette) use as a public health epidemic.[8] In 2020, over 3.6 million youth used e-cigarettes.[9]

Tobacco, lead paint, prescription opioids, and e-cigarettes, once revered as innovative products, now represent public nuisances. In other words, these products interfere with a right common to the general public: health.

Tobacco, lead paint, opioids, and e-cigarettes share a similar history that has time and again repeated itself.[10] Companies marketed the products when society knew little about

3. A notifiable disease is one that by law must be reported to the appropriate government agency. *See National Notifiable Diseases Surveillance System (NNDSS)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://wwwn.cdc.gov/nndss/ (Mar. 13, 2019).

4. *Data and Statistics, Childhood Lead Poisoning Prevention,* CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nceh/lead/data/index.htm (July 30, 2019) (footnote not included in original).

5. Sarah Frostenson, *1.2 Million Children in the US Have Lead Poisoning. We're Only Treating Half of Them.*, VOX (Apr. 27, 2017, 4:30 PM), https://www.vox.com/science-and-health/2017/4/27/15424050.

6. *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, U.S. DEP'T HEALTH & HUM. SERVS. (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

7. *What is the U.S. Opioid Epidemic?*, U.S. DEP'T HEALTH & HUM. SERVS, https://www.hhs.gov/opioids/about-the-epidemic/index.html (Sept. 4, 2019).

8. *Surgeon General's Advisory on E-cigarette Use Among Youth, Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION [hereinafter *Smoking & Tobacco Use: Surgeon General's Advisory*], https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (Apr. 9, 2019).

9. *Youth Tobacco Use: Results from the National Youth Tobacco Survey*, U.S. FOOD & DRUG ADMIN. [hereinafter *FDA National Youth Tobacco Survey*], https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey (Sept. 10, 2020).

10. *See infra* Section II.A.

associated long-term health and safety risks.[11] The public accepted the products as safe for long-term use, but widespread disease, illness, and death ensued.[12] The health community published early research linking the products to disease, illness, and death,[13] demonstrating the need for public health interventions. The various industries combatted and discredited evidence that associated these products with adverse health effects.[14] Victims individually sued companies and failed.[15] Finally, state attorneys general filed public nuisance claims against the industries to redress the harm to public health caused by each product.[16] History is set to repeat itself again if society continues to rely on such a reactive, resource-intensive, and backward-looking intervention as public nuisance lawsuits. However, a simple trade of public nuisance for technology assessment can break the cycle.

This Note proposes that the former Office of Technology Assessment (OTA) should be revived in the United States Patent and Trademark Office (USPTO) to proactively, cost effectively, and preventively monitor and report emerging evidence of long-term health and safety risks of new consumer products to guide federal regulatory action. Part I provides a general overview of public nuisance law, past and current federal technology assessment activities, and operations of the USPTO. Part II describes four major public health epidemics in

11. *See History of Tobacco*, TOBACCO FREE LIFE, https://tobaccofreelife.org/tobacco/tobacco-history/ (last visited Oct. 16, 2020); Richard Rabin, *Warnings Unheeded: A History of Child Lead Poisoning*, 79 AM. J. PUB. HEALTH 1668, 1668 (1989); Michael J. Purcell, *Settling High: A Common Law Public Nuisance Response to the Opioid Epidemic*, 52 COLUM. J.L. & SOC. PROBS. 135, 139–40 (2018).

12. *See* Michael L. Rustad & Thomas H. Koenig, *Reforming Public Interest Tort Law to Redress Public Health Epidemics*, 14 J. HEALTH CARE L. & POL'Y 331, 357 (2011); Rabin, *supra* note 11, at 1672; Purcell, *supra* note 11, at 140–41.

13. *See* Patrick Luff, *Regulating Tobacco Through Litigation*, 47 ARIZ. ST. L.J. 125, 134 (2015); Rabin, *supra* note 11, at 1668–69; Purcell, *supra* note 11, at 139–41.

14. *See* Luff, *supra* note 13, at 135–36; Rabin, *supra* note 11, at 1671–72.

15. *See* Luff, *supra* note 13, at 144; Victor E. Schwartz & Phil Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort*, 45 WASHBURN L.J. 541, 557 (2006); Purcell, *supra* note 11, at 159.

16. Lindsay F. Wiley, *Rethinking the New Public Health*, 69 WASH. & LEE L. REV. 207, 243–45 (2012); Purcell, *supra* note 11, at 159–60; *see* Schwartz & Goldberg, *supra* note 15, at 554.

American history and demonstrates how each epidemic proceeds in a cyclical pattern that consistently ends with state actors filing public nuisance lawsuits. Part III proffers a solution to break the epidemic cycle. Part III first proposes how the OTA and current federal technology assessment activities may be revived in the USPTO. Part III then discusses how this solution, despite some drawbacks, is ultimately worthwhile to address America's epidemic cycle of public nuisance products.

I. BACKGROUND

Public nuisance law and federal technology assessment activities both serve public health functions. Public nuisance law serves as a modern tool for attorneys general to hold companies liable for the national health epidemics resulting from consumer use of tobacco, lead paint, opioids, and e-cigarette products.[17] Similarly, technology assessment activities by the federal government help guide federal agencies and Congress in regulating innovative technology and products that pose potential long-term health and safety risks to the public. However, technology assessment provides a more effective preventive approach and achieves similar goals as public nuisance liability. Technology assessment can be an effective preventive public health measure if conducted in a federal agency with access to the information, resources, and capacity necessary for an expansive technology assessment program. One such agency is the USPTO. This Part provides background information on public nuisance law, past and present federal technology assessment activities, and an overview of the USPTO to understand how these components add up to a public health intervention that breaks America's epidemic cycle of public nuisance products.

17. *See infra* Part II.

A. *Public Nuisance*

The Restatement (Second) of Torts provides a contemporary model of public nuisance jurisprudence. Section 821B defines public nuisance as "an unreasonable interference with a right common to the general public."[18] Unreasonable interferences with a public right include: (1) conduct that involves significant interference with public health, safety, peace, comfort, or convenience; (2) "conduct . . . proscribed by a statute, ordinance, or administrative regulation"; and (3) conduct the actor has reason to know significantly affects a public right, and that is of a continuing nature or that produces a long-lasting effect.[19] A public right is "one common to all members of the general public" that is "collective in nature."[20]

Public nuisance law has evolved into a legal mechanism to protect the public welfare. Early American common law primarily recognized non-trespassory interferences with land use as public nuisances, along with some minor offenses against public morals or welfare.[21] Nineteenth-century industrialization initiated conflicts about proper land use, which changed the emerging common law and statutory boundaries of the tort.[22] Before industrialization, most public nuisance claims involved obstruction of public highways or

18. RESTATEMENT (SECOND) OF TORTS § 821B(1) (AM. L. INST. 1965); Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. CIN. L. REV. 741, 807 (2003).

19. RESTATEMENT (SECOND) OF TORTS § 821B(2)(a)–(c). This list is neither exclusive nor exhaustive; intentional, reckless, negligent, or abnormally dangerous activities all embody some degree of unreasonableness. *Id.* § 821B cmt. b, cmt. e.

20. *Id.* § 821B cmt. g.

21. Gifford, *supra* note 18, at 800–01; Schwartz & Goldberg, *supra* note 15, at 545. Comment b of the Restatement gives examples of typical interferences included in common law public nuisance jurisprudence, e.g., diseased mosquitoes emanating from a pond, explosives or fireworks in a city, loud noises, widespread bad odors or smoke, and obstruction of public highways or streams. RESTATEMENT (SECOND) OF TORTS § 821B cmt. b. Comment b incorporates the idea that these typical examples are products of their time; these activities constituted public nuisances during the times they appeared in jurisprudence because that is what society at the time thought was worthy of a criminal offense. *See id.* Public nuisance emerged as a civil remedy for conduct that was once considered criminal but which eventually evolved into civil offenses. *See* Schwartz & Goldberg, *supra* note 15.

22. *See* Gifford, *supra* note 18, at 802; *see also* Schwartz & Goldberg, *supra* note 15, at 546–47.

waterways; after industrialization, public nuisance suits alleged water and air pollution as new types of legally cognizable injuries.[23] Thus, public nuisance emerged as a substitute for regulation when governments could not anticipate the industrial activities that might impede public health and welfare.[24]

Public nuisance lawsuits were less common in the Progressive and New Deal eras but expanded rapidly again in the 1970s.[25] The Progressive and New Deal eras enacted comprehensive regulation over the former industrial targets of early public nuisance lawsuits.[26] As a result, public nuisance lawsuits were unnecessary during these times because expansive legislation prescribed acceptable societal behaviors, more effectively anticipating and regulating harmful industry conduct than after-the-fact litigation.[27] The 1970s marked a dramatic change in the application of the tort because it was the first time governments used public nuisance as a theory of liability against product manufacturers.[28] After governments first used public nuisance as a theory of liability against automobile manufacturers for causing air pollution, government officials popularized the tort as a theory of liability for municipal lawsuits against a variety of other industries, such as asbestos, firearms, and tobacco.[29]

State governments continue to use public nuisance law as a tool to protect public health and often invoke parens patriae to launch public nuisance claims.[30] Parens patriae roughly means

23. Gifford, *supra* note 18, at 800–03.

24. Schwartz & Goldberg, *supra* note 15, at 545–46 (citing Gifford, *supra* note 18, at 800–01).

25. Gifford, *supra* note 18, at 745–47, 805–06; *see* Schwartz & Goldberg, *supra* note 15, at 546.

26. Gifford, *supra* note 18, at 745–47, 805–06; *see* Schwartz & Goldberg, *supra* note 15, at 546.

27. *See* Gifford, *supra* note 18, at 745–47, 805–06; Schwartz & Goldberg, *supra* note 15, at 546.

28. Gifford, *supra* note 18, at 745–47.

29. *See id.* at 750–53.

30. *See generally* Rustad & Koenig, *supra* note 12 (discussing the public law model as an important legal mechanism for resolving health or environmental problems in the era of hazardous technologies).

"parent of the country," invoking English common law roots.[31] Attorneys general exercise parens patriae power to file public nuisance actions against industry to abate conduct injurious to public health, safety, and welfare.[32] Comment d of the Restatement explains one reason why public nuisance actions appeal to governments: "a municipal corporation, which cannot be prosecuted for a crime, may still be liable in tort for the creation or maintenance of a public nuisance if the conduct is such that a private individual would be liable."[33] Over the last fifty years, the combination of public nuisance and parens patriae forged a path for state attorneys general to redress grave matters of public health: tobacco, lead paint, opioids, and e-cigarettes.[34]

B. *Technology Assessment*

Like public nuisance lawsuits,[35] technology assessment, in part, serves a public health function. Unlike public nuisance lawsuits, technology assessment provides the government with an advantageous ability to anticipate long-term safety concerns of consumer products. Technology assessment is "a form of policy research that examines short- and long-term consequences (for example, societal, economic, ethical, legal) of the application of technology. The goal of technology assessment [is] . . . to provide policy makers with information on policy alternatives."[36] This Note uses "technology" as a

31. *Id.* at 338. The Crown used its status as parens patriae to protect vulnerable groups of people or those that generally lacked a legally cognizable interest. *Id.* This legal concept transferred to American common law in the colonial era, and by the end of World War II, the United States Supreme Court confirmed that states in their parens patriae capacity may redress "matters of grave public concern." Georgia v. Pa. R.R. Co., 324 U.S. 439, 451 (1945); *see also* Rustad & Koenig, *supra* note 12, at 341 (discussing *Georgia v. Pa. R.R. Co.*).

32. Lainie Rutkow & Stephen P. Teret, *The Potential for State Attorneys General To Promote the Public's Health: Theory, Evidence, and Practice*, 30 ST. LOUIS U. PUB. L. REV. 267, 274, (2011).

33. RESTATEMENT (SECOND) OF TORTS § 821B cmt. d (AM. L. INST. 1965).

34. *See infra* Part II.

35. *See infra* Part II.

36. David Banta, *What Is Technology Assessment?*, 25 INT'L J. TECH. ASSESSMENT HEALTH CARE 7, 7 (Supp. 1 2009).

broad umbrella term, encompassing consumer products and the processes creating such products.[37]

Understanding technology and its influence on society is important to congressional and agency decision-making. Congress recognized the importance of technology assessment and opted to institute the OTA in 1972 to help guide policy-making with complex technological issues.[38] While the OTA no longer exists, there are calls to revive it,[39] including this Note's proposal to revive the OTA within the USPTO for public health purposes.[40] Despite the OTA's current absence, technology assessment remains a vital part of several federal regulatory agencies, particularly the Food and Drug Administration[41] and the Consumer Product Safety Commission.[42] These agencies use technology assessment to help fulfill their public health function in regulating consumer product safety; however, their technology assessment activities address niche safety concerns limited in ways that do not effectively address the epidemic cycle of public nuisance products. This section provides information about these past and present technology assessment activities that ultimately inform this Note's

37. *See What Is Technology?*, LAW DICTIONARY, https://thelawdictionary.org/technology/ (last visited Oct. 17, 2020) (defining technology as "[i]nformation application to design, production and utilization of services and goods and organizing human activities"); *Technology*, CAMBRIDGE DICTIONARY, https://dictionary.cambridge.org/us/dictionary/english/technology (last visited Oct. 17, 2020) (defining technology as "the practical, especially industrial, use of scientific discoveries"); *Technology*, DICTIONARY.COM, https://www.dictionary.com/browse/technology (last visited Oct. 17, 2020) (defining technology as "the sum of the ways in which social groups provide themselves with the material objects of their civilization"); *Technology*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/technology (last visited Oct. 17, 2020) (defining technology as "a manner of accomplishing a task especially using technical processes, methods, or knowledge").

38. The Technology Assessment Act of 1972, Pub. L. No. 92-484, 86 Stat. 797 (codified as amended at 2 U.S.C. §§ 471–481).

39. Grant Tudor & Justin Warner, *Congress Should Revive the Office of Technology Assessment. Here's How To Do It*, BROOKINGS (Dec. 18, 2019), https://www.brookings.edu/blog/fixgov/2019/12/18/congress-should-revive-the-office-of-technology-assessment-heres-how-to-do-it/.

40. *See infra* Part III.

41. *See infra* Section I.B.2.a.

42. *See infra* Section I.B.2.b.

proposed solution to the epidemic cycle of public nuisance products.

1. *Office of Technology Assessment*

The OTA "provided Congressional members and committees with objective and authoritative analysis of the complex scientific and technical issues of the late 20th century."[43] The Office of Technology Assessment Act established the OTA in 1972.[44] The OTA helped Congress craft public policy and legislation by providing a more thorough analysis compared to other congressional research offices.[45]

The Technology Assessment Board (TAB) directed OTA oversight and consisted of twelve bipartisan congressional representatives and senators.[46] The TAB appointed various advisory councils to advise and incorporate public participation in the OTA's process; advisory councils consisted of industry, academia, and public representatives outside of government.[47] The OTA operated with approximately 200 staff members, two-thirds of whom consisted of researchers.[48] Eighty-eight percent of research staff held advanced degrees in science, economics, engineering, and other technical fields.[49] The OTA collaborated with other congressional support agencies to form an "interagency Research Notification System" to coordinate activities, exchange information, and

43. *The OTA Legacy*, PRINCETON U.: OFF. TECH. ASSESSMENT, https://www.princeton.edu/~ota/ (last visited Oct. 31, 2020).

44. The Technology Assessment Act of 1972, Pub. L. No. 92-484, 86 Stat. 797 (codified as amended at 2 U.S.C. §§ 471–481).

45. *Technology Assessment and the Work of Congress*, PRINCETON U.: OFF. TECH. ASSESSMENT, https://www.princeton.edu/~ota/ns20/cong_f.html (last visited Oct. 17, 2020). The Government Accountability Office evaluated ongoing government programs, and the Congressional Research Service provided rapid but more superficial information on legislative topics. *Id.*

46. *See The Assessment Process*, OFF. TECH. ASSESSMENT ARCHIVE [hereinafter *The Assessment Process*, OTA], https://ota.fas.org/technology_assessment_and_congress/theassessmentprocess/ (last visited Oct. 31, 2020).

47. *Id.*

48. *Id.*

49. *Id.*

avoid duplicative efforts.[50] The OTA consisted of two main divisions: (1) the Industry, Commerce, and International Security Division and (2) the Health, Education, and Environment Division.[51] The former division investigated technologies in energy resources, transportation, infrastructure, computing technologies, national defense, and space technologies.[52] The latter division researched various health-related technologies and policy issues implicating technology, such as health care, renewable resources, pollution mitigation and prevention, hazardous waste management, biotechnology, genetics, and drug abuse prevention.[53]

The OTA instituted a formal assessment process that was intended to produce comprehensive technology assessment research in one-to-two years.[54] The process initiated when a congressional committee, the TAB, or the OTA Director submitted a formal assessment request.[55] Next, the OTA determined whether sufficient resources and information existed to effectively conduct an assessment.[56] The OTA Director then submitted a study proposal to the TAB, which rendered the final decision to proceed on a particular technology assessment.[57] During the study period, OTA researchers collected and analyzed data, consulted two or three times with an advisory council, compiled the data into a draft final report, and sent the draft to the OTA Director and TAB for approval.[58] Once approved, the OTA released the full technology assessment report to Congress and the public.[59] Congress took policy action based on the report findings.[60]

50. *Id.*
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*

The OTA existed for twenty-three years until Congress dismantled the agency in 1995 due to congressional downsizing.[61] Over the years, Congress systematically cut the agency's budget,[62] and the agency became susceptible to partisan politics.[63] Critics of the OTA claimed the agency prioritized research according to specific congressional member preferences and produced results that would support specific political positions.[64] The TAB, providing agency oversight, consisted of equal numbers of Republicans and Democrats, which made the OTA vulnerable to partisan gridlock that at times overpowered the agency's intended focus on technology assessment.[65] Despite the OTA's political drawbacks, the agency evolved into a nonpartisan force,[66] and other countries aspired to create a similar agency.[67] Ultimately, it appears the political ties of the OTA officials were the issue,[68] rather than the idea that technology assessment could provide "expert and unbiased advice before [Congress] approve[d] programs that call[ed] for spending millions of dollars for technological advances that may have unknown side effects."[69]

As the modern Congress increasingly recognizes the need for government technology assessment to adequately legislate on advancing technology impacting health and safety in the twenty-first century, some proponents of the OTA are now attempting to revive it.[70] The 2017 State of Congress Report demonstrates that Congress currently does not have the

61. *The OTA Legacy*, *supra* note 43; Tudor & Warner, *supra* note 39.

62. *See* Colin Norman, *O.T.A. Caught in Partisan Crossfire*, TECH. REV. (Oct.–Nov. 1977), https://ota.fas.org/technology_assessment_and_congress/norman/; M. Granger Morgan, *Death by Congressional Ignorance*, PITTSBURGH POST-GAZETTE, Aug. 2, 1995, at A-11.

63. Norman, *supra* note 62.

64. *See id.*

65. *Id.*

66. Barton Reppert, *OTA Emerges as Nonpartisan Player*, WASH. POST, Jan. 5, 1988, at A17.

67. David Burnham, *Little-Known Agency Draws Worldwide Interest*, N.Y. TIMES, Jan. 12, 1984, at B10.

68. *See* sources cited *supra* note 62.

69. *The Debate Over Assessing Technology*, BUS. WEEK (Apr. 8, 1972) [hereinafter *TA Debate*], https://ota.fas.org/technology_assessment_and_congress/businessweek/.

70. Tudor & Warner, *supra* note 39.

institutional capacity and resources to sufficiently understand and develop legislation and policy addressing complex technical subjects. Senior congressional staffers reported that "Senators and Representatives lack the necessary time and resources to understand, consider and deliberate public policy and legislation."[71] Sixty-seven percent of senior staffers said it was very important for the effective functioning of their chamber that members have adequate time and resources to understand, consider, and deliberate policy and legislation, but only 6% said they were satisfied with their chamber's performance in this area.[72]

Since the State of Congress Report was published in 2017, various committees and members of Congress have advocated to reinstate the OTA. On July 25, 2019, the House Select Committee on the Modernization of Congress unanimously recommended "[r]eestablishing and restructuring an improved Office of Technology Assessment."[73] On September 19, 2019, bills were introduced in both the House and the Senate for a new and improved version of the OTA.[74] On November 14, 2019, a congressional report on science and technology policy assessment conducted by the National Academy of Public Administration recommended enhancing existing congressional entities and creating an Office of the Congressional Science and Technology Advisor.[75] On

71. KATHY GOLDSCHMIDT, CONG. MGMT. FOUND., STATE OF THE CONGRESS: STAFF PERSPECTIVES ON INSTITUTIONAL CAPACITY IN THE HOUSE AND SENATE 6 (2017), http://congressfoundation.org/storage/documents/CMF_Pubs/cmf-state-of-the-congress.pdf.

72. *Id.* at 9.

73. *Select Committee Unanimously Approves Second Round of Congressional Recommendations*, SELECT COMM. ON MODERNIZATION CONG. (July 25, 2019), https://modernizecongress.house.gov/news/press-releases/select-committee-unanimously-approves-second-round-congressional-recommendations.

74. *See* Office of Technology Assessment Improvement and Enhancement Act, H.R. 4426/S.2509, 116th Cong. (2019). The bills have been referred to and currently remain with the House Committee on House Administration and Senate Committee on Rules and Administration, respectively.

75. ELIZABETH FRETWELL, DAVID REJESKI, JAMES HENDLER, KATHLEEN PEROFF & MICHAEL MCCORD, NAT'L ACAD. OF PUB. ADMIN., SCIENCE AND TECHNOLOGY POLICY ASSESSMENT: A CONGRESSIONALLY DIRECTED REVIEW 51 (Oct. 31, 2019), https://www.napawash.org/uploads

December 5, 2019, the House Committee on Science, Space, and Technology invited experts to weigh in on improving science and technology advice for Congress, noting that since the OTA has been disbanded, Congress has had difficulty addressing evolving scientific and technological issues.[76] These proposals demonstrate that our leaders need technology assessment in order to regulate effectively. Although the OTA does not currently exist in the federal legislature, various federal executive agencies have developed similar technology assessment activities since the agency's closing that show potential for a federal executive agency to house a revived OTA.

2. *Current technology assessment activities*

Several federal agencies currently conduct technology assessment activities, including the Food and Drug Administration (FDA) and the Consumer Products Safety Commission (CPSC). Together, these two agencies regulate the safety of numerous consumer products, including the products discussed in Part II. Because tobacco, lead paint, opioids, and e-cigarettes are regulated by either the FDA or CPSC, this section is limited to a discussion of the technology assessment activities within these two agencies specifically. The FDA's and CPSC's technology assessment activities serve similar public health functions as public nuisance lawsuits; however, these activities are limited in scope and do not provide a complete solution to preventively address long-term health and safety concerns of consumer products.

a. Food and Drug Administration

The FDA ensures the safety, efficacy, and security of drugs, biological products, medical devices, food, cosmetics, and

/Academy_Studies/NAPA_FinalReport_forCRS_110119.pdf (failing to explore executive agencies as an option).

76. *Experts Needed: Options for Improved Science and Technology Advice for Congress: Hearing Before the H. Comm. on Sci., Space, & Tech.*, 116th Cong. (2019) (opening statement of Sen. Eddie Bernice, Chairwoman, H.R. Comm. on Sci., Space & Tech.).

tobacco products.[77] One way the Agency advances public health is by "helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get accurate, science-based information they need to use . . .products."[78] However, the FDA's safety and innovation goals are not cheap. In 2019, the Agency's operations, including its technology assessment activities, cost $5.7 billion, with $3.1 billion (55%) funded by federal appropriations and $2.6 billion (45%) funded by industry-paid user fees.[79]

The FDA's innovation and safety goals incorporate technology assessment into the Agency's regular activities. Technology assessment inherently resides in the FDA pre-market approval process[80] and in post-market pharmacovigilance activities.[81] The FDA only approves drugs and devices for marketing if clinical data demonstrates the product is "safe and effective" for its intended uses, with some exceptions.[82] However, a significant limitation of premarket clinical trials is that they are relatively short in duration and therefore only collect short-term product safety data.[83] Once the

77. *What We Do*, U.S. FOOD & DRUG ADMIN. [hereinafter *What FDA Does*], https://www.fda.gov/about-fda/what-we-do (Mar. 28, 2018); *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (Aug. 3, 2020).

78. *What FDA Does*, *supra* note 77.

79. U.S. FOOD & DRUG ADMIN., FDA AT A GLANCE (2019) [hereinafter FDA AT A GLANCE], https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance.

80. *Development & Approval Process: Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs (Oct. 28, 2019).

81. KIM SWANK, U.S. FOOD & DRUG ADMIN., FDA DRUG TOPICS: AN OVERVIEW OF PHARMACOVIGILANCE IN THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) 13 (2019), https://www.fda.gov/media/122835/download. Pharmacovigilance is "[t]he science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems." *Id.* at 8.

82. *Is It Really 'FDA Approved?'*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (Jan. 17, 2017). Moderate- or low-risk medical devices may be exempt from the premarketing approval process entirely, or may only be subject to a lower approval standard of demonstrating the product is "substantially equivalent" to an approved product on the market. *Id.* Similarly, tobacco products approved for marketing are not actually considered by the agency to be safe; approval merely indicates the tobacco product has complied with current regulations. *Id.*

83. SWANK, *supra* note 81, at 14.

FDA approves a product for marketing, the Agency requires companies to report adverse events or complaints associated with approved products for ongoing safety surveillance.[84]

The FDA has recently incorporated into its regulatory activities two new technology assessment programs, the National Evaluation System for health Technology (NEST) and the Emerging Technology Program (ETP). NEST is a publicly and privately funded[85] collaborative program that collects real-world evidence over the entire medical device product lifecycle to efficiently generate better evidence for medical device evaluation and regulatory decision-making.[86] The program's emphasis on real-world evidence for active surveillance of medical devices addresses several issues with previous product safety surveillance.[87] First, collection of real-world evidence identifies unanticipated device risks after devices have entered the market.[88] Second, active surveillance of device safety risks makes up for the difficulty in recruiting subjects for post-approval studies investigating long-term safety risks.[89] Finally, the current post-approval safety surveillance system relies on individuals to identify and report problems, relying on the unlikely chance that individuals will take affirmative steps to report their adverse experiences with a medical device.[90] While the NEST program is a step in the right direction, this program still exposes consumers to a potentially dangerous product in order for the FDA to further study the long-term safety and effectiveness of a medical device.

84. *CFSAN Adverse Event Reporting System (CAERS)*, U.S. FOOD & DRUG ADMIN. [hereinafter *CAERS*] https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers (July 29, 2020).

85. Rachael L. Fleurence & Jeffrey Shuren, *Advances in the Use of Real-World Evidence for Medical Devices: An Update from the National Evaluation System for Health Technology*, 106 CLINICAL PHARMACOLOGY & THERAPEUTICS 30, 31 (2019).

86. *National Evaluation System for Health Technology (NEST)*, U.S. FOOD & DRUG ADMIN. [hereinafter *FDA Nest*], https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest (Oct. 29, 2019).

87. Fleurence & Shuren, *supra* note 85, at 32.

88. *Id.*

89. *Id.*

90. *Id.*

Finally, the ETP is an FDA-funded program that allows pharmaceutical companies using innovative or novel technologies to consult with the FDA about compliance concerns surrounding the new technologies.[91] The ultimate goal of the ETP is to "encourage the adoption of innovative approaches . . . involving novel technologies likely to improve product quality and availability throughout a product's lifecycle."[92] The ETP is primarily concerned with new manufacturing technologies for drugs and biologics, such as new technologies that affect the testing, packaging, labeling, and quality assurance of drugs and biologics.[93] The FDA initiated the ETP, in part, to address the inherent risks of new technology, which include a lack of experiential use and limited knowledge of the technology's effects on health.[94] Thus, through the ETP, NEST collaborative, and routine activities, technology assessment is a central tenet weaved throughout the FDA's history and operation; moreover, the FDA is not the only federal agency to rely on technology assessment to advance consumer safety.

b. Consumer Product Safety Commission

The CPSC is an independent federal regulatory agency, formed in 1972, charged with "protect[ing] the public against unreasonable risks of injury or death from consumer products through education, safety standards activities, regulation, and enforcement."[95] The CPSC regulates thousands of products from laboratory chemicals to children's toys to cigarette lighters

91. CTR. FOR DRUG EVALUATION & RSCH., U.S. FOOD & DRUG ADMIN., 2483881 FNL, ADVANCEMENT OF EMERGING TECHNOLOGY APPLICATIONS FOR PHARMACEUTICAL INNOVATION & MODERNIZATION: GUIDANCE FOR INDUSTRY 3 (2017).

92. *Id.*

93. *Id.* at 1 n.4.

94. *See id.* at 3.

95. *Contact/FAQ*, U.S. CONSUMER PROD. SAFETY COMM'N [hereinafter *CPSC FAQs*], https://www.cpsc.gov/About-CPSC/Contact-Information (last visited Dec. 15, 2020). Compare the mission of the CPSC to the Restatement (Second) of Torts which defines public nuisance as "an unreasonable interference with a right common to the general public." RESTATEMENT (SECOND) OF TORTS § 821(B) (AM. L. INST. 1965).

to mattresses to garage doors.[96] Although the Agency has broad jurisdiction over a wide variety of products, the CPSC generally lacks legal authority to certify products for safety before they are sold to consumers,[97] with only a few exceptions.[98] Therefore, the CPSC primarily resorts to technology assessment to develop voluntary industry safety standards to meet its preventive health goals.[99]

One way the CPSC fulfills its mission to protect consumers from unreasonable injury or death is by researching potentially hazardous consumer products.[100] In 2017, the CPSC published a report about recently developed products that present new or increased hazards for consumers.[101] The report identified ten emerging technologies that posed six potential consumer hazards worth considering in future Agency activities.[102] The emerging technologies included 3D printers and their printed products,[103] internet-home based smart technologies,[104] software as a component part,[105] wearable products and

96. *Regulations, Mandatory Standards and Bans*, U.S. CONSUMER PROD. SAFETY COMM'N [hereinafter *CPSC Standards*], https://www.cpsc.gov/Regulations-Laws--Standards/Regulations-Mandatory-Standards-Bans (last visited Dec. 15, 2020).

97. *CPSC FAQs*, *supra* note 95.

98. *See Rules Requiring a General Certificate of Conformity (GCC)*, U.S. CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-a-General-Certificate-of-Conformity (Nov. 28, 2014).

99. *Voluntary Standards*, U.S. CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Regulations-Laws--Standards/Voluntary-Standards (last visited Dec. 15, 2020).

100. *CPSC FAQs*, *supra* note 95.

101. U.S. CONSUMER PROD. SAFETY COMM'N, STAFF REPORT: POTENTIAL HAZARDS ASSOCIATED WITH EMERGING AND FUTURE TECHNOLOGIES, at Executive Summary (2017) [hereinafter CPSC POTENTIAL HAZARDS REPORT], https://www.cpsc.gov/About-CPSC/Agency-Reports.

102. *Id.* The six potential consumer hazards are loss of safety functions; fires and burns; shocks; chemical exposure; laceration, contusion, trauma, crush, impact, and/or amputation; and choking, strangulation, and/or asphyxiation. *Id.* at 15–16.

103. *Id.* at 3.

104. *Id.* at 4–5 (such as thermostats, light fixtures, security systems, and home appliances with internet capabilities).

105. *Id.* at 6 (such as watches, phones, cars, robots, or drones that require embedded software to operate).

technologies,[106] new materials such as nanomaterials,[107] virtual reality and augmented reality games,[108] personal transportation products,[109] high capacity energy storage and energy generation,[110] robotics, including robotic products to assist older adults,[111] and brain-machine interface/implantable technologies.[112] The report recommended that the CPSC consider these new technologies in further consumer risk assessment and management.[113] The report indicates the CPSC's initial response to the listed hazards will be to collaborate with consumers, industries, and federal stakeholders to implement voluntary safety standards to reduce consumer risks.[114] The report indicates that acquiring new skills and expertise, collaborating with stakeholders, and soliciting public opinion will be valuable to understanding and preventing hazardous technology from reaching consumers.[115]

After the release of this report, CPSC integrated technology assessment into its 2018–2022 strategic plan.[116] CPSC identified its second most important objective as preventing hazardous products from reaching consumers.[117] The Commission plans to prevent hazardous products from reaching consumers by

106. *Id.* at 6–7 (such as devices or objects that are directly or indirectly connected to the body to improve muscle power, increase fine motor skills, or conduct real-time data processing related to the body, e.g., smart watches, GPS trackers, and sweat sensors).

107. *Id.* at 7–10 (such as the new materials developed for "computer technology, diagnostics, chemistry, materials science, and other related fields").

108. *Id.* at 10–11.

109. *Id.* at 11–13 (such as hoverboards, electric scooters, and electric skateboards).

110. *Id.* at 14–15.

111. *Id.* at 13.

112. *Id.* at 15.

113. *Id.* at Executive Summary.

114. *Id.* at 1.

115. *Id.* at 16.

116. U.S. CONSUMER PROD. SAFETY COMM'N, STRATEGIC PLAN 2018–2022, at 5 [hereinafter CPSC STRATEGIC PLAN], https://www.cpsc.gov/s3fs-public/CPSC_2018-2022_Strategic_Plan.pdf.

117. *Id.* The CSPC recognized increasing manufacture of safe products combined with improving hazard identification before products enter the market as "the most effective way[] to prevent hazardous products from reaching consumers." *Id.* at 20.

"[i]mprov[ing] identification and assessment of hazards to consumers."[118] The plan notes the enormity of this task:

> Determining when a consumer product is hazardous to consumers depends on a critical analysis of data at a sufficient level of detail to characterize the risk and the severity of the injury associated with the hazard. An enormous quantity of hazard-related data from multiple sources must be processed and analyzed systematically to identify quickly patterns and trends.[119]

The Agency indicated one of its goals was to increase its capacity to examine hazard data, improve the quality of such data, and improve its ability to identify and assess new and chronic hazards.[120] These preventive efforts have proven expensive, with $81.5 million of the Agency's entire $127 million budget going to the Commission's efforts to prevent hazardous products from reaching consumers in 2019.[121]

Despite the FDA's and CPSC's efforts to integrate and use technology assessment to prevent unreasonable interferences with public health, latently dangerous consumer products continue to enter the market and harm the public.[122]

C. *United States Patent and Trademark Office*

This Note proposes that the FDA and CPSC technology assessment activities can contribute to a larger technology assessment regulatory scheme housed within the USPTO.[123] The USPTO is the federal agency that fulfills the Intellectual Property Clause of the Constitution, which provides that

118. *Id.* at 22.

119. *Id.*

120. *Id.*

121. U.S. CONSUMER PROD. SAFETY COMM'N, AGENCY FINANCIAL REPORT: FISCAL YEAR 2019, at 3 (2019), https://www.cpsc.gov/s3fs-public/FY2019CPSCAgencyFinancialReport.pdf.

122. *See infra* Part II.

123. *See infra* Part III.

Congress shall have the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[124] The USPTO fulfills the Intellectual Property Clause in part by granting patents.[125] Part of the agency's role is to advise the federal executive and legislative branches on matters related to intellectual property.[126] Nearly 75% of the 11,000 or so employees at the agency possess technical or legal training.[127]

The USPTO grants patents through an application process[128] that establishes patent rights for the first person who files a satisfactory patent application.[129] There are three types of patent applications[130] that together allow for the patenting of "practically everything that is made by man and the processes for making the products."[131] Patent applications must demonstrate that the invention is patentable, meaning the

124. U.S. CONST. art. I, § 8, cl. 8.

125. *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. [hereinafter *USPTO Patent Info*], https://www.uspto.gov/patents-getting-started/general-information-concerning-patents (June 1, 2020, 12:04 PM); *United States Patent and Trademark Office*, ALLGOV.COM, http://www.allgov.com/departments/department-of-commerce/united-states-patent-and-trademark-office?agencyid=7143 (last visited Jan. 3, 2021). A patent is defined as an exclusive property right that prevents all but the patent holder from making, using, selling, or offering to sell a particular invention without the patent owner's permission. *Id.*

126. *About Us*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/about-us (Dec. 9, 2020, 5:25 PM).

127. *USPTO Patent Info*, *supra* note 125.

128. *Id.* In general, the patent application process proceeds as follows: (1) applications are submitted and sent to a Technology Center with jurisdiction over the assigned field of technology; (2) the Technology Center's group of directors, examiners, and support staff review the application; (3) patent examiners at the Technology Center render a determination of whether a patent should be granted. *Id.*

129. Leahy-Smith America Invents Act § 3(a), 35 U.S.C. § 100(i)(1)(A)-(B).

130. *USPTO Patent Info*, *supra* note 125. Utility patents are granted for inventions or discoveries of "any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof." *Id.* Design patents are granted for a "new, original, and ornamental design for an article of manufacture." *Id.* Plant patents are granted for the "invent[ion] or discover[y] and asexual[] reproduc[tion] [of] any distinct and new variety of plant." *Id.*

131. *Id.*

invention is (1) useful,[132] (2) novel,[133] and (3) non-obvious.[134] The USPTO receives over 500,000 patent applications per year.[135] Once a patent is granted, the patent holder generally holds the patent for a term of twenty years.[136] The applicant pays user fees to apply for the patent,[137] and the patentee continues to pay fees to maintain the patent.[138] The USPTO operates solely on these user fees and does not rely on taxpayer dollars.[139] In 2019, the USPTO collected approximately $3.4 billion in user fees.[140] Given its structure and expertise, the USPTO is an ideal agency to implement comprehensive technology assessment activities that can change the trajectory of recent public health epidemics in American history.

II. THE PROBLEM: AN EPIDEMIC CYCLE OF PUBLIC NUISANCE PRODUCTS

Despite past and present technology assessment efforts, several consumer products have plagued American history as public health crises. The tobacco, lead paint, prescription opioids, and e-cigarette epidemics[141] follow a similar cyclical

132. *Id.* An invention is "useful" if it provides a benefit to the public. *See id.*

133. *Id.* An invention is "novel" if it is not available to the public before the effective filing date, or not previously claimed by another inventor in another patent or application. 35 U.S.C. § 102(a).

134. *USPTO Patent Info*, *supra* note 125. An invention is "non-obvious" if the subject matter sought to be patented is sufficiently different from what has been used or described before such that it would not be obvious "to a person having ordinary skill" in the area of technology related to the invention. 35 U.S.C. § 103.

135. *USPTO Patent Info*, *supra* note 125.

136. 35 U.S.C. § 154(a)(2).

137. *USPTO Patent Info*, *supra* note 125.

138. § 154(a)(2).

139. GLENN J. MCLOUGHLIN, CONG. RSCH. SERV., RS20906, U.S. PATENT AND TRADEMARK OFFICE APPROPRIATIONS PROCESS: A BRIEF EXPLANATION 4 (2014) (quoting Letter from Am. Intell. Prop. L. Ass'n, to The Hon. Sylvia Mathews Burwell, Dir., Off. of Mgmt. & Budget (May 21, 2013)).

140. U.S. PAT. & TRADEMARK OFF., FISCAL YEAR 2021 CONGRESSIONAL JUSTIFICATION 25 (2020) [hereinafter USPTO BUDGET 2021], https://www.uspto.gov/sites/default/files/documents/fy21pbr.pdf.

141. The CDC defines an epidemic as "the occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a particular period. Usually, the cases are presumed to have a common cause or to be

pattern that consistently ends with government officials filing a public nuisance lawsuit against product manufacturers after thousands to millions of Americans have been injured. The epidemic cycle of public nuisance products fails public health because society ultimately relies on a last resort, resource-intensive, and backward-looking intervention that is incompatible with the basic public health principle of prevention.

A. *The Cycle*

The tobacco, lead paint, opioid, and e-cigarette epidemics share a similar cyclical pattern. Each of the applicable industries has marketed products with unassessed long-term safety risks, combatted or discredited emerging evidence of harm associated with the product, evaded liability in personal injury or products liability lawsuits, and finally accepted responsibility only when government officials have filed public nuisance lawsuits.[142] This Section identifies six distinct phases in the epidemic cycle of public nuisance products by examining the common characteristics and facts of the tobacco, lead paint, opioid, and e-cigarette epidemics.

First, industry markets a new product for which little is initially known about its long-term safety or health implications. Tobacco companies sold cigarettes in the United States beginning in the late 1850s, but cigarettes peaked in popularity through the First and Second World Wars.[143] Prior to the 1850s, people generally recognized that tobacco users suffered "scorched lungs," addiction, and nose cancer;

related to one another in some way." *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/csels/dsepd/ss1978/glossary.html (July 2, 2014). The World Health Organization defines an epidemic as "[t]he occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy." *Glossary of Humanitarian Terms*, WORLD HEALTH ORG., https://www.who.int/hac/about/definitions/en (last visited Jan. 3, 2021).

142. *See supra* notes 11–16 and accompanying text.

143. *History of Tobacco*, *supra* note 11.

however, American doctors only began to definitively link tobacco use to lung cancer after World War I.[144] Similarly, companies added lead compounds to household paints in the late 1800s to improve paint durability.[145] At least 70% of homes built before 1940 used lead paint,[146] but research started to link lead with negative bodily effects in the early 1900s.[147] Opioids reemerged as a popular pain treatment method during the 1990s when major pharmaceutical companies, such as Purdue Pharma, aggressively advertised that opioids presented minimal addiction risks.[148] Before that, doctors generally refrained from prescribing opioids because of their observed addictive nature.[149] Most recently, e-cigarettes entered the U.S. market in 2007 without any prior evidence about the long-term effects of inhaling vaporized nicotine.[150]

Second, widespread harm emerges as the public continues to use the product despite early signs the product could be dangerous to health. For example, lung cancer rates in smokers increased twenty-fold from 1914 to 1950,[151] while adult cigarette

144. *Id.*

145. *See This Lead Is Killing Us: A History of Citizens Fighting Lead Poisoning in Their Communities*, NAT'L INSTS. HEALTH: NAT'L LIBR. MED. [hereinafter *This Lead Is Killing Us*], https://www.nlm.nih.gov/exhibition/thisleadiskillingus/index.html (Dec. 13, 2019); Rabin, *supra* note 11 ("It is well known that the major source of [child lead] poisoning[] is the lead paint applied to homes 40, 50, and 100 years ago.").

146. *See* WESTAT, REPORT ON THE NATIONAL SURVEY OF LEAD-BASED PAINT IN HOUSING 1–2 (1995), https://www.epa.gov/sites/production/files/documents/r95-003.pdf.

147. Rabin, *supra* note 11 ("As early as 1904 . . . a physician . . . concluded that lead paint in the home was responsible for lead poisoning in children.").

148. *See* Patrick Radden Keefe, *The Sackler Family's Plan to Keep Its Billions*, NEW YORKER (Oct. 4, 2020), https://www.newyorker.com/news/news-desk/the-sackler-familys-plan-to-keep-its-billions.

149. Purcell, *supra* note 11, at 139 ("Opioids became increasingly unpopular as legitimately prescribed pain relievers within the medical standard of care until the late 1970s and the early 1980s, when a string of studies published in newspapers and medical journals attempted to undercut the notion that opioids are addictive.").

150. *Adult Smoking Cessation—The Use of E-Cigarettes*, *Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html (Jan. 23, 2020); *see also* Caitlin O. Bradley, *Legal Challenges to FDA's Deeming Rule as Regulation Looms Large on Vaping Industry*, BENDER'S HEALTH CARE L. MONTHLY, Mar. 2018.

151. Rustad & Koenig, *supra* note 12, at 356–57.

consumption continued to rise significantly until 1964.[152] Doctors recognized child lead poisoning as a common childhood disease by the 1920s when society commonly used lead paint for interior residential use.[153] Prescriptions for opioids, as well as opioid-related abuse, overdose, and death, increased between 1999 and 2010[154] due in major part to aggressive industry marketing.[155] Thousands of vaping-related lung injuries and deaths occurred beginning in 2019, just twelve years after e-cigarettes entered the U.S. market and just two years after the federal government declared youth vaping a public health epidemic.[156] However, research on the long-term health effects of e-cigarettes is still underway.[157]

Third, industry combats or discredits concerns about the product's adverse health effects until the federal government asserts the product is harmful to health. For example, as research linking tobacco use and cancer emerged in the 1950s,[158] the tobacco industry marketed modified cigarettes as "safer" alternatives to traditional cigarettes, lobbied Congress for favorable regulation, and funded the Tobacco Institute to produce research that conflicted with credible claims about the adverse health effects of cigarette smoking.[159] Smoking trends

152. *U.S. Tobacco Use 1900–1999*, *supra* note 1.

153. *This Lead Is Killing Us*, *supra* note 145; *see also* Rabin, *supra* note 11, at 1668–71.

154. *See* Purcell, *supra* note 11, at 140–42; Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365, 1365–66 (2016); Sarah Deweerdt, *The Natural History of an Epidemic*, NATURE, Sept. 2019, at S10–11.

155. *See* Purcell, *supra* note 11, at 139–41; *see also* Meldrum, *supra* note 154, at 1366; Deweerdt, *supra* note 154, at S11.

156. *See* Bradley, *supra* note 150; *see also* Bailey King, *First U.S. Death Caused by Vaping Confirmed in Illinois*, PHILLYVOICE (Aug. 26, 2019), https://www.phillyvoice.com/vaping-death-e-cigarettes-illinois/; Ned Sharpless, *How FDA is Regulating E-Cigarettes*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes (Sept. 10, 2019); *Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping, Products*, *Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION [hereinafter *CDC Vaping Lung Injuries*], https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information (Feb. 25, 2020, 1:00 PM).

157. Sharpless, *supra* note 156.

158. *U.S. Tobacco Use 1900–1999*, *supra* note 1.

159. Luff, *supra* note 13, at 135–36.

did not decrease until after the 1964 Surgeon General's report definitively concluded smoking causes lung cancer.[160] Next, as child lead poisoning research developed from 1900 to 1950, lead paint companies combatted the significance of child lead poisoning with unsupported claims that few children were affected and continued to develop ads and promotions implying lead paint was safe for indoor residential use.[161] Companies did not completely quit selling lead paint until Congress banned the product in 1978.[162] Then, as national prescription opioid overdose deaths reached over 10,000 by 2005,[163] the pharmaceutical industry fraudulently discredited evidence of the addictive qualities of opioids by overemphasizing questionable research minimizing addiction risks and marketing aggressively to doctors and consumers.[164] President Donald Trump declared the opioid crisis a public health emergency in 2017,[165] but the effect of declaring a public health emergency on pharmaceutical companies' marketing tactics is unknown. Most recently, as youth vaping visibly increased between 2007 and 2018, e-cigarette companies targeted youth in marketing, promoted e-cigarettes as healthy and safe alternatives to traditional cigarettes, and failed to

160. *History of Tobacco*, *supra* note 11; *History of the Surgeon General's Reports on Smoking and Health, supra* note 1.

161. *See* Rabin, *supra* note 11, at 1671; *see also This Lead Is Killing Us*, *supra* note 145; Teresa Wiltz, *HUD Spends Millions on Lead Abatement. Why are Public Housing Authorities Still Struggling?*, PEW (Dec. 17, 2019), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/12/17/hud-spends-millions-on-lead-abatement-why-are-public-housing-authorities-still-struggling; Tik Root, *These Companies Created a Lead Paint Crisis—and Refuse To Clean It Up*, MOTHER JONES (Mar./Apr. 2018), https://www.motherjones.com/environment/2018/03/lead-paint-toxic-lawsuit-california-house-fidelma-ftizpatrick/.

162. *See* Rabin, *supra* note 11, at 1673; *see also This Lead is Killing Us*, *supra* note 145; Wiltz, *supra* note 161; Wiley, *supra* note 16, at 243; Root, *supra* note 161.

163. *Overdose Death Rates*, NAT'L INSTS. HEALTH: NAT'L INST. ON DRUG ABUSE fig.4 (Mar. 10, 2020), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

164. *See* Purcell, *supra* note 11, at 139; Meldrum, *supra* note 154; Deweerdt, *supra* note 154, at S10–12.

165. *President Donald J. Trump Is Combatting the Opioid Crisis*, THE WHITE HOUSE: HEALTHCARE (Mar. 1, 2018), https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-combatting-opioid-crisis/.

verify buyer ages.[166] In 2018, the FDA instituted "the largest enforcement effort in the agency's history" against e-cigarette retailers.[167] Similar to the opioid epidemic, the effects of this recent action by the FDA remain to be seen.

In the fourth part of the cycle, individuals injured by the products file products liability or personal injury claims that often fail or are difficult to successfully establish. In the first and second waves of tobacco litigation from the 1950s to the 1990s, plaintiffs often lost personal injury and products liability claims because industry launched aggressive victim-blaming defenses that identified jurors' beliefs that individuals assume responsibility for health choices.[168] Plaintiffs in lead paint litigation in the 1980s and 1990s generally failed to establish causation because their lead poisoning symptoms were difficult to trace to a particular paint product;[169] some products liability claims failed simply because the statute of limitations had passed.[170] Beginning in the first decade of the twenty-first century, opioid overdose victims initiated personal injury, deceptive marketing, and fraud litigation that largely failed because the chain of causation was broken by the prescriber's or victim's actions.[171] Parents, on behalf of youth experiencing injury, illness, or nicotine addiction linked to vaping, have filed individual and class-action lawsuits against Juul Labs that were combined into a mass litigation action in October 2019, but matters are still pending before the courts.[172]

166. Wendy E. Parmet, *Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes*, 70 U. MIAMI L. REV. 879, 924–26 (2016); Sharpless, *supra* note 156; *FDA Warns JUUL Labs for Marketing Unauthorized Modified Risk Tobacco Products, Including in Outreach to Youth*, U.S. FOOD & DRUG ADMIN. (Sept. 9, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth.

167. Sharpless, *supra* note 156.

168. Rustad & Koenig, *supra* note 12, at 357–58; *see also* Luff, *supra* note 13, at 142–49.

169. Wiley, *supra* note 16, at 243–44.

170. Schwartz & Goldberg, *supra* note 15, at 557–58.

171. Purcell, *supra* note 11, at 159–64.

172. *See* Emily Field, *JPML Sends Juul Marketing Suits to Calif.*, LAW360 (Oct. 2, 2019, 5:23 PM), https://www.law360.com/articles/1205263/jpml-sends-juul-marketing-suits-to-calif-.

In the fifth step of the cycle, attorneys general file public nuisance claims to abate the public health epidemic linked to the specific product. Between 1994 and 1998, every state in the United States had filed a public nuisance action against the largest tobacco companies to recover state-incurred medical costs for treating tobacco-related illnesses and diseases.[173] Following this initiative, beginning in the late 1990s and still ongoing today, various states and cities filed public nuisance actions against lead paint manufacturers to recover costs for lead paint abatement and removal.[174] Similarly, in 2012, attorneys general filed the first public nuisance actions against opioid manufacturers.[175] States, cities, and school districts filed the first public nuisance actions against e-cigarette manufacturers in 2019 to abate the youth vaping epidemic.[176]

Finally, when public nuisance litigation concludes for one epidemic, another product emerges as the next threat to public health, thereby catalyzing the next iteration of the epidemic cycle. Cigarette use in the United States started in the late 1840s,[177] lung cancer reached epidemic proportions by 1964,[178] and tobacco public nuisance litigation commenced in 1994.[179] Lead paint became popular in the nineteenth century,[180] child

173. Rustad & Koenig, *supra* note 12, at 358–59; *see also* Luff, *supra* note 13, at 155–58; Rutkow & Teret, *supra* note 32, at 281.

174. Wiley, *supra* note 16, at 244.

175. Purcell, *supra* note 11, at 159–65.

176. *See* Verena Dobnik, *New York Joins States Suing E-cigarette Maker Juul*, AP NEWS (Nov. 19, 2019), https://apnews.com/c7817694fdb34156bb6e39c419825800; Tiffany Kary & Jef Feeley, *Juul Accused by School Districts of Creating Vaping 'Nuisance'*, BLOOMBERG, https://www.bloomberg.com/news/articles/2019-10-07/juul-accused-by-school-districts-of-creating-vaping-nuisance (Oct. 8, 2019. 11:15 AM); Ray Sanchez, *NYC Files Federal Lawsuit Accusing 22 Online Sellers of Targeting Young with Flavored E-cigarettes*, CNN, https://www.cnn.com/2019/10/09/health/new-york-city-e-cigarette-website-lawsuit/index.html (Oct. 9, 2019, 5:09 PM).

177. *History of Tobacco*, *supra* note 11.

178. *U.S. Tobacco Use 1900–1999*, *supra* note 1.

179. Luff, *supra* note 13, at 154–58.

180. Leif Fredrickson, *The Surprising Link Between Postwar Suburban Development and Today's Inner-City Lead Poisoning*, GOV. TECH. (Feb. 26, 2016), https://www.govtech.com/fs/infrastructure/The-Surprising-Link-Between-Postwar-Suburban-Development-and-Todays-Inner-City-Lead-Poisoning.html.

lead poisoning reached epidemic proportions in 1995,[181] and lead paint public nuisance litigation started in the late 1990s and early 2000s.[182] Companies popularized opioids in the 1990s,[183] opioid addiction reached epidemic proportions in the late 2010s,[184] and opioids public nuisance litigation initiated in 2012.[185] "E-cigarettes entered the U.S. marketplace around 2007,"[186] youth use reached epidemic proportions in 2018,[187] and public nuisance litigation commenced in 2019.[188] Notice the waterfall effect in how each epidemic overlaps with the next. The country was well into the tobacco and lead poisoning epidemics by the time attorneys general initiated public nuisance litigation. Opioid use dramatically increased while attorneys general sorted out the tobacco and lead paint litigation. Then, youth vaping rapidly progressed while attorneys general focused their public nuisance claims on opioid manufacturers. Comparing each iteration of the cycle reveals the country was deep into the next public health crisis by the time attorneys general stepped in to litigate the preceding crisis.

B. *Lessons (Not) Learned*

There is a pattern, and it is a problem: without a more effective intervention, history is set to repeat itself again with a latent public nuisance product currently on the market. The epidemic cycle demonstrates that public nuisance lawsuits are a last resort, resource-intensive, and backward-looking intervention. Successful public nuisance litigation does serve

181. *See Data and Statistics, Childhood Lead Poisoning Prevention*, *supra* note 4.

182. *See* Schwartz & Goldberg, *supra* note 15, at 559.

183. *See* Purcell, *supra* note 11.

184. *See President Donald J. Trump Is Combatting the Opioid Crisis*, *supra* note 165; *What Is the U.S. Opioid Epidemic?*, *supra* note 7.

185. *See* Purcell, *supra* note 11, at 160.

186. *Smoking & Tobacco Use: Surgeon General's Advisory*, *supra* note 8.

187. *Id.*

188. *See* Dobnik, *supra* note 176.

public health by instituting a plan to abate the epidemics.[189] However, public nuisance litigation also harms public health by fueling a detrimental cycle that permits widespread harm before an impactful intervention takes place, drains resources away from more effective preventive measures, and reinforces a bad habit of relying on the government to step in at the eleventh hour.[190]

First and foremost, public nuisance is a last resort intervention that permits widespread injury or death before effective public health action is taken. In tobacco, lead paint, opioid, and e-cigarette litigation cycles, government officials filed public nuisance actions only after years of continuous harm and individual litigation.[191] In the fifty years following the 1964 Surgeon General's report on tobacco, nearly twenty million people died from smoking-related causes.[192] Today, at least 1.2 million children have lead poisoning.[193] Over 300,000 Americans have died of opioid overdose since 2000 when opioid use took off on its epidemic trajectory.[194] Roughly 3.6

189. *See, e.g.*, *Master Settlement Agreement*, PUB. HEALTH L. CTR., https://www.publichealthlawcenter.org/topics/commercial-tobacco-control/commercial-tobacco-control-litigation/master-settlement-agreement (last visited Oct. 20, 2020) (imposing sales and marketing restrictions on cigarette manufacturers and requiring manufacturers to pay $27.5 billion to states for smoking prevention efforts); *California Counties and Cities Announce Groundbreaking $305 Million Settlement of Landmark Lead Paint Litigation*, CNTY. SANTA CLARA, https://www.sccgov.org/sites/opa/newsroom/Pages/lead-paint-litigation-settlement.aspx (Aug. 9, 2019, 11:59 AM) (discussing municipality's plan to use settlement as lead paint abatement fund); Nate Raymond & Jonathan Stempel, *Oklahoma Judge Reduces Johnson & Johnson Opioid Payout to $465 Million*, REUTERS (Nov. 15, 2019, 3:12 PM), https://www.reuters.com/article/us-usa-opioids-litigation-oklahoma/oklahoma-judge-reduces-johnson-johnson-opioid-payout-to-465-million-idUSKBN1XP27F (explaining Oklahoma sought monetary damages from Johnson & Johnson "to help fund addiction treatment and other services to repair damage from the opioid epidemic").

190. *See supra* Section II.A (describing the cycle of these industries marketing products with unassessed long-term safety risks, discrediting evidence of harm associated with the products, evading liability in lawsuits, and finally accepting responsibility when government officials file public nuisance lawsuits).

191. *See supra* Section II.A.

192. Off. of the Surgeon Gen., *Health Consequences of Smoking, Surgeon General Fact Sheet*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/consequences-smoking-factsheet/index.html (Jan. 16, 2014).

193. Frostenson, *supra* note 5.

194. *See* Purcell, *supra* note 11, at 141.

million youth used e-cigarettes in 2020,[195] placing them all at risk of lung illness or death linked to vaping.[196] These current statistics demonstrate that, despite public nuisance lawsuits and settlements, millions of people still suffer harm from these products permitted to enter the market without appropriate and adequate long-term safety assessment.[197]

Second, the entire cycle emphasizes litigation, which is resource-intensive and drains time, money, and effort away from more effective preventive measures. For example, the team of lawyers representing the first few states to settle with tobacco companies received approximately $8 billion in attorney fees.[198] One lead paint lawsuit resulted in a $305 million settlement, [199] but that lawsuit only addresses the lead paint epidemic in ten cities and counties.[200] Lead paint abatement measures will cost billions of dollars for the millions of houses in the United States that still contain lead paint.[201] The first successful opioid public nuisance litigation resulted in a $465 million verdict in favor of the State of Oklahoma.[202] E-cigarette public nuisance litigation has not reached a verdict or settlement at the time of this Note, but the epidemic cycle indicates e-cigarette litigation will similarly produce a high payout.[203] These litigation costs do not even consider the costs incurred by individual products liability and personal injury lawsuits outside of public nuisance litigation. Investing such

195. *FDA National Youth Tobacco Survey*, *supra* note 9.

196. *See id.*; *CDC Vaping Lung Injuries*, *supra* note 156.

197. *See* Off. of the Surgeon Gen., *supra* note 192; Frostenson, *supra* note 5; Purcell, *supra* note 11 at 162–63; *FDA National Youth Tobacco Survey*, *supra* note 9.

198. Barry Meier, *Lawyers in Early Tobacco Suits to Get $8 Billion*, N.Y. TIMES (Dec. 12, 1998), https://www.nytimes.com/1998/12/12/us/lawyers-in-early-tobacco-suits-to-get-8-billion.html.

199. Press Release, James R. Williams, Cnty. Counsel, Cnty. of Santa Clara, California Counties and Cities Announce Groundbreaking $305 Million Settlement of Landmark Lead Paint Litigation (July 17, 2019), https://www.sccgov.org/sites/cco/leadpaint/.

200. *Id.*

201. Wiltz, *supra* note 161.

202. Sean Murphy & Ken Miller, *Oklahoma Judge Reduces J&J Order in Opioid Lawsuit by $107M*, AP NEWS (Nov. 15, 2019), https://apnews.com/article/f2ca0f4bb033450b8efe109312b4aa93#.

203. *See supra* Section II.A.

resources into front-end preventive efforts would ameliorate the exposure issue: injury and death rates will decrease if fewer consumers are exposed to a dangerous product. Preventive efforts address the dangers that would otherwise await future consumers inevitably exposed to a hazardous product the longer it remains on the market in its dangerous condition.

Third, public nuisance litigation at the end of the cycle imposes a backward-looking intervention that educates on industry wrongdoing but fails to meaningfully apply the lessons learned from preceding cycles. A prime example is society's failure to anticipate long-term safety effects of the electronic analog to combustible cigarettes.[204] The tobacco litigation of the 1990s revealed various tactics by which the tobacco industry misled consumers about the risks associated with tobacco consumption.[205] Now, government officials initiating public nuisance litigation against e-cigarette manufacturers accuse the companies of taking "a page from Big Tobacco's playbook."[206] Approximately ten years passed between the tobacco Master Settlement Agreement[207] and the entrance of e-cigarettes into the U.S. market.[208] In ten years, the government and the public could reflect on the similarity of electronic and combustible cigarettes to consider how the vaping industry might employ deceitful marketing tactics similar to the tobacco companies.[209] The tobacco industry's marketing tactics relied on a decades-long period when little public information existed on the long-term safety of combustible cigarettes.[210] Similar circumstances existed when e-cigarettes entered the market: society did not, and still does not,

204. *See, e.g.*, Dobnik, *supra* note 176.

205. *See* Luff, *supra* note 13, at 142–49; Rustad & Koenig, *supra* note 12, at 357–58.

206. Dobnik, *supra* note 176.

207. *Master Settlement Agreement*, *supra* note 189.

208. Parmet, *supra* note 166, at 936–37; Rutkow & Teret, *supra* note 32, at 281; Bradley, *supra* note 150.

209. *See* Parmet, *supra* note 166, at 934–37; Rutkow & Teret, *supra* note 32, at 281; Bradley, *supra* note 150.

210. *See History of Tobacco*, *supra* note 11.

know much about the long-term health effects of e-cigarettes.[211] Therefore, the government and the public could have drawn on these similarities to anticipate that e-cigarettes might also have negative long-term health consequences. Rather than apply the lessons learned from the tobacco public nuisance cycle to preventively investigate the safety of e-cigarettes and thereby decrease the severity of the youth vaping epidemic, the government merely looked back to the tobacco public nuisance cycle as a model theory of liability.

In sum, public nuisance is a regulatory intervention that comes too late in the epidemic cycle to have an effective impact on public health. Technology assessment presents a more promising solution.

III. A SOLUTION: REVIVE THE OTA IN THE USPTO

If public nuisance lawsuits are a last resort, resource-intensive, backward-looking approach, then the epidemic cycle of public nuisance products can be broken with a proactive, cost-effective, forward-looking intervention. This Note proposes one such intervention: to revive the OTA in the USPTO as a "Technology Assessment Division" (TAD) that conducts objective studies based on emerging technology trends analyzed in patent applications and other sources.[212] This proposed model fits into USPTO administration and integrates elements of the FDA and CPSC technology assessment activities.[213] A USPTO TAD presents a preventive public health measure to break the epidemic cycle of public nuisance products: early regulatory action can be asserted when fewer consumers have been exposed to a potentially dangerous product; industry dollars are cost effectively used to conduct early risk assessment rather than fund expensive, after-the-fact settlements to abate epidemic harms; and government

211. *See* Bradley, *supra* note 150.

212. *See infra* Section III.A.

213. *See infra* Section III.A.

regulators can create forward-looking preventive measures for emerging products without stifling innovation. Despite some potential drawbacks of this solution, this proposal should be adopted to better serve public health.

A. *Establishing a USPTO Technology Assessment Division*

The OTA model serves as a framework for how a TAD may operate, adapted to the USPTO patent application process and integrated with FDA and CPSC technology assessment activities. The TAD's technology assessment function might proceed as follows.

Generally, the TAD would conduct a one-to-two-year technology assessment study on potentially hazardous consumer products. The agency would conduct a study on its own accord or upon a formal public request when emerging technology trends reveal new or increased hazards to consumers.[214] Staff at the proposed agency would routinely monitor emerging technology trends through a combination of sources,[215] including patent applications sorted by subject matter.[216] The TAD would prioritize technology assessment study topics according to several considerations, including the number of patent applications submitted within a particular subject matter, the pervasiveness of the emerging technology in everyday life, and whether sufficient resources and information exist to effectively conduct an assessment.[217]

The proposed agency would operate similarly to the OTA and would be funded through the USPTO's $3.4 billion user fee budget, or a combination of user fees and government

214. *See The Assessment Process*, OTA, *supra* note 46; CPSC POTENTIAL HAZARDS REPORT, *supra* note 101.

215. This would include requests by other agencies, Congress, and interest groups suggesting areas for more research, social media and public information, adverse event reporting from other agencies that monitor product safety, and consumer sales information, if available. *See* CPSC POTENTIAL HAZARDS REPORT, *supra* note 101; *The Assessment Process*, OTA, *supra* note 46; *CAERS*, *supra* note 84.

216. *See USPTO Patent Info*, *supra* note 125.

217. *See The Assessment Process*, OTA, *supra* note 46; *USPTO Patent Info*, *supra* note 125.

appropriations.[218] Like the OTA, the TAD would employ about 200 staff devoted to technology assessment activities, with a majority of staff holding advanced technical degrees and at least one subdivision focused on technology impacting health and safety.[219] The TAD would collaborate with other congressional research agencies as well as other federal agencies involved in regulating consumer product safety, such as the FDA and CPSC.[220] The proposed agency would be responsible for streamlining and centralizing current government technology assessment programs to establish a collaborative research- and expertise-sharing network among the participating agencies.[221] Throughout the one-to-two-year study period, the TAD would consult with an advisory panel, including members from the collaborative agency network who can contribute their particular expertise to the study.[222] The TAD would conclude the study and issue a final report within two years of the study's initiation,[223] ultimately answering the question of whether there are emerging consumer products that government regulators should consider for further safety regulation.[224] The final report would be shared with Congress and the public,[225] as well as other federal executive officials and agencies. Congress and federal agencies may then consider the report's information and take regulatory action to address long-term safety concerns posed by products identified as potential health hazards.[226]

218. *See* Reppert, *supra* note 66; *The Assessment Process*, OTA, *supra* note 46; MCLOUGHLIN, *supra* note 139, at 2.

219. *See The Assessment Process*, OTA, *supra* note 46.

220. *See id.*; *What FDA Does*, *supra* note 77; *CPSC FAQs*, *supra* note 95.

221. *See The Assessment Process*, OTA, *supra* note 46; *FDA Nest*, *supra* note 86; CPSC POTENTIAL HAZARDS REPORT, *supra* note 101, at 16–17.

222. *See The Assessment Process*, OTA, *supra* note 46.

223. *See id.*

224. *See id.*

225. *See id.*

226. *See id.*

B. *Breaking the Epidemic Cycle of Public Nuisance Products*

The TAD framework would break the epidemic cycle of public nuisance products because it would institute a proactive, cost-effective, forward-looking intervention that could better serve public health. If the TAD produces technology assessment reports, it will engage the government to proactively regulate when fewer consumers have been exposed to a potentially hazardous product. The TAD framework would centralize current technology assessment efforts into an existing federal agency that is already a repository of experts to assess hazardous technology before costs increase in money, life, and limb. Ultimately, this proposal incorporates a safety inquiry into an early phase of the product lifecycle that looks forward to potential health consequences so the government may take informed regulatory action to prevent the next public nuisance product from harming public health in epidemic proportions.

1. *A proactive public health intervention*

This intervention is proactive because the government would assume its role as parens patriae and industry would be forced to practice corporate social responsibility before many consumers are exposed to a potentially dangerous product.[227] The epidemic cycle demonstrates that government eventually addresses the mounting safety concerns because each iteration ended with a government official filing a public nuisance lawsuit seeking damages from the industry for state-incurred medical and nuisance abatement costs.[228] The cycle also demonstrates that industry typically loses or settles the public nuisance lawsuit, ultimately paying for at least some of the damages sought by the state.[229] The government currently

227. *See supra* Section II.B.; Rutkow & Teret, *supra* note 32, at 281.

228. *See supra* Section II.A.

229. *See* Luff, *supra* note 13, at 155–56; Rustad & Koenig, *supra* note 12, at 359; Purcell, *supra* note 11, at 160. *But see* Wiley, *supra* note 16, at 244–45 (describing reasons why public nuisance litigation against the lead paint industry has not been as successful as it has against other industries).

fronts the medical and nuisance abatement costs, and industry eventually pays for them at a later phase. This proposal advocates that the industry should instead contribute funds for a proactive safety assessment conducted by the government. Under the TAD framework, industry user fees submitted to the USPTO would pay for the agency to conduct a technology safety assessment early in the product lifecycle when fewer consumers have been exposed to a potentially dangerous product, maintaining the primary roles of both government and industry actors.[230]

Opponents might argue that the TAD model is proactive at democracy's expense: an unelected agency applies industry dollars toward a public health program that primarily benefits individual taxpayers.[231] However, this argument overlooks that (1) companies already agree to pay user fees to unelected agencies for property and marketing rights that are not necessarily guaranteed; and (2) the executive branch of government retains the ultimate authority to promulgate regulations based on the USPTO's technology assessment study.

Companies already agree to pay user fees to unelected agencies that determine the fate of a company's interest in a particular consumer product. Companies in total pay billions of dollars in patent application user fees to obtain property rights to an invention on a first-come, first-served basis.[232] Similarly, pharmaceutical companies fund a portion of the FDA's operating costs through user fees paid to the agency to decide whether a pharmaceutical product is safe enough to market to the public.[233] Thus, companies currently agree to fund unelected

230. *See supra* Sections II.A, III.A; MCLOUGHLIN, *supra* note 139.

231. *See* Rustad & Koenig, *supra* note 12, at 368; MCLOUGHLIN, *supra* note 139 (summarizing congressional oversight of USPTO's fee-based budget); FDA AT A GLANCE, *supra* note 79 (exemplifying an agency applying industry money, as well as highlighting the existing responsibility of the FDA to provide oversight for a number of products and facilities, including tobacco).

232. *See* USPTO BUDGET 2021, *supra* note 140, at 127.

233. FDA AT A GLANCE, *supra* note 79.

agencies that determine the fate of the company's interests in a particular product or invention, so funding a technology assessment program does not significantly affect the industry's interests in the consumer products developed and sold to the public.

Moreover, the TAD framework will not undemocratically burden the companies' interests any more than the patent application process does already because the USPTO would not itself be changing health and safety regulations. Under the TAD framework, the USPTO would simply prepare a report estimating the various costs and consequences of technology on society,[234] while other elected regulatory bodies—like Congress and federal executive officials—develop the regulatory policy that flows from the technology assessment findings. This makes the proposed framework preferable to public nuisance litigation to remedy public health epidemics. Public nuisance litigation dilutes democratic accountability by allocating decision-making authority to unelected judges who decide whether a company is responsible for a public health problem and whether the government's abatement plan will satisfactorily address that problem.[235] Conversely, the TAD framework would influence public health policy through the USPTO, charged with fulfilling part of Congress's constitutional duties and required to follow laws governing federal executive agencies; thus, the USPTO is a product of our democratic process. Furthermore, industry would still retain its opportunity to influence the regulatory policy developed by elected representatives or agencies through lobbying or the rulemaking process, respectively.[236]

234. *See supra* Section III.A; *The Assessment Process*, OTA, *supra* note 46.

235. Peter D. Jacobson & Soheil Soliman, *Fields of Law: Litigation as Public Health Policy: Theory or Reality?*, 30 J.L. MED. & ETHICS 224, 225–28 (2002).

236. *See supra* Section III.A; Administrative Procedure Act, 5 U.S.C. § 553(c) (providing that interested persons may submit comments on proposed regulations).

2. *A cost-effective public health intervention*

Additionally, the TAD framework is cost-effective in several ways. The TAD framework centralizes all government technology assessment activities into one agency that already contains the expertise and resources to conduct a comprehensive technology assessment program.[237] The FDA only employs experts in drugs, medical devices, cosmetics, and foods,[238] and the CPSC is limited in its capacity, resources, and enforcement power to effectively investigate emerging technology.[239] The USPTO, on the other hand, employs a wide variety of subject matter experts to assess these products in patent applications[240] and can draw on a steady stream of user fees to fund technology assessment activities.[241] Many innovative consumer products that present potential health hazards will be or are in the process of being patented; thus, the TAD framework fills in the resource and capacity gaps that exist in the more limited technology assessment activities by the FDA and CPSC.

More importantly, this framework reduces the costs incurred outside the traditional market transaction, such as increased healthcare costs, reduced lifespans, and decreased productivity that often accompany a public health epidemic and are often paid for by the public via insurance programs or taxes to abate epidemic harms.[242] For example, the CDC estimates prescription opioid misuse alone costs the United States $78.5 billion a year in "healthcare, lost productivity, addiction treatment, and criminal justice involvement," not to mention

237. *See USPTO Patent Info*, *supra* note 125; FDA AT A GLANCE, *supra* note 79; CPSC STRATEGIC PLAN, *supra* note 116, at 22.

238. *What FDA Does*, *supra* note 77; *What Does FDA Regulate?*, *supra* note 77.

239. CPSC POTENTIAL HAZARDS REPORT, *supra* note 101, at 15–16; *see CPSC Standards*, *supra* note 96.

240. *USPTO Patent Info*, *supra* note 125.

241. *See* USPTO BUDGET 2021, *supra* note 140, at 10.

242. *See* Luff, *supra* note 13, at 132–34.

the 128 lives lost daily to overdose.[243] In theory, these societal costs will decrease if the government uses the TAD's technology assessment reports to address product safety hazards before a product is on the market long enough to cause an epidemic harm costing the country billions of dollars in healthcare, lost productivity, and abatement programs.[244]

Furthermore, TAD's estimated costs are less than the litigation costs incurred by both government and industry, plain and simple. If the TAD operates similarly to the OTA, then the TAD's estimated operating budget will be approximately $16.6 million.[245] Compare this to the near $35 billion in litigation costs spent by both government and industry in the tobacco epidemic cycle alone: state governments owed approximately $8 billion in attorney fees and the industry owed over $27 billion in settlement.[246]

Opponents may argue that, because the proposed agency adds to the USPTO budget, the increase in user fees may prove too expensive (especially for smaller businesses) and deter innovation as fewer companies will pursue patents.[247] Yet, if the USPTO receives at least 500,000 patent applications per year,[248] then the agency would only have to increase the patent application fee by approximately $33.20 per application to adequately fund the TAD.[249]

243. *Opioid Overdose Crisis*, NAT'L INSTS. HEALTH, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (May 27, 2020).

244. *See* Luff, *supra* note 13, at 132–34; *Opioid Overdose Crisis*, *supra* note 243.

245. *See* Reppert, *supra* note 66.

246. *See* source cited *supra* note 198 and accompanying text.

247. *See* Reppert, *supra* note 66; MCLOUGHLIN, *supra* note 139, at 3–4; *TA Debate*, *supra* note 69.

248. *USPTO Patent Info*, *supra* note 125.

249. *See* Reppert, *supra* note 66; *USPTO Patent Info*, *supra* note 125. Divide the OTA operating budget ($16,600,000) by the number of patent applications submitted annually (500,000) to get the dollars per patent application ($33.20) increase the USPTO would have to institute to expand the agency's budget to incorporate the TAD. To see current patent application fees, consult *USPTO Fee Schedule*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule (Jan. 2, 2021, 12:05 AM) (showing basic patent application filing fees range from $55.00 to $320.00 depending on the type of application and applicant).

Opponents may also argue that increasing user fees is unfair to companies that pursue patents for products minimally contributing to health and safety concerns.[250] Ultimately, this argument requires the answer to a critical question: what should our society value more, innovation or safety? While the TAD framework may result in increased user fees, this may just be the cost of prioritizing consumer health and safety over innovation. Recall that today in the United States over sixteen million people live with a smoking-related disease;[251] at least 1.2 million children have lead poisoning;[252] over 300,000 people have died from an opioid overdose;[253] and, as of this Note's publication, at least 3.6 million minors are at risk for lung injury because of e-cigarette use.[254] Remember also that public nuisance litigation and abatement costs to remedy product injuries ran into the billions of dollars for government and industry alike.[255] The money spent by industry on litigation and abatement costs also prevents companies from investing money to develop new products.[256] Industry loses money to invest in innovative products either way, by investing it up front in user fees to fund preventive technology assessment or in litigation and settlement costs for the injuries that could have been prevented with the information learned from preventive technology assessment.[257] However, the number of people injured or killed differs significantly at these two points in the cycle. If the government instituted preventive regulations based on an early technology assessment of the products' safety, necessarily fewer people would have been injured or died from the products by the time public nuisance litigation commenced. If fewer people would have been harmed by the time public

250. *See* MCLOUGHLIN, *supra* note 139, at 3–4; *TA Debate*, *supra* note 69.

251. *Fast Facts*, *supra* note 2.

252. Frostenson, *supra* note 5.

253. Purcell, *supra* note 11, at 141–42.

254. *FDA National Youth Tobacco Survey*, *supra* note 9.

255. *See* Meier, *supra* note 198; *Master Settlement Agreement*, *supra* note 189.

256. *See* Meier, *supra* note 198; *Master Settlement Agreement*, *supra* note 189.

257. *See supra* Section II.A.

nuisance litigation commenced, it is possible litigation may not have been necessary; at the very least, industry would have paid less in abatement costs because there would simply be fewer injuries to remedy. Therefore, the TAD framework seems to have significantly more of a positive effect on saving human life and limb than it has a negative effect on industry costs and innovation. Ultimately, comparing economic costs with human costs is unfair, and industry owes it to their consumers to value their lives more than the bottom line.

3. *A forward-looking public health intervention*

Finally, the TAD intervention is forward-looking by utilizing the technology assessment report generated by the proposed agency. Regulators would be forced to examine the potential health hazards that consumers may face in the future with new technology rather than allowing government actors to simply look back to former epidemic cycles as models of litigation.[258] Patent applications must be filed within one year of the invention's first public disclosure, so patent applications should put the government on notice of a potentially hazardous product before consumers know about and purchase the product.[259] Therefore, the government would be able to take early regulatory action to prevent product safety hazards from reaching epidemic proportions. Under the TAD framework, a technology assessment study would be initiated when emerging technology trends indicate products in a particular subject matter present a new or increased hazard to consumers and is concluded within two years of trend identification.[260] The

258. *See supra* Section II.B (describing the backward-looking nature of public nuisance litigation).

259. *See Provisional Application for Patent*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/provisional-application-patent (Jan. 12, 2015, 2:11 PM) ("[A] provisional application can be filed up to 12 months following an inventor's public disclosure of the invention.").

260. *See USPTO Patent Info*, *supra* note 125, at 6 ("The work of examining applications for patents is divided among a number of examining technology centers (TCs), each TC having jurisdiction over certain assigned fields of technology."); CPSC POTENTIAL HAZARDS REPORT,

TAD would preventively examine emerging technology trends within one year of a product's public debut, while allowing the patent application process to proceed normally—without impeding businesses in their patent pursuits—concurrently with the technology assessment. Assuming regulators would review the TAD's final technology assessment report in a timely manner, regulatory action could take place as early as two years into the product lifecycle, which would address the exposure issue: fewer consumers would be harmed within the product's first two years on the market than would be if the product were on the market for a longer period of time without any regulatory action implemented to improve product safety.[261]

CONCLUSION

In 1929, President Herbert Hoover stated in his inaugural address: "Public health service should be as fully organized and as universally incorporated into our governmental system as is public education. The returns are a thousand fold in economic benefits, and infinitely more in reduction of suffering and promotion of human happiness."[262] Nearly 100 years later and after several public health crises, the United States has yet to achieve universal integration of public health service and has, in some respects, taken steps in the opposite direction.

Attorneys general serve a crucial role in our country's public health service. They stepped in at the eleventh hour to hold industry accountable for the disastrous public health epidemics

supra note 101, at 1 ("Consumer products introduced in the next 3 to 5 years and beyond are likely to be influenced by several societal and technology trends. The trends mentioned here have the potential to change hazard patterns, as well as provide opportunities for CPSC to mitigate new hazards and encourage the acceptance of safer technologies."); *The Assessment Process*, OTA *supra* note 46 ("The bulk of OTA's work centered on comprehensive assessments that took one to two years to complete.").

261. Consider the e-cigarette example posed in Section II.B. If the FDA had exerted regulatory authority over e-cigarettes within the first five years of the product being on the market, fewer minors than the current five million middle and high school students would have suffered negative health consequences associated with vaping. *See supra* Section II.B.

262. Herbert Hoover, U.S. President, Inaugural Address at Yale Law School (Mar. 4, 1929), https://avalon.law.yale.edu/20th_century/hoover.asp.

plaguing recent American history. The tobacco, lead paint, prescription opioids, and e-cigarette epidemics are evidence that there is a pattern of public nuisance products. Time and again, the industry markets products with unanticipated long-term health hazards, combats or discredits emerging evidence of harm associated with the products, evades liability in personal injury or products liability lawsuits, and finally accepts responsibility when government officials file public nuisance lawsuits. This pattern only begs a question of when, not if, another product will emerge as the next public health epidemic.

If this country seriously wishes to prioritize public health, we cannot rely on attorneys general to intervene with such a reactive, expensive, and backward-looking approach as public nuisance litigation. Rather than allow this cycle to continue, the government should revive the Office of Technology Assessment in the United States Patent and Trademark Office as the USPTO's Technology Assessment Division. This revived agency could allow the government to preventively monitor health and safety risks and intervene before a latent public nuisance product transforms into the next public health crisis. History does not have to repeat itself again.