BUYER, BEWARE OF ADDICTION

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Addictive products kill more than 700,000 people in the United States every year. Despite the large-scale risks that addiction poses, the law requires manufacturers of addictive products to disclose little-to-no information about the risk of addiction—the single most consequential characteristic of a class of products contributing to mass death every year.

While consumers understand that addictive products are, in fact, addictive, they generally do not understand the magnitude of the addiction risks that they face. Metaphorically, consumers understand that they are playing a game of "Russian roulette" when they consume an addictive product—but they play without knowing how many bullets are in the gun.

This Article considers how and why the law fails to require meaningful addiction risk disclosure. It goes on to discuss what meaningful risk disclosure might entail, including easily digestible quantitative measures of how likely addiction is, information about risky patterns of use, and warning signs of early-stage addiction. This Article suggests that an overhaul of the current approach to addiction research and disclosure is necessary to bring decades-old disclosure requirements in line with current medical research.

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INTRODUCTION

Addictive products kill more than 700,000 people in the United States every year.[1] Despite the colossal risks associated with their use, millions of people regularly use and abuse alcohol, cocaine, marijuana, nicotine, opioids, hallucinogens, inhalants, and other stimulants and

[1] *See Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL (Aug. 22, 2023), [https://web.archive.org/web/20230901064548/https://www.cdc.gov/drugoverdose/deaths/index.html] ("In 2021, 106,699 drug overdose deaths occurred in the United States."); *Burden of Cigarette Use in the U.S.*, CTRS. FOR DISEASE CONTROL (May 4, 2023), https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html [https://perma.cc/FEV5-KU55] ("Cigarette smoking kills more than 480,000 Americans each year."); *Deaths from Excessive Alcohol Use in the United States*, CTRS. FOR DISEASE CONTROL (July 6, 2022), [https://web.archive.org/web/20230517140621/https://www.cdc.gov/alcohol/features/excessive-alcohol-deaths.html] ("More than 140,000 people die from excessive alcohol use in the U.S. each year.").

substances.[2] The reason why, of course, is in the name—they are addictive, and once individuals become dependent on addictive substances, it can be extremely difficult to curtail their use. Despite the large-scale risks that addiction poses, the law requires manufacturers of addictive products to disclose scant information about addiction risks—the most consequential characteristic of a class of products contributing to mass death every year.

While consumers generally understand that addictive products are addictive, they usually do not understand the magnitude of the addiction risks that they face.[3] For example, alcohol users know that alcohol is addictive but do not know what percentage of people who drink a glass of wine a day will become physically or psychologically dependent on alcohol following a period of regular use.[4] Metaphorically, consumers generally understand that they are playing a game of "Russian roulette" when they consume an addictive product—but they play without knowing how many bullets are in the gun.

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2 *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUM. SERVS., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2019 NATIONAL SURVEY ON DRUG USE AND HEALTH 1 (2020) ("In particular, 50.8 percent (or 139.7 million people) drank alcohol in the past month, 21.1 percent (or 58.1 million people) used a tobacco product in the past month, and 13.0 percent (or 35.8 million people) used an illicit drug in the past month.").

3 There is no generally agreed-upon definition for addiction. *E.g.*, Richard J. Rosenthal & Suzanne B. Faris, *The Etymology and Early History of 'Addiction,'* 27 ADDICTION RSCH. & THEORY 437, 437 (2019) (explaining that earlier versions of the Diagnostic and Statistical Manual of Mental Disorder (DSM) rejected the term, in part, because it lacked a "universally agreed upon definition"). This Article defines "substance addiction" as persistent and compulsive use of a substance despite adverse consequences, drawing on the most recent DSM (usually referred to as the DSM-V) criteria for substance and alcohol use disorders. The eleven criteria for diagnosis of substance use disorder include: using more of the substance than intended or using it for longer than meant to; being unable to cut down or stop using despite trying; spending large amounts of time obtaining, using, or recovering from the substance's effects; intense cravings or urges; resulting failure to fulfill obligations at work, home, or school; social or interpersonal problems caused or exacerbated by the substance; giving up or reducing important social, occupational, or recreational activities; using the substance in a way that creates physical risk; continued use despite knowing it causes physical or psychological problems; building a tolerance to the substance; and developing withdrawal symptoms when not using the substance. JENNIFER MCNEELY & ANGELINE ADAM, NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE SUBSTANCE USE SCREENING AND RISK ASSESSMENT IN ADULTS 16 tbl.3 (2020). Within a twelve-month period, the presence of two to three symptoms indicates mild substance use disorder, four to five moderate, and six or more severe. The ten criteria for alcohol use disorder diagnosis are similar. *See Alcohol Use Disorder: A Comparison Between DSM–IV and DSM–5*, NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM (April 2021), https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/alcohol-use-disorder-comparison-between-dsm [https://perma.cc/F5JR-EC8T].

4 *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUM. SERVS., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2021 NATIONAL SURVEY ON DRUG USE AND HEALTH A-13 tbl.A.16B (Dec. 2022) (noting that 10.6% of individuals in 2021 had an alcohol use disorder).

Consumers lack full information about addiction risks not because the information is unknowable—rather, it is because firms that sell addictive products have no incentive to research or disclose it. Indeed, medical research continues to identify addiction rates that differ by substance as well as predictive risk factors that enable individuals to evaluate their own risks.[5] The law fails to require meaningful addiction risk disclosure for at least two reasons. First, and as explored fully in Part I, a patchwork of federal statutory and regulatory disclosure requirements requires sellers either to disclose the existence of an addiction risk but not its magnitude or worse, does not require disclosure of addiction risks at all. Yet, as discussed in Part II, courts generally hold that those inadequate requirements preempt state tort claims that would incentivize more robust disclosure.[6]

The light regulatory and tort approach to addiction stands in stark contrast to how the law deals with other risky products. Automobiles, for example, resulted in approximately 43,000 deaths in the United States in 2022.[7] Given the social risks automobiles impose, bodies of law and regulation exist to limit those risks and to help individuals make informed choices regarding their risks. The National Highway Traffic Safety Administration requires car manufacturers to disclose damage susceptibility and crashworthiness for their products.[8] Products liability law additionally incentivizes car manufacturers to warn their customers about risks their cars present. Indeed, the systematic overlap of regulatory disclosure requirements and tort law is not unique to automobiles—the two bodies of law provide multiple layers of incentives to companies to disclose safety risks. The National Electronic Injury Surveillance System from the Consumer Product Safety Commission discloses injury risks for almost every product on the market.[9] And failure-to-warn law generally requires companies to warn consumers about risks the products present.[10]

Moreover, there is a mistaken belief that because the public and medical community are generally aware that an addiction risk exists for relevant products, any further warnings are unlikely to change behavior

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5 *See infra* Section III.A.

6 *See infra* Part II.

7 NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., U.S. DEP'T OF TRANSP., EARLY ESTIMATE OF MOTOR VEHICLE TRAFFIC FATALITIES IN 2022, at 1 (2023), https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/v813428 [https://perma.cc/7RHK-4DRT].

8 49 U.S.C. § 32302(a)(1)–(2), (b).

9 *National Electronic Injury Surveillance System (NEISS)*, CONSUMER PROD. SAFETY COMM'N, https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data [https://perma.cc/J2CN-J8EC].

10 *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (AM. L. INST. 1998) (defining categories of product defects).

or reduce harm. That argument misses the mark. Part III presents insight from behavioral and addiction science to show that consumption choices will vary with the perceived benefits of a product, as well as the existence and magnitude of addiction risks.[11] The core insight is that binary addiction risks will fail to affect consumption decisions by partially naïve consumers—those who understand a product is addictive, but not how addictive the product is. In contrast, scientific developments in addiction and consumer risk perception demonstrate that it is possible for consumers to know how addictive products are, and that disclosing such information to consumers encourages welfare-maximizing consumption decisions.

The current system permits sellers of addictive products to occupy a uniquely privileged position in the economy, with lack of consumer information effectively subsidizing manufacturers of addictive products. If manufacturers disclosed accurate addiction rates and other material information about addiction risk, demand for addictive products would likely fall,[12] yielding a market equilibrium in which the consumption of addictive products would fall relative to prevailing conditions.[13] Instead, for example, while excessive alcohol use costs the U.S. economy approximately $249 billion annually,[14] alcohol manufacturers have no incentive to research and disclose ways their products can be used in less risky ways, who is at risk for harm by their products, or anything at all about addiction risk. This lack of regulation occurs even though approximately one in ten people aged twelve and older have alcohol use disorder.[15] All consumers are left with is advertisements that state please

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11 *See infra* Part III.

12 *See, e.g.*, W. Kip Viscusi, *A Bayesian Analysis of E-Cigarette Risk Perceptions in the United Kingdom*, 90 S. ECON. J. 612, 625–26 (2024) (showing that e-cigarette consumption falls as perceived risks increase); W. Kip Viscusi & Jahn K. Hakes, *Risk Beliefs and Smoking Behavior*, 46 ECON. INQUIRY 45, 50 tbl.2 (2008) (showing that cigarette consumption falls as perceived risks of cigarettes increase).

13 To be sure, consumers may also overestimate how addictive some products are. As discussed *infra* Part III, current evidence supports the conclusion that consumers tend to underestimate addiction risks for most products. But even if consumers overestimate addiction risks, naïve consumers would be better off with accurate information disclosure that permits them to make informed consumption decisions. *See infra* Part III.

14 *The Cost of Excessive Alcohol Use*, CTRS. FOR DISEASE CONTROL (Mar. 6, 2024), https://www.cdc.gov/alcohol/excessive-drinking-data/index.html [https://perma.cc/6XPV-EY8Z].

15 *Alcohol Use Disorder (AUD) in the United States: Age Groups and Demographic Characteristics*, NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM (2024), https://www.niaaa.nih.gov/alcohols-effects-health/alcohol-topics/alcohol-facts-and-statistics/alcohol-use-disorder-aud-united-states-age-groups-and-demographic-characteristics [https://perma.cc/Q8H4-WXZ2].

"drink responsibly," with no indication of what that might entail.[16] Individuals, accordingly, likely drink more and pay higher prices, than they otherwise would but for the information gap subsidy. The addiction information subsidy leads to greater use of addiction products, likely materially contributing to the 700,000 annual deaths such products cause.[17]

This Article argues Congress, agencies, and courts must overhaul the current approach to addiction research and disclosure. This Article presents a proposal in Part IV, which argues that addiction risk disclosure should take a layered approach, consistent with other products, that eliminates the addiction subsidy the current regime creates. First, federal agencies with relevant existing authority should expand addiction disclosure rules to require manufacturers to disclose all material information regarding addiction risks. Material information includes, at a minimum, an easily digestible quantitative measure of how likely addiction is, on average. It should also include information about risky patterns of use and warning signs for early stages of addiction and potentially individual risk factors. Second, an optimal regime would permit plaintiffs to bring failure-to-warn claims against manufacturers that fail to disclose material risks. The two-pronged approach properly incentivizes appropriate risk disclosure while hedging against the weaknesses that an exclusively regulatory or private law approach would yield.

I. FEDERAL ADDICTION DISCLOSURE REGULATION

Most mandatory risk disclosures for addictive products occur pursuant to federal law. Congress and various federal agencies have created detailed statutory schemes compelling or more often, not compelling, addiction disclosure for prescription drugs, nicotine products like tobacco, and alcohol. Broadly, current law requires manufacturers to provide a binary addiction disclosure for prescription drugs and some nicotine products, but not alcohol. A binary disclosure informs consumers that a product is addictive but provides no additional information about the extent of the risk, patterns of use that affect the risk, or individual characteristics that might impact the risk.

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16 *'Drink Responsibly' Messages in Alcohol Ads Promote Products, Not Public Health*, JOHNS HOPKINS (Sept. 3, 2014), https://publichealth.jhu.edu/2014/drink-responsibly-messages-in-alcohol-ads-promote-products-not-public-health [https://perma.cc/T3PJ-G4CM] ("While responsibility messages were present in almost nine out of ten ads, none of them provided any information about what it means to drink responsibly[.]").

17 *See supra* note 1.

This Part provides an overview of the various statutes and agencies that inform consumers whether a product is addictive. Section I.A begins with the Food and Drug Administration (FDA) and presents the circumstances under which it requires manufacturers to disclose addiction risks in drug labels. Next, Section I.B examines federal nicotine disclosure requirements. Section I.C then examines the sparser regulation of alcohol risk disclosure.

At the outset, it is worth acknowledging that the regimes explored in this Part (and the next) focus on prescription drugs, nicotine, and alcohol to the exclusion of other potentially addictive products. These products represent the vast majority of contemporary regulatory and litigatory activity concerning addiction, but certainly not all of it.[18] Accordingly, this Article focuses on the three categories of products because most of the legal requirements and constraints concerning addiction disclosure concern them. However, as discussed in Part III, our argument extends beyond regulation of these substances.

A. *Prescription Drugs*

The FDA primarily regulates the disclosure of addiction information through its authority to require manufacturers to label drugs. The Food, Drug, and Cosmetic Act requires that prescription drugs bear adequate directions for use and adequate warnings against dangerous uses and dosages.[19] The FDA accordingly requires drug manufacturers to create drug labels that include approved uses, circumstances under which use may harm a patient, recommended dosages, and administration instructions, as well as any risks of adverse reactions.[20]

Healthcare providers are the intended audience for drug labels; as a result, the information can be denser and more technical than patients

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18 *E.g.*, Vivek H. Murthy, *Surgeon General: Why I'm Calling for a Warning Label on Social Media Platforms*, N.Y. TIMES (June 17, 2024), https://www.nytimes.com/2024/06/17/opinion/social-media-health-warning.html [https://perma.cc/JB24-AWAT] (calling on Congress to require social media to warn adolescents about the addictiveness and mental health dangers of social media); *In re* Social Media Addiction/Personal Injury Prods. Liab. Litig., 702 F. Supp. 3d 809 (N.D. Cal. 2023) (granting in part and denying in part a motion to dismiss products liability litigation against social media companies alleging that their services are addictive and harm adolescent mental health).

19 21 U.S.C. § 352(f).

20 21 C.F.R. §§ 201.56, 201.57 (2024).

can easily understand.[21] Prescription drug labels are not made directly available to patients, though curious patients can find them using the internet. FDA regulations outline the order that manufacturers must provide information, as well as the contents of a section if it is appropriate to include it in a prescription drug's label.[22]

If the mandatory human studies used to assess a drug's safety reveal evidence that a drug presents a risk of abuse, dependence, or addiction, manufacturers must include a section in the label titled "Drug abuse and dependence."[23] FDA regulations require the section to identify: (1) whether the drug is a controlled substance; (2) what types of abuse can occur; (3) pertinent adverse reactions; (4) particularly susceptible patient populations; (5) the characteristic effects of dependence on the drug; and (6) the quantity of the drug over a period of time that may lead to tolerance and dependence, to the extent such information is known from safety studies.[24] Few drug labels actually contain all of the information the regulation purports to require.[25] For instance, the current OxyContin label states that the drug "exposes users to the risks of addiction, abuse, and misuse," and that "addiction can occur at recommended doses," but does not identify characteristics of opioid addiction or the time frame in which addiction can develop.[26] In contrast, the label identifies the percentage of patients who experience several common side effects of OxyContin, including nausea, dizziness, headache, and asthenia—but not the percentage of patients who experience addiction.[27]

FDA guidance also encourages manufacturers to define abuse, misuse, dependence, addiction within the label, and identify whether there are known risks of abuse.[28] For example, the FDA encourages manufacturers to include the following sentence in the label of drugs with

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21 *See* U.S. FDA, DRUG ABUSE AND DEPENDENCE SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS—CONTENT AND FORMAT 2 (July 2019), https://www.fda.gov/media/128443/download [https://perma.cc/C6LC-Z7RW] ("Information on a drug's potential for abuse, misuse, addiction, physical dependence, and tolerance is generally conveyed to health care providers in the DRUG ABUSE AND DEPENDENCE section of labeling.").

22 *See* 21 C.F.R. § 201.57 (listing required sections).

23 21 C.F.R. § 201.57(10)(ii). *See generally* U.S. FDA, ASSESSMENT OF ABUSE POTENTIAL OF DRUGS (Jan. 2017) (providing guidance to industry on how to assess the risk of abuse in prescription drugs).

24 21 C.F.R. § 201.57(10)(ii)–(iii).

25 *E.g.*, U.S. FDA, HIGHLIGHTS OF PRESCRIBING INFORMATION, OXYCONTIN § 5.1 (Aug. 2015), https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022272s027lbl.pdf [https://perma.cc/MJN9-Z37F] (referencing risks of addiction but not establishing what affects them or what those risks numerically are).

26 *Id.*

27 *Id.* § 6.1.

28 U.S. FDA, *supra* note 21, at 6–10.

a risk of addiction: "Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use . . . and possible tolerance or physical dependence."[29] But the FDA does not require manufacturers to enumerate the proportion of patients taking the drug that become addicted. Indeed, the FDA actively discourages manufacturers from providing detailed information that would be necessary to assess how large a risk of addiction is.[30]

If patient-directed labeling is needed for patients to safely use the drug, the FDA also requires that manufacturers create a nontechnical label called a medication guide.[31] Patients receive a medication guide at the pharmacy with their prescription. The FDA will require a medication guide if patient-directed information could prevent serious adverse effects, if the drug has serious risks of which a patient should be aware because information concerning the risk could affect the patient's decision to use the drug, or if the drug is important to health and adherence to directions is critical to ensure the drug's effectiveness.[32] The FDA must approve the language included in medication guides, though the FDA does not require the same format or level of detail as in provider-directed labeling.[33] Medication guides should, however, state "the risk, if there is one, of patients' developing dependence on the drug product."[34] The risk disclosure regarding addiction for patients, however, is just as generic as the label for providers.[35] Given that medication guides are less detailed than labels, they too do not disclose addiction rates, warning signs of addiction, or individual risk factors.

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29 *Id.* at 9.

30 *See* U.S. FDA, *supra* note 21, at 12 ("FDA recommends that the following information generally not be included in the DRUG ABUSE AND DEPENDENCE section of labeling: . . . Lengthy definitions—other than those recommended for inclusion in labeling in this guidance—or discussions related to abuse and dependence.").

31 21 C.F.R. § 208.1(c) (2024).

32 *Id.* Some drugs—particularly oral contraceptives and estrogens-containing medications—require an individualized form of patient-directed labeling, called a patient package insert. 21 C.F.R. §§ 310.501, 310.515.

33 *See, e.g.*, 21 C.F.R. § 208.20.

34 *Id.* § 208.20(b)(7)(ii).

35 *Compare* OxyContin Label, *supra* note 25, at § 5.1 ("Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed OXYCONTIN. Addiction can occur at recommended doses and if the drug is misused or abused."), *with id.* at Medication Guide ("Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.").

B. *Nicotine*

Broadly, current law requires nicotine manufacturers to disclose that nicotine is addictive for only some products. The current regulation is a product of the long history of smoking as a public health issue in the United States. In 1964, a surgeon general report concluded that "cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate."[36] At the time, forty-two percent of Americans smoked.[37] On the heels of the surgeon general's report, the Federal Trade Commission (FTC) released a notice of proposed rulemaking that would have required cigarette manufacturers to disclose "in all advertising and on every pack, box, carton or other container in which cigarettes are sold" that "cigarette smoking is dangerous to health and may cause death from cancer and other diseases."[38]

In 1965, in lieu of the proposed regulations, Congress passed the Federal Cigarette Labeling and Advertising Act to set national standards for cigarette packaging to convey the health risks to consumers.[39] In stark contrast to the surgeon general report that prompted it, the Federal Cigarette Labeling and Advertising Act required only weak warnings about the risks of smoking, none of which included a warning about addiction.[40] When Congress ultimately passed legislation on the issue, it required only a label reading: "Caution: Cigarette Smoking May Be Hazardous To Your Health."[41] The New York Times wrote that the Act was a "shocking piece of special interest legislation . . . to protect the economic health of the tobacco industry by freeing it of proper regulation."[42]

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36 U.S. DEP'T OF HEALTH, EDUC. & WELFARE, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE 31 (1964), https://digirepo.nlm.nih.gov/ext/document/101584932X202/PDF/101584932X202.pdf [https://perma.cc/HVS4-C5ZF].

37 *Surgeon General's 1964 Report: Making Smoking History*, HARV. HEALTH BLOG (Jan. 10, 2014), https://www.health.harvard.edu/blog/surgeon-generals-1964-report-making-smoking-history-201401106970 [https://perma.cc/FN8T-NCCP].

38 Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8325 (1964).

39 Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92 (1965).

40 Statement of Basis and Purpose of Trade Regulation Rule, 29 Fed. Reg. 8325 (July 2, 1964).

41 Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92 (1965). In 1970, with the passage of the Public Health Cigarette Smoking Act, warning labels took a more definitive tone, requiring labeling stating "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Pub. L. No. 91-222 (1970).

42 Sylvia A. Law, *Addiction, Autonomy, and Advertising*, 77 IOWA L. REV. 909, 914 (1992) (quoting Editorial, N.Y. TIMES, July 9, 1965, at A28).

Over time, the risk disclosures required on cigarettes have expanded somewhat. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act ("the 2009 Act"), which required manufacturers to include one of nine specific warnings in cigarette advertisements and packaging.[43] One of the nine potential warnings is: "WARNING: Cigarettes are addictive."[44] The nine warnings must be displayed in rotation, with approximately equal exposure.[45]

The 2009 Act also delegated authority to the FDA to enhance the required disclosures by "requir[ing] color graphics depicting the negative health consequences of smoking to accompany the label statements."[46] Graphic warnings about the risk of addiction may have been an effective way to convey addiction risk.[47] However, the required graphic warnings never appeared on cigarette packages.[48] The FDA promulgated its final rule requiring warnings in June 2011, but cigarette manufacturers immediately challenged them, arguing that the graphic images violated the First Amendment, ultimately prevailing.[49] After several years, the FDA attempted to promulgate new graphic warnings,[50] but cigarette manufacturers once again convinced a district court in the Eastern District of Texas that the warnings violated the First Amendment.[51] Interestingly, the rules declined to require a warning about addiction in favor of other warnings about diseases highlighted in a 2014 surgeon general's report.[52]

Today, the warnings that cigarette manufacturers must include have reverted to those required by the 1984 Comprehensive Smoking

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43 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1842, 1842–43 (2009).

44 The other required warnings focused on the long-term health consequences of smoking. *See* 15 U.S.C. § 1333(a)(1) (requiring one of the following warning labels: "Cigarettes are addictive," "Tobacco smoke can harm your children," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," "Smoking can kill you," "Tobacco smoke causes fatal lung disease in nonsmokers," or "Quitting smoking now greatly reduces serious risks to your health").

45 § 1333(c)(1).

46 § 1333(d).

47 *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36633–35 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141) (reviewing evidence that graphic warnings are effective at conveying risk information).

48 *See* R.J. Reynolds Tobacco Co. v. U.S. FDA, 696 F.3d 1205, 1221–22 (D.C. Cir. 2012).

49 *Id.*

50 *See generally* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 15638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141).

51 *See* R.J. Reynolds Tobacco Co. v. U.S. FDA, No. 20-cv-00176, 2022 WL 17489170, at *1 (E.D. Tex. Dec. 7, 2022).

52 Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. at 15640.

Education Act.[53] The 1984 Act contains no mention of addictiveness. As such, there are no FDA requirements that cigarette labels or advertising contain any mention of their addictive properties. One exception exists: after becoming the first company to admit publicly that smoking is addictive, Liggett Group became the first company to add "Smoking is Addictive" as a warning label on its cigarettes as a condition of the Master Settlement Agreement that resolved the major tobacco litigation of the 1990s.[54] To date, it is the only U.S. cigarette manufacturer to add that warning.[55]

Despite the lack of required addiction warning on cigarettes, the FDA has implemented a warning requirement for most non-cigarette products that contain nicotine. Any packaging or advertisement for these products must display the following warning: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."[56] So, for example, a warning about nicotine's addictiveness in any advertising or labeling must accompany nicotine pouches and pods for vaping.[57]

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53 *See* Comprehensive Smoking Education Act, Pub L. No. 98-484, 98 Stat. 2200 (codified as amended at 15 U.S.C. § 1331); U.S. FDA, CIGARETTE LABELING AND HEALTH WARNING REQUIREMENTS, https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements [https://perma.cc/3KHV-EL9G]; U.S. FDA, RETAILERS: CHART OF REQUIRED WARNING STATEMENTS ON TOBACCO PRODUCT PACKAGING AND ADVERTISING, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailers-chart-required-warning-statements-tobacco-product-packaging-and-advertising [https://web.archive.org/web/20240301181933/https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailers-chart-required-warning-statements-tobacco-product-packaging-and-advertising] (listing the warnings for cigarettes as either: "Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy," "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health," "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight," or "Cigarette Smoke Contains Carbon Monoxide").

54 *E.g.*, MONTEGO ORANGE BX 100 FSC—CTN, https://www.vons.com/shop/product-details.960491174.html [https://perma.cc/AB3L-TKUD]; *see* LIGGETT VECTOR BRANDS, *Tobacco Industry Settlements*, https://liggettvectorbrands.com/about-us/tobacco-industry-settlements [https://perma.cc/HSM2-J5HX].

55 *See* LIGGETT VECTOR BRANDS, *supra* note 54.

56 21 C.F.R. § 1143.3 (2024); U.S. FOOD & DRUG ADMIN., COVERED TOBACCO PRODUCTS AND ROLL-YOUR-OWN/CIGARETTE TOBACCO LABELING AND WARNING STATEMENT REQUIREMENTS, https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/covered-tobacco-products-and-roll-your-own-cigarette-tobacco-labeling-and-warning-statement [https://perma.cc/F3JX-AQHB].

57 *E.g.*, ZYN, https://us.zyn.com [https://perma.cc/A7YS-FVZU]; JUUL, https://www.juul.com/signin [https://perma.cc/UN86-T3GR].

C. *Alcohol*

Alcohol, in contrast to nicotine and prescription drugs, is subject to no disclosure requirements regarding its addictiveness. Alcohol regulation has a long history in the United States, but most disclosure regulation has focused on informing consumers what they are drinking, rather than the risks it presents. Alcohol's most prominent reckoning occurred in the 1920s, when the Eighteenth Amendment prohibited the manufacture, sale, or transportation of alcohol for thirteen years.[58]

In contrast to the Prohibition Era, there is minimal modern regulation of alcohol labeling and advertising.[59] The first and only time Congress mandated alcohol risk disclosure was in the Alcoholic Beverage Labeling Act of 1988 ("the 1988 Act"). The Act requires manufacturers to warn consumers that "women should not drink alcoholic beverages during pregnancy because of the risk of birth defects," that consuming "alcoholic beverages impairs your ability to drive a car or operate machinery," and that it "may cause health problems."[60] The tepid language of "may cause health problems" is described by public health researcher Dr. Marissa Hall as "a phrase so vague that it borders on being misleading."[61]

The Act places enforcement power and the power to issue regulations to carry out its requirements with the Secretary of the Treasury, who exercises those powers through the Alcohol and Tobacco Tax and Trade Bureau (TTB).[62] The Secretary also must "consult and coordinate the health awareness efforts" with the Surgeon General.[63]

Despite occasional regulatory efforts, the federal government has not expanded alcohol health disclosure requirements beyond those in the 1988 Act.[64] In response to a petition by the Center for Science in the

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58 U.S. CONST. amend. XVIII, *repealed by* U.S. CONST. amend. XXI.

59 CTRS. FOR DISEASE CONTROL, FACTS ABOUT U.S. DEATHS FROM EXCESSIVE ALCOHOL USE (Aug. 6, 2024), https://www.cdc.gov/alcohol/facts-stats/?CDC_AAref_Val=https://www.cdc.gov/alcohol/features/excessive-alcohol-deaths.html [https://perma.cc/6S2W-EF7P] ("About 178,000 people die from excessive drinking each year.").

60 27 U.S.C. § 215(a).

61 *Researchers Suggest More Detailed Alcohol Warning Labels Could Reduce Health Harms*, U. N.C. GILLINGS SCH. GLOB. PUB. HEALTH (Aug. 27, 2022), https://sph.unc.edu/sph-news/researchers-suggest-more-detailed-alcohol-warning-labels-could-reduce-health-harms [https://perma.cc/5QDA-SQ94].

62 27 U.S.C. § 215(d); *see, e.g.*, Implementation of Alcoholic Beverage Labeling Act of 1988, https://archives.federalregister.gov/issue_slice/1990/2/14/5383-5422.pdf#page=32 [https://perma.cc/HU6Z-HSXL].

63 *Id.*

64 Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages; Request for Public Comment, 70 Fed. Reg. 22274-01 (Apr. 29, 2005).

Public Interest and others, the TTB did consider some major changes to its labeling requirements in 2005.[65] Ultimately, though, the TTB did not alter its labeling regulations.[66] In fact, the group that initially filed the petition recently sued the U.S. Department of the Treasury to force it to act, stating the TTB "failed to act on a 19-year-old petition urging it to require alcohol labeling with the same basic transparency consumers expect in foods."[67]

The TTB also regulates alcohol advertising but requires manufacturers to disclose very little information.[68] Alcohol advertisements must disclose the advertiser's name, a way to contact the advertiser, the class of alcohol to which the product belongs, and—for some beverages—the alcohol content as a percent by volume.[69] While advertisements may not make false statements about the health benefits of alcohol,[70] there is no requirement that alcohol advertising disclose any of the health determinants of alcohol.

* * *

As demonstrated, federal intervention plays a critical role in conveying risk information about addictive products to the public. However, the patchwork of existing regulation fails to meaningfully disclose addiction risks. Prescription drug labels do so generically, particularly in consumer-oriented documentation, and lack even nominally required detail.[71] Tobacco addiction risk disclosure is sporadic and subject to an evolving battle between the FDA and the First Amendment.[72] Alcohol addiction risk disclosure is nonexistent.[73] As a result, the current system of federal rules fails to provide consumers with material information about addiction risks.

In a federalist system in which states possess the police power to promote the general welfare,[74] one might expect states to provide residual incentives for manufacturers to promote public health by disclosing

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65 *Id.*

66 *Coalition Sues to Force Treasury Department Decision on Alcohol Labeling*, CTR. SCI. PUB. INTEREST (Oct. 3, 2022), https://www.cspinet.org/press-release/coalition-sues-force-treasury-department-decision-alcohol-labeling [https://perma.cc/BES3-7LUT].

67 *Id.*

68 27 C.F.R. §§ 4.62, 5.233 (2024).

69 *Id.* § 5.233.

70 27 C.F.R. § 4.64 (2024).

71 *See supra* Section I.A.

72 *See supra* Section I.B.

73 *See supra* Section I.C.

74 U.S. CONST. amend. X.

addiction risks. The next Part examines how states, particularly through tort law, can require manufacturers to disclose addiction risks. As the discussion will reveal, however, it provides little incentive beyond the patchwork of federal regulation.

II. TORT LAW AND ADDICTION RISK DISCLOSURE

Products liability law could, in theory, require manufacturers[75] to disclose addiction risks when their products pose a foreseeable risk to consumers. Inadequate disclosure of a product's risky features, such as addiction, is a classic failure-to-warn defect.[76] A product has a failure-to-warn defect if it lacks reasonable instructions or warnings that could have reduced or avoided foreseeable risks of harm.[77] While failure-to-warn claims nominally hold defendants strictly liable,[78] the modern doctrine of failure-to-warn is difficult to distinguish from negligence.[79] Reasonableness is the crux of a failure-to-warn claim, just like a claim for ordinary negligence, because a defendant is liable for the manufacture or sale of a product that lacks reasonable warnings.

Failure-to-warn claims should theoretically incentivize companies to disclose product risks when legislatures and agencies have failed or declined to require addiction risk disclosure. However, courts have routinely held that federal law preempts state failure-to-warn claims

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75 Unlike many of the regulatory requirements discussed in Part I, failure-to-warn law applies equally to manufacturers, distributors, or retailers of products. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. c (AM. L. INST. 1998). For ease of exposition, this Article continues to refer to potential defendants as manufacturers.

76 Claims based on the theory that a manufacturer provided inadequate instructions or warnings with a product are referred to variously as marketing defect claims, warning defect claims, and failure-to-warn claims. *E.g.*, Sims v. Washex Mach. Corp., 932 S.W.2d 559, 562 (Tex. Ct. App. 1995) ("To establish a theory of recovery based on marketing defect, a claimant must prove . . . the absence of a warning . . . renders the product unreasonably dangerous to the ultimate user or consumer of the product."); Moss v. Wyeth, 872 F. Supp. 2d 162, 166 (D. Conn. 2012) ("[A] warning defect exists when a product is unreasonably dangerous because it lacks adequate warnings or instructions concerning the product's dangerous propensities."); Igwe v. Skaggs, 258 F. Supp. 3d 596, 612 (W.D. Penn. 2017) ("An otherwise properly designed product may still be unreasonably dangerous (and therefore 'defective') . . . if the product is distributed without sufficient warnings to apprise the ultimate user of the latent dangers in the product.").

77 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (AM. L. INST. 1998).

78 *See id.* § 1 ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.").

79 *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (AM. L. INST. 1998) ("Subsections (b) and (c), which impose liability for products that are defectively designed or sold without adequate warnings or instructions and are thus not reasonably safe, achieve the same general objectives as does liability predicated on negligence.").

against defendants that sell addictive products subject to federal regulation. Section I.A reviews current preemption law, identifying the categories of cases which the statutory schemes in Part I likely preempt. But even the cases that survive federal preemption meet resistance under the common knowledge doctrine, which holds that a manufacturer does not need to warn consumers about risks that are common knowledge. Section II.B considers the cases in which the common knowledge doctrine has blocked plaintiffs' suits. Section II.C discusses the learned intermediary doctrine, which often blocks suits against prescription drug manufacturers. Finally, Section II.D considers academic commentary on the role of tort law in regulating addictive products.

A. *Federal Preemption*

Federal law preempts state law that interferes with or is contrary to the federal law. Federal law can preempt state law in three ways: express preemption, conflict preemption, and field preemption.[80] Express is the most straightforward of the three—federal laws that expressly say they preempt state laws do so.[81] Conflict preemption nullifies state laws that conflict with federal laws or regulations.[82] Finally, field preemption occurs when the federal scheme of regulation is so extensive that it indicates Congress intended for federal regulation to be exclusive.[83] Federal law can preempt any "state law, including civil actions based on state law."[84]

Federal law expressly preempts state regulation of the content of cigarette labels, including through failure-to-warn litigation. The Public Health Cigarette Smoking Act of 1969 ("the 1969 Act") prohibits states from placing any "requirement or prohibition based on smoking and health . . . with respect to the advertising or promotion of any cigarettes," for cigarettes with federally compliant labels.[85] The Supreme Court has also interpreted the 1969 Act to bar consumers' failure-to-warn claims.[86]

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80 Farina v. Nokia, 625 F.3d 97, 115 (3d Cir. 2010).

81 *E.g.*, 29 U.S.C. § 1144(a) ("Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan . . . .").

82 *E.g.*, Fellner v. Tri-Union Seafoods, LLC, 539 F.3d 237, 243 (3d Cir. 2008) ("Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency's delegated authority.").

83 US Airways, Inc. v. O'Donnell, 627 F.3d 1318, 1324 (10th Cir. 2010).

84 *Farina*, 625 F.3d at 115.

85 15 U.S.C. § 1334.

86 Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 524 (1992).

In *Cipollone v. Liggett Group, Inc.*, the Supreme Court held that the above language from the 1969 Act preempts not only state regulation but also any state-law failure-to-warn claims regarding cigarettes.[87] The Court reasoned that failure-to-warn claims "rely on a state-law 'requirement or prohibition . . . with respect to . . . advertising or promotion,'" and therefore fall under the preemption clause.[88] Professor Sylvia Law describes this requirement-plus-preemption in the cigarette context as "a nearly unique protection from state regulation and common law liability."[89]

Federal law likely fully preempts state laws that would regulate the content of alcohol labels as well. Like the 1969 Act, the Alcoholic Beverage Labeling Act of 1988 prohibits states from requiring any "statement relating to alcoholic beverages and health . . . on any container of an alcoholic beverage."[90] And while the Supreme Court has not considered whether that language also preempts failure-to-warn claims, it would likely decide that it does. The language of the Alcohol Beverage Labeling Act is nearly identical to the language governing cigarettes.[91]

Failure-to-warn claims against manufacturers of addictive prescription brand name drugs, in turn, are not generally preempted, but whether a claim can succeed remains a function of federal law.[92] Despite the extensive regulatory requirements discussed above, the Supreme Court has reasoned that brand name drug manufacturers can add reasonable warnings to drug labels and medication guides without violating federal law.[93] Brand name drug manufacturers can raise a "regulatory compliance" defense, however, if they can demonstrate that the FDA would not approve a label with the warnings that a plaintiff alleges should have been included.[94]

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87 *Id.*

88 *Id.*

89 Law, *supra* note 42, at 916–17.

90 27 U.S.C. § 216.

91 *Compare* 15 U.S.C. § 1334 ("Except [as required by federal regulation] . . . , no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package."), *with* 27 U.S.C. § 216 ("No statement relating to alcoholic beverages and health, other than the statement required by section 215 of this title, shall be required under State law to be placed on any container of an alcoholic beverage . . . .").

92 Wyeth v. Levine, 555 U.S. 555, 568–69 (2009).

93 *Id.* at 568 ("There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things . . . if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' . . . it need not wait for FDA approval." (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C) (2008))).

94 *Id.* at 571.

Federal law does, however, preempt failure-to-warn claims against manufacturers of generic drugs.[95] The peculiar asymmetry between brand name and generic drugs arises out of the federal labeling requirements for generic drugs.[96] Generic drug manufacturers must label their products consistently with corresponding brand name drugs.[97] Amending a label to avoid state failure-to-warn liability would, accordingly, necessarily violate federal law.[98] Because generic drugs account for ninety-one percent of prescriptions filled in the United States,[99] the preemption of generic drug claims leaves many plaintiffs unable to sue under state failure-to-warn claims.

In sum, failure-to-warn claims are largely unavailable to consumers of cigarettes, alcohol, and prescription opioids, and so the contours of what a "reasonable warning" entails is left to Congress and federal agencies to determine.

B. *Common Knowledge*

Despite the major preemption issue, some failure-to-warn claims regarding addiction and health risks have been considered on the merits.[100] Examples include tobacco claims that predate the 1969 Act and claims against manufacturers of brand drugs.[101]

The success of these claims has largely depended on whether courts considered the relevant risks to be common knowledge.[102] Under the common knowledge doctrine, manufacturers are not required to provide

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95 PLIVA, Inc. v. Mensing, 564 U.S. 604, 617–18 (2011).

96 *Id.* at 618–19.

97 21 C.F.R. § 314.150(b)(10) (2016).

98 *PLIVA*, 564 U.S. at 617–18 ("State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. . . . Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. . . . It was not lawful under federal law for the Manufacturers to do was state law required of them.").

99 U.S. FDA, OFFICE OF GENERIC DRUGS 2022 ANNUAL REPORT (2022), https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report [https://perma.cc/99RC-C7BL].

100 For example, some claims related to alcohol have been considered without deciding the preemption issue. *See, e.g.*, Hon v. Stroh Brewery Co., 835 F.2d 510, 517 n.9 (3d Cir. 1987). Another major subset of these claims is based on failure-to-warn for cigarettes for occurrences prior to 1969, which are not preempted. *Id.*

101 *E.g.*, Burton v. R.J. Reynolds Tobacco Co., 397 F.3d 906, 918 (10th Cir. 2005); Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 598 (S.D. Ohio 2003).

102 *E.g.*, Badon v. RJR Nabisco Inc., 224 F.3d 382, 401 (5th Cir. 2000) (certifying a question to the Louisiana Supreme Court regarding whether a plaintiff has a cause of action over smoking due to the nature of common addiction knowledge).

instructions or warnings as to generally known risks.[103] The Restatement (Second) of Torts explains that "a seller is not required to warn with respect to products . . . when the danger, or potentiality of danger, is generally known and recognized."[104] The Restatement offered alcohol, particularly its intoxicating properties, as an example of a product that has generally known and recognized dangers.[105] The Restatement (Third) has a similar provision: a seller is not liable for failing to provide a warning for risks "that should be obvious to, or generally known by, foreseeable product users."[106]

Many courts that have considered failure-to-warn claims based on alcohol and nicotine health risks have dismissed them based on the common knowledge doctrine.[107] However, notable exceptions exist, particularly when courts found the risks at issue were not well known even though the product, like nicotine, is generally known to present risks.

For tobacco, courts have focused largely on when the addictive nature of cigarettes became common knowledge. For example, in *American Tobacco Co. v. Grinell*, the Supreme Court of Texas rejected the proposition that it was common knowledge that cigarettes were addictive in 1952.[108] In reversing summary judgment in favor of defendants, it explained that "[a]ddiction is a danger apart from the direct physical dangers of smoking because the addictive nature of cigarettes multiplies the likelihood of and contributes to the smoker's ultimate injury . . . ."[109] Similarly, the Tenth Circuit upheld a jury verdict based in part on negligent failure-to-warn of the addictive nature of cigarettes from pre-1969 activity because the addictive risks of cigarettes were not common knowledge at that time.[110] And the Ninth Circuit reversed a grant of summary judgment in favor of the plaintiffs in a pre-1969 failure-to-warn suit, reasoning that whether the addictive properties of cigarettes were common knowledge at the time was a question for the jury.[111] In contrast, the First Circuit held that the addictive nature of smoking was

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103 *E.g.*, Wright v. Brooke Grp. Ltd., 114 F. Supp. 2d 797, 810 (N.D. Iowa 2000).

104 RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. L. INST. 1965).

105 *Id.*

106 RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. j (AM. L. INST. 1998).

107 *See* James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263, 1323 & n.240 (summarizing and collecting cases).

108 Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 429 (Tex. 1997).

109 *Id.*

110 Burton v. R.J. Reynolds Tobacco Co., 397 F.3d 906, 920 (10th Cir. 2005). Preemption by federal cigarette labeling law does not apply for occurrences before the labeling law was passed. *Id.* at 914.

111 Rivera v. Philip Morris, Inc., 395 F.3d 1142, 1154 (9th Cir. 2005).

common knowledge (at least in Puerto Rico) in the 1960s, dooming a failure-to-warn claim due to the common knowledge doctrine.[112] Note, however, that all of these cases treated addiction as a binary fact. As discussed later, the binary fact of addiction may be common knowledge, but a useful quantitative assessment and other individual risk factors are likely not.[113]

The most notable success in an alcohol failure-to-warn claim came immediately before the passage of the Alcoholic Beverage Labeling Act. In *Hon v. Stroh Brewery Co.*, the Third Circuit held that the public's knowledge of alcohol-related risks from moderate drinking—rather than being common knowledge as a matter of law—was an issue for the jury.[114] William Hon consumed approximately eight to twelve beers per week for six years, purportedly leading to his death from pancreatitis.[115] His widow sued the manufacturer of the beers on a failure-to-warn theory. The trial court dismissed the claim due to obviousness of the risk, but the Third Circuit reversed, noting that a trier of fact could find that "while the amount of beer consumed by Mr. Hon was potentially lethal, the fact was known neither to him nor the consuming public."[116]

The court in *Hon* examined the Restatement's language extensively and explained that it does not preclude failure-to-warn liability for alcohol merely because it mentioned it as an example.[117] Instead, the court focused on the requirement that "the danger, or potentiality of danger is generally known and recognized."[118] It further held that "nothing in [the Restatement commentary] suggests that the consumption of alcohol for any extended period, no matter how short, in any quantity, no matter how small, presents generally known dangers."[119] In other words, the crux of the question remains whether the dangers of the particular pattern of consumption were generally known. Notably though, *Hon* remains an outlier.

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112 Cruz-Vargas v. R.J. Reynolds Tobacco Co., 348 F.3d 271, 278–80 (1st Cir. 2003).

113 *But see* Henderson & Twerski, *supra* note 107, at 1324 (criticizing "call[ing] for specificity that add[s] nothing more than useless detail to what [are] generally understood risks").

114 835 F.2d 510, 514 (3d Cir. 1987).

115 *Id.* at 511.

116 *Id.* at 514.

117 *Id.* at 515.

118 *Id.* (quoting and emphasizing RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. L. INST. 1965)).

119 *Id.* Indeed, reading comment j alongside comment i illustrates that the Restatement was referring to the danger of "mak[ing] some people drunk." RESTATEMENT (SECOND) OF TORTS § 402A cmts. i–j (AM. L. INST. 1965).

C. *Learned Intermediaries*

Prescription drug failure-to-warn claims, like the tobacco and alcohol claims discussed above, face additional barriers if they escape preemption. Generally, a manufacturer can escape liability for a failure-to-warn claim if the consumer acquires the product through a "learned intermediary" who the manufacturer did properly warn.[120] Though one can articulate the doctrine generally, courts apply it nearly exclusively to pharmaceuticals.[121] Courts reason that the manufacturer's duty is to properly inform healthcare practitioners, who in turn owe independent duties to their patients to convey the risks of any drugs they recommend and prescribe.[122]

Manufacturers of addictive pharmaceutical drugs routinely argue that the learned intermediary doctrine bars failure-to-warn claims against them.[123] For example, in *Fleming v. Endo International PLC*, the plaintiff's son received an opioid prescription while in prison to treat pain associated with an assault and cancer.[124] The plaintiff alleged that the prescriptions left her son addicted to opioids and argued that the manufacturer should have warned patients, particularly prisoners with mentall illnesses, about the risk of addiction.[125] A court in the Southern District of New York held that the manufacturer "had no duty to directly warn [the plaintiff's son] of the potential side effects of risks of taking Percocet because that was the responsibility of his physicians."[126] Similarly, in *Harris v. Purdue Pharma, L.P.*, a district court in the Southern District of Ohio relied on the learned intermediary doctrine in denying a motion to certify a class of opioid users in a failure-to-warn claim against an opioid manufacturer.[127] The court ruled that class certification was improper because analyzing whether Purdue properly warned each class member's physician, and whether those physicians in

120 *E.g.*, Ohuche v. Merck & Co., Inc., 903 F. Supp. 2d 143, 151 (S.D.N.Y. 2012).

121 Some cases have applied it to other medical products, such as medical devices and surgical implants. *See, e.g.*, Cates v. Zeltiq Aesthetics, Inc., 73 F.4th 1342 (11th Cir. 2023); *In re* Zimmer, NexGen Knee Implant Prods. Liab. Litig., 884 F.3d 746 (7th Cir. 2018).

122 *Ohuche*, 903 F. Supp. 2d at 151; *see also* Canterbury v. Spence, 464 F.2d 772, 779 (D.C. Cir. 1972) (holding that physicians have a duty to disclose material risks of treatment to their patients).

123 *E.g.*, Foister v. Purdue, 295 F. Supp. 2d 693, 705–06 (E.D. Ky. 2003) (granting summary judgment to defendant because the plaintiffs received opioids from their physicians to whom the manufacturer provided warnings).

124 No. 18 Civ. 4866, 2019 WL 4378964, at *1 (S.D.N.Y. Aug. 27, 2019).

125 *Id.*

126 *Id.* at *4.

127 218 F.R.D. 590, 596–98 (S.D. Oh. 2003).

turn properly warned the class members, would predominate the litigation.[128]

D. *Scholarly Perspectives*

Legal commentators have occasionally considered whether a product's addictive properties merit a warning to consumers.[129] However, the scholarship in the area has dwindled since the late 1980s, and this Article's authors have not identified any legal scholarship considering the subject in the past twenty-five years.[130] Alan Schwartz authored the most recent work squarely addressing whether failure to warn about a product's risk of addiction should be actionable, ultimately arguing that plaintiffs should not be able to bring a claim.[131] Later work by James Henderson and Aaron Twerski, and Jon Hanson and Kyle Logue, addressed addictive products as part of broader arguments about the scope of products liability law.[132]

Schwartz, in his article arguing that undisclosed addiction should not give rise to a failure-to-warn claim, describes three competing theories of addiction—a "strong substance caused view," a "biological view," and a "characterological view."[133] Under the strong substance caused view, Schwartz defines addictive substances as ones that "can hook (almost) anyone who consumes a nontrivial amount of it."[134] Under the biological view, "only persons with particular biological predispositions will become hooked; the remainder can consume the substance with impunity."[135] And under the characterological view, "some people choose to be addicts because, given their characters, substance abuse provides them with pleasures that exceed the (often great) pains."[136] In other

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128 *Id.* To be sure, it is not clear whether the holding in *Harris* is well-reasoned. As discussed in Part I, pharmaceutical companies typically warn providers about the risks of their drugs through the drug label made available to practitioners. A court would seemingly be able to evaluate whether a manufacturer properly warned all learned intermediaries simultaneously by evaluating the drug label.

129 *See, e.g.*, Alan Schwartz, *Views of Addiction and Duty to Warn*, 75 VA. L. REV. 509 (1989); Carter H. Dukes, Comment, *Alcohol Manufacturers and the Duty to Warn: An Analysis of Recent Case Law in Light of the Alcoholic Beverage Labeling Act of 1988*, 38 EMORY L.J. 1189 (1989).

130 *See* Karl A. Boedecker, Fred W. Morgan & Jeffrey J. Stoltman, *Excessive Consumption: Marketing and Legal Perspectives*, 36 AM. BUS. L.J. 301 (1999).

131 Schwartz, *supra* note 129.

132 Henderson & Twerski, *supra* note 107; Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163 (1998).

133 Schwartz, *supra* note 129, at 512.

134 *Id.*

135 *Id.*

136 *Id.* at 559.

words, the characterological view endorses the idea that addiction is a rational choice, and "the best way to stop [consuming addictive substances] is to alter one's character."[137] The three views indicate different optimal legal warnings. Schwartz ultimately favors the characterological view, arguing that it is most consistent with then-current scientific understanding and that, accordingly, individuals who become substance-addicted are maximizing their own welfare.[138]

For two reasons, this Article argues that Schwartz's conclusions are incorrect. First, Schwartz's conclusion that science supports what he calls the characterological view is no longer viable.[139] Rather, contemporary scientific evidence indicates that a combination of all three views is more likely.[140] Second, Schwartz treats addiction risk as though it is a binary—a product is either addictive, and likely to addict almost anyone who consumes it, or it is not and will not.[141] He does not consider what a warning might look like considering that one product can be more addictive than another, and that consumers might benefit from warnings about differential addiction rates. And he rejects the idea that consumers would change their behavior in response to warnings.[142] In essence, and as discussed in Part III, contemporary medical understandings of addiction require departing from the approach that Schwartz takes.

In a 1991 piece arguing that courts should not permit products liability suits without requiring plaintiffs to prove that a defect exists, Henderson and Twerski argue that requiring addiction warnings for alcohol or cigarettes would inappropriately impose liability on entire categories of products.[143] They argue that the dangers of chronic alcohol abuse are well-known, and that adding sufficient detail to warnings to inform the public about risks that are less well-known is impractical.[144] Indeed, because there will likely always be some additional risk warning that could be added, a requirement to provide detailed warnings about

137 Schwartz, *supra* note 129, at 513. The health economics literature was developing rational actor models of addiction during the same time period that Schwartz wrote his piece. *See, e.g.*, Gary S. Becker & Kevin M. Murphy, *A Theory of Rational Addiction*, 96 J. POL. ECON. 675, 676–80 (1988) (presenting a theoretical model of rational addiction). Contemporary work in health economics casts doubt on the rational addiction model. *See, e.g.*, Audrey Laporte, Adrian Rohit Dass & Brian S. Ferguson, *Is the Rational Addiction Model Inherently Impossible to Estimate?*, 54 J. HEALTH ECON. 161, 162–63 (2017) (arguing against rational addiction models in empirical work).

138 Schwartz, *supra* note 129, at 544–46.

139 *See infra* Part III.

140 *See infra* Part III.

141 Schwartz, *supra* note 129, at 517–23.

142 *Id.* at 548.

143 Henderson & Twerski, *supra* note 107, at 1322–26.

144 *Id.* at 1324–25.

such products could be tantamount to categorically imposing absolute liability on alcohol manufacturers.[145]

Our proposal for addiction warnings that convey how likely a consumer is to become addicted, the warning signs of early-stage addiction, and the individual risk factors do not raise the specter of endless absolute liability as Henderson and Twerski describe.[146] First, the disclosures concern very particular risks that pose a unique and salient threat to consumers. And second, these warnings are not small details that provide no new information, but rather critical pieces of information in individual decisions about whether to consume addictive goods.

In a 1997 piece arguing that ex post, consumer-driven suits are the best way of regulating cigarettes, Hanson and Logue address the role that the addictive nature of cigarettes plays in their public health harm.[147] While Hanson and Logue do not consider specifically whether warnings on addictiveness should be required, their framework is helpful for considering the question.

Hanson and Logue argue that smokers are likely to make decisions about whether to consume cigarettes in progressive fashion.[148] In other words, it is hard to imagine that anyone decides to "become a smoker."[149] Rather, individuals make incremental decisions to smoke, drink, or use opioids. And consumers may correctly estimate that the lifetime health risks of a single cigarette, drink, or pill are low. As described by Hanson and Logue, to the extent consumers underestimate the risk of addiction, "[a] smoker could smoke one cigarette at a time over the course of a lifetime without ever making a conscious decision to encounter a health risk perceived as significant."[150]

At bottom, even if a consumer is well-versed in the health risks posed by extended use of a particular addictive product, that knowledge is nearly irrelevant if the consumer strongly believes they themself will never become addicted.[151] In other words, as described by one court, "there is a considerable difference between knowing that smoking is bad and knowing that smoking is addictive."[152]

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145 *Id.*

146 Henderson & Twerski, *supra* note 107.

147 Hanson & Logue, *supra* note 132, at 1199–200.

148 *Id.*

149 *Id.* at 1196.

150 *Id.* at 1199–1200.

151 Wright v. Brooke Grp. Ltd., 114 F. Supp. 2d 797, 815 (N.D. Iowa 2000).

152 *Id.*

Contemporary tort law does not incentivize manufacturers to disclose how addictive their products are. Many claims are preempted, and those that are not often fail because of common knowledge or learned intermediary defenses. The regulatory ecosystem that permits manufacturers to avoid disclosing meaningful addiction risks has persisted for approximately fifty years without substantial change. Yet in the past fifty years, research on addiction has evolved drastically, the United States has experienced an opioid epidemic, nicotine products have meaningfully changed, and researchers have shown that Americans are dying "deaths of despair" due to substance abuse and other causes at an alarming and increasing rate.[153] As the next Part demonstrates, the evolution of addiction science and the substantial public policy concern that addiction presents require overhauling addiction warning regulation.

III. ADDICTION SCIENCE AND THE EFFECT OF RISK DISCLOSURES

Addiction science has developed significantly since the prevailing regulatory regime took shape in the latter half of the twentieth century. Indeed, as discussed in Section II.D, the most recent legal scholarship to fully explore whether addiction disclosure is appropriate was published in 1987—the very first year that the American Medical Association (AMA) officially deemed addiction to be a disease.[154] This Part examines the medical and scientific literatures to analyze how different risk disclosure regimes might impact consumer decisions to use addictive substances.

Section III.A explores relevant advances in addiction science, identifying features of individual decision-making that are useful for evaluating risk disclosure regimes. The important features this Article identifies are that addiction rates are knowable and vary by substance and identifiable individual risk factors; that consumption decisions vary with perceived addiction risk but that individuals systematically misperceive addiction risks; and that chronic use of addictive substances transforms individual preferences over those substances, often in difficult to predict ways.

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153 "Deaths of despair" generally refers to deaths from suicide, drug overdoses, or alcohol liver poisoning, particularly among middle-aged individuals. Pia Orrenius, *Anne Case and Angus Deaton: Deaths of Despair and the Future of Capitalism*, 56 BUS. ECON. 186, 186 (2021) (reviewing ANNE CASE & ANGUS DEATON, DEATHS OF DESPAIR AND THE FUTURE OF CAPITALISM (2020)). Deaths of despair have been rising in the United States during the twenty-first century. CASE & DEATON, *supra* note 153, at 143.

154 *See infra* Section II.D.

The implication of the modern framework for addiction is that accurate and nonbinary risk disclosure is necessary for consumers to make optimal consumption decisions over addictive goods. Using the framework developed in Section III.A, Section III.B evaluates the current regime and finds that it effectively subsidizes the consumption of addictive goods. A benefit-cost analysis akin to negligence demonstrates that the massive harm that addiction currently causes justifies a more detailed warning. If most individuals currently underestimate addiction risks, then they will consume more than they would if they knew how likely addiction is. Accordingly, more detailed addiction risk disclosure is appropriate.

A. *Addiction Decision-Making and Addiction Science*

The understanding of addiction as a disease meriting scientific study is relatively new.[155] Addiction has existed throughout human history, but society has generally considered it a moral failing, deserving of punishment or requiring salvation.[156] The AMA did not define alcoholism as a chronic disease until 1956.[157] In 1987, the AMA expanded its classification to other substances and described addiction in general as a disease. Likewise, the first version of the DSM, published in 1952, described addiction as a "personality disorder,"[158] while modern sources typically call addiction a "brain disorder."[159]

As the medical community's understanding of addiction as a disease developed, so too did scientific research into prevention, causes, and

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155 Peter E. Nathan, Mandy Conrad & Anne Helene Skinstad, *History of the Concept of Addiction*, 12 ANN. REV. CLINICAL PSYCH. 29, 38, 47 (2016) ("For most of recorded history, human beings viewed alcohol and drug addiction/dependence largely as actions of the gods, often as a consequence of immoral acts committed against their wishes.").

156 Yngvild Olsen, *What is Addiction? History, Terminology, and Core Concepts*, MED. CLINICS N. AM., Jan. 2022, at 1–2. While the understanding of addiction as a disease has become prominent, the rhetoric around tobacco and alcohol often still encompasses morality issues. *See, e.g.*, David G. Owens, *Products Liability: User Misconduct Defenses*, 52 S.C. L. REV. 1, 74 (2000) (referencing the "widespread publicity about the evils of drinking and smoking").

157 David J. Mersy, *Recognition of Alcohol and Substance Abuse*, 67 AM. FAM. PHYSICIAN 1529, 1529 (2003). Examples exist of isolated physicians considering alcoholism as a treatable disease. *E.g.*, Edward V. Nunes, Kevin Kunz, Marc Galanter & Patrick G. O'Connor, *Addiction Psychiatry and Addiction Medicine: The Evolution of Addiction Physician Specialists*, 29 AM. J. ADDICTIONS 390, 393 (2020) (discussing a physician who made such a claim in 1784).

158 Zhiling Zou et al., *Definition of Substance and Non-substance Addiction*, *in* 1010 ADVANCES OF EXPERIMENTAL MEDICINE & BIOLOGY: SUBSTANCE AND NON-SUBSTANCE ADDICTION 21, 23 (Xiaochu Zhang, Jie Shi & Ran Tao eds., 2017).

159 *E.g.*, *Drug Misuse and Addiction*, NAT'L INST. ON DRUG ABUSE (July 1, 2011), https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction [https://perma.cc/XQQ5-CT35].

treatment.[160] This Section examines that research, particularly developments concerning addiction likelihood, how individuals understand and evaluate addiction risks, and how addiction affects decision-making.

1. Addiction Rates Vary by Substance and Person Along Both Predictable and Unknown Dimensions

To begin, the risk that any individual becomes addicted to a substance varies by known risk factors and unidentifiable individual characteristics. The substance an individual uses and individual and environmental characteristics play a role in the risk of addiction.

Some substances are more addictive than others. While the notion that addictiveness varies by substance is not controversial, there is no universally accepted method for measuring how addictive a substance is. Common methods include capture rates and dependence scores. The capture rate represents the percentage of users that are addicted to a substance, measured as the number of current users of a substance who satisfy medical criteria for a substance use disorder divided by the total population of users of that substance.[161] For example, in 1994, researchers studying a nationally representative sample of fifteen to fifty-four-year-olds found that approximately one in four current heroin users became heroin dependent, one in three current tobacco users became tobacco dependent, and approximately one in seven current alcohol users became alcohol dependent.[162] Capture rates are intuitive, though they sacrifice nuance in favor of ease of understanding. A high capture rate does not identify, for example, the length of time or pattern of use associated with addiction.

Dependence scores, in turn, combine information about the pleasure a drug provides, as well as the physical and psychological dependence a drug causes in users, to measure how addictive substances are.[163] Researchers first proposed dependence scores as part of a "rational scale to assess the harm of drugs of potential misuse."[164] Among nineteen

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160 *See generally* David F. Musto, *Drug Abuse Research in Historical Perspective*, *in* PATHWAYS OF ADDICTION: OPPORTUNITIES IN DRUG ABUSE RESEARCH (1996) (reviewing the history of addiction research in the United States as of the late twentieth-century).

161 James C. Anthony, Lynn A. Warner & Ronald C. Kessler, *Comparative Epidemiology of Dependence on Tobacco, Alcohol, Controlled Substances, and Inhalants: Basic Findings from the National Comorbidity Survey*, 2 EXPERIMENTAL & CLIN. PSYCH. 244, 247–48 (1994).

162 *Id.* at 256–57.

163 David Nutt, Leslie A King, William Saulsbury & Colin Blakemore, *Development of a Rational Scale to Assess the Harm of Drugs of Potential Misuse*, 369 LANCET 1047, 1051 (2007).

164 *Id.* at 1047.

categories of drugs, tobacco had the third-highest dependence score, while alcohol had the sixth-highest score. Heroin, the drug they evaluated which is closest to the prescription opioids that precipitated the modern drug overdose epidemic, had the highest dependence score. Tobacco, alcohol, and heroin all had higher dependence scores than ecstasy, amphetamines, and benzodiazepines.[165] Dependence scores may be scientifically useful for comparing different substances, but they lack intuitive or objective meaning. A dependence score of "3" is quite high—but consumers would have no idea what to do with that rating, since it is a combination of other factors, without more information.[166]

Equally important as the substance used, however, are individual characteristics and circumstances of use. Research has provided significant insight into various risk factors for addiction, generally split into individual and environmental risk factors. For example, the National Institute of Health describes the following risk factors for addiction: aggressive behavior in childhood, lack of parental supervision, low peer refusal skills, drug experimentation, availability of drugs at school, and community poverty.[167] In contrast, the following factors are protective against addiction: belief in self-control, parental monitoring and support, positive relationships, good grades, school anti-drug policies, and neighborhood resources.[168] Significant evidence demonstrates that adverse childhood experiences, including experiencing or witnessing violence, familial suicide or substance use, and household instability due to parental separation or incarceration, are associated with later addiction.[169] Genetics also play a major role, with numerous studies linking genes that affect the dopaminergic system with addiction.[170]

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165 *Id.* at 1051.

166 *Id.*

167 *Drug Misuse and Addiction*, NAT'L INST. ON DRUG ABUSE, https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction [https://perma.cc/6HWZ-FSGZ].

168 *Id.*

169 *See generally* Jennifer Hays-Grudo, Amanda Sheffield Morris, Erin L. Ratliff & Julie M. Croff, *Adverse Childhood Experiences and Addiction*, *in* FAMILY RESILIENCE AND RECOVERY FROM OPIOIDS AND OTHER ADDICTIONS 91–108 (Julie Croff & Jason Beaman eds., 2021) (reviewing evidence on the relationship between adverse childhood events and addiction).

170 Philip Gorwood et al., *Genetics of Dopamine Receptors and Drug Addiction*, 131 HUM. GENETICS 803, 805–08 (2012) (reviewing evidence).

2. Consumption Decisions over Addictive Substances Vary with Perceived Risks, but Consumers Systematically Misperceive Risks

Next, individual consumption of addictive substances varies with perceived risks of those substances.[171] Researchers have found, for example, that a ten percentage point increase in the perceived likelihood of lifetime alcohol addiction made teenagers 2.2 percentage points less likely to consume alcohol.[172] Likewise, young individuals who describe quitting smoking as easy, rather than hard, very hard, or almost impossible, are fifty percent more likely to smoke.[173] Consumption decisions also vary with other perceived risks of addictive substances, including mortality and other health risks.[174] Such reactions to risks are why, for example, researchers in the addiction literature have called for changes to alcohol labeling to meaningfully disclose addiction risks.[175]

However, existing research indicates that individuals are overly optimistic about their own personal risk of addiction.[176] A consumer's belief that they will experience addiction is informed by teir own personal experience and prior beliefs, plus any knowledge gleaned from external sources, like addiction warnings.[177] The most abundant research on the topic exists for nicotine addiction, though the evidence for other substances is broadly consistent.[178]

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171 Consumption variation with addiction risk, among other risks, is one component of a rational response to addiction. However, this Article does not argue that addiction is "rational" in the same sense as Schwartz's characterological model or as in the other sources. *See supra* note 129.

172 Petter Lundborg & Bjorn Lindgren, *Risk Perceptions and Alcohol Consumption Among Young People*, 25 J. RISK & UNCERTAINTY 165, 178 (2002). Interestingly, these researchers also found evidence that young individuals in their Swedish sample overestimated alcohol addiction risks, though it is not clear whether young Americans in 2002 would have done the same.

173 Shelby Gerking & Raman Khaddaria, *Perceptions of Health Risk and Smoking Decisions of Young People*, 21 HEALTH ECON. 865, 873 (2011).

174 *E.g.*, RACHEL N. LIPARI, THE CBHSQ REPORT, TRENDS IN ADOLESCENT SUBSTANCE USE AND PERCEPTION OF RISK FROM SUBSTANCE USE (2013) (showing that individuals who perceive having five or more drinks once or twice a week as exposing users to a "great" risk are less than half as likely to engage in binge drinking); *see also* Viscusi, *supra* note 12 (showing that cigarette use decreases with perceived mortality risks of smoking).

175 Norman Giesbrecht, Emilene Reisdorfer & Isabelle Rios, *Alcohol Warning Labels: A Rapid Review with Action Recommendations*, INT. J. ENVIRO. RES. PUB. HEALTH, Sept. 2022, at 1 (summarizing evidence presented that label design components and specific health messaging are likely to "have some desired impact on knowledge, awareness of risk and even the drinking behavior" of those who see them).

176 *See* W. Kip Viscusi, *Age Variations in Risk Perceptions and Smoking Decisions*, 73 REV. ECON. & STAT. 577, 580 (1991) (explaining that consumers gain information from three sources of information—prior beliefs, individual experience, and public information).

177 *Id.*

178 *But see* Lundborg & Lindgren, *supra* note 172, at 174 (showing that Swedish teenagers overestimated the addiction risks of alcohol).

Many studies find that consumers underestimate their likelihood of cigarette addiction and overestimate their ability to quit smoking.[179] A 2016 longitudinal study examined whether adolescents are optimistically biased about the risks and benefits of cigarette smoking.[180] The researchers examined multiple measures over three years, including perceptions of the health risks, social risks, addiction risks, and benefits related to cigarette smoking.[181] While finding that adolescents were relatively accurate in their perceptions of the health risks, they underestimated the risk of addiction.[182] This finding highlights how warnings of long-term health risks may be ineffective if addiction risks are underappreciated.

Alcohol research in the United States has not determined how individual perception of alcohol addiction risk correlates with actual risk, though it is well-documented that individuals underestimate other alcohol risks.[183] Most studies have found that people are unaware that alcohol poses an increased risk of multiple cancers,[184] even though the World Health Organization deemed alcohol a Class 1 carcinogen more than thirty years ago.[185] The federal government has finally begun to recognize the cancer risks of alcohol—however, the Surgeon General released an advisory regarding alcohol and cancer risks in early 2025.[186] A 1991 study that looks at attitudes towards an addiction warning found that college-age consumers of alcohol—both frequent users and occasional/non-users—rate the believability of the warning "Alcohol is a

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179 *See* Required Warnings for Cigarette Packages and Advertisements, 21 C.F.R. § 1141 (2011) (reviewing studies in Supplementary Information II.C Consumers' Lack of Knowledge of the Health Risks).

180 *See* Lucy Popova & Bonnie L. Halpern-Felsher, *A Longitudinal Study of Adolescents' Optimistic Bias about Risks and Benefits of Cigarette Smoking*, 40 AM. J. HEALTH BEHAV. 341 (2016).

181 *Id.*

182 *Id.*

183 Daša Kokole, Peter Anderson & Eva Jané-Llopis, *Nature and Potential Impact of Alcohol Health Warnings Labels: A Scoping Review*, 13 NUTRIENTS 3065 (2021); Marc T. Kiviniemi, Heather Orom, Jennifer L. Hay & Erika A. Waters, *Limitations in American Adults' Awareness of and Beliefs About Alcohol as a Risk Factor for Cancer*, PREVENTATIVE. MED. RPT., June 2021; Tim Stockwell, Robert Solomon, Paula O'Brien, Kate Vallance & Erin Hobin, *Cancer Warning Labels on Alcohol Containers: A Consumer's Right to Know, a Government's Responsibility to Inform, and an Industry's Power to Thwart*, 81 J. STUDS. ALCOHOL & DRUGS 284 (2020).

184 Kokole, *supra* note 183, at 1 ("[I]n most studies, less than half of the respondents correctly identified the alcohol-cancer link."). A 2019 study found that sixty-six percent of U.S. adults were unaware that alcohol is a cancer risk factor. Kiviniemi, *supra* note 183, at 3–5.

185 *See* Stockwell, *supra* note 183.

186 U.S. SURGEON GEN., ALCOHOL AND CANCER RISK 3 (2025), https://www.hhs.gov/sites/default/files/oash-alcohol-cancer-risk.pdf [https://perma.cc/VJ7M-5KKE] ("Alcohol consumption is the third leading preventable cause of cancer in the United States, after tobacco and obesity.").

drug and may be addictive" the lowest of all warnings they tested.[187] Interestingly, the subjects found warnings about birth defects and driving impairments "significantly more believable" than the other warnings tested.[188] These are the only two specific warnings that are mandated on alcohol, consistent with warning labels affecting subjects' beliefs.[189]

Even opioids, which are frequently discussed as addictive in contemporary news, are subject to misperceptions about their addiction risks. In a 2016 study surveying discharged emergency department patients' perceptions of addiction risks, researchers found that, surprisingly, some patients did not know opioids were addictive, and some underestimated their personal risk of addiction, while others feared addiction.[190]

Moreover, behavioral economics and psychology research demonstrates that individuals do not rationally evaluate risks that are ambiguous.[191] An ambiguous risk is one that an individual knows exists, but which has an uncertain magnitude.[192] The current disclosure regime, which for some products requires the mere disclosure that an addiction risk exists, ensures that addiction is an ambiguous risk.[193] Researchers have found in a variety of circumstances that subjects will exhibit ambiguity-seeking behavior—meaning acting as if the probability of a risk is smaller than its perceived expected value—when the risk is a moderate or high probability negative consequence.[194] Alternatively, individuals are typically averse to low probability negative risks.[195]

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187 The researchers also tested warnings about birth defects, driving impairment, hypertension, and drug combination. J. Craig Andrews, Richard G. Netemeyer & Srinivas Durvasula, *Effects of Consumption Frequency on Believability and Attitudes Toward Alcohol Warning Labels*, 25 J. CONSUMER AFF. 323, 332 (1991) [hereinafter "1991 Warning Label Study"]; *see also* J. Craig Andrews, Richard G. Netemeyer, Srinivas Durvasula, *The Role of Cognitive Responses as Mediators of Alcohol Warning Label Effects*, 12 J. PUB. POL'Y & MKTG. 57, 65 (1993) (finding consistent results in follow-up study).

188 *See* 1991 Warning Label Study, *supra* note 187, at 334.

189 These labels would have been present on alcohol containers for approximately three years at the time the study was conducted. *Id.* at 323–24.

190 *See* Michael Conrardy et al., *Emergency Department Patient Perspectives on the Risk of Addiction to Prescription Opioids*, 17 PAIN MED. 114 (2016).

191 *E.g.*, Cass Sunstein, *Behavioral Analysis of Law*, 64 CHI. L. REV. 1175, 1191 (1997) (describing ambiguity aversion).

192 Craig R. Fox & Amos Tversky, *Ambiguity Aversion & Comparative Ignorance*, 110 Q.J. ECON. 585, 585–86 (1995).

193 *See supra* Part II.

194 *See, e.g.*, W. Kip Viscusi & Harrell Chesson, *Hopes and Fears: The Conflicting Effects of Risk Ambiguity*, 47 THEORY & DECISION 153, 154–55 (1999) (presenting evidence that individuals are ambiguity seeking for moderate and large probability losses).

195 *Id.*

Accordingly, even if consumers' average perception of addiction risks were correct, ambiguity likely leads to suboptimal consumption.

3. Chronic Use of Addictive Substances Changes Preferences

Finally, addictive drugs change an individual's preferences for future consumption of the substance. Addictive substances do so by causing durable changes to the brain itself.[196] Specifically, using addictive substances alters the neurons involved in reward, stress, or self-control.[197] As addictive substances reach the brain, they trigger large surges of dopamine (the primary chemical that functions as a reward in the brain), to which neural pathways adapt by becoming less sensitive.[198] Recent developments in brain imaging technology have enabled researchers to directly observe the effect of addictive substances on brain structure and function.[199] The products capable of causing fundamental changes to brain function, structure, and chemistry include the prototypical addictive products, including alcohol, cannabis, cocaine, hallucinogens, inhalants, nicotine, opioids, other stimulants, and sedatives.[200]

Functional changes to the brain cause individuals who suffer from addiction to exhibit drug-seeking behavior, as the perceived need for the drug increases and the cost of not using grows. Individuals with more intense substance use disorders exhibit changes to their brain chemistry in which the motivation to acquire and use drugs overpowers the drive for other goals.[201] In other words, the desensitization that occurs in the brain due to the dopamine surge from addictive substances makes other sources of dopamine less important in comparison to the substance to which the brain has acclimated. Likewise, not using drugs typically leads to deeply painful or uncomfortable withdrawal that users will seek to

196 Zou et al., *supra* note 158, at 23–24 (noting addiction "causes stable changes in the brain at the molecular and cellular level").

197 *Id.*; *Drugs and the Brain*, NAT. INST. ON DRUG ABUSE (July 1, 2011), https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drugs-brain [https://perma.cc/6RTF-EYZ7].

198 *How an Addicted Brain Works*, YALE MED. (May 25, 2022), https://www.yalemedicine.org/news/how-an-addicted-brain-works [https://perma.cc/VRB9-BF3K].

199 Alexandra Hayes, Katherine Herlinger, Louise Paterson & Anne Lingford-Hughes, *The Neurobiology of Substance Use and Addiction: Evidence from Neuroimaging and Relevance to Treatment*, 26 B.J. PSYCH ADVANCES 367, 367 (2020); Nora D. Volkow, Joanna S. Fowler & Gene-Jack Wang, *The Addicted Human Brain: Insights from Imaging Studies*, 111 J. CLINICAL INVESTIGATION 1444, 1444 (2003).

200 *See Mental and Behavioral Disorders Due to Psychoactive Substance Use*, ICD10DATA, https://www.icd10data.com/ICD10CM/Codes/F01-F99/F10-F19 [https://perma.cc/D26T-SCWF] (providing diagnosis codes for disorders associated with the listed substances).

201 Hayes et al., *supra* note 199, at 368.

avoid. Researchers have found that more intense withdrawal symptoms are associated with a greater likelihood of future use.[202] The physical changes to the brain differentiate addictive substances from other goods for which consumers discover or develop their preferences as they use or search for them.[203] Sugar, for example, is not generally recognized as addictive, despite chronic use or strong urges for use.[204]

B. *The Need for Addiction Warnings*

The prevailing risk regime is out of step with scientific understanding.[205] A consumer evaluating whether to fill an opioid prescription or try vaping currently sees a warning that identifies the product as addictive, but not any information as to how likely addiction is. As the prior Section demonstrated, binary risk addiction is inconsistent with scientific understanding of decision-making over addictive products. Consumers do not know how often the average person gets addicted, much less what risk factors they might have that are associated with above average or below average risks. Buyers of alcohol receive even less information and must rely entirely on their prior beliefs to assess the addiction of the products they purchase.

It is suboptimal for consumers to make purchases in the face of incomplete information when manufacturers can effectively provide that information at relatively low cost. Whatever merit a simple binary disclosure may have had when prevailing regimes were adopted, the evolution of scientific information illustrates that it is incomplete today. Consumer misinformation in the absence of that information likely causes consumers to over-purchase addictive products.

Ideally, consumers would have full information about addiction risks and would consume products accordingly. However, this information is often unknowable to consumers. In a second-best world, consumers' knowledge would reflect the most up-to-date scientific consensus on addiction risk. Any difference between scientific knowledge

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202 Frank J. Meye, Massimo Trusel, Mariano Soiza-Reilly & Manuel Mameli, *Neural Circuit Adaptations During Drug Withdrawal—Spotlight on the Lateral Habenula*, 162 PHARMACOLOGY BIOCHEMISTRY & BEHAV. 87, 88 (2017) ("In subjects with substance use disorder, positive correlations have been reported between the intensity of withdrawal symptoms such as anhedonia, and the degree of drug craving . . . .").

203 *See generally* Jason Delaney, Sarah Jacobson & Thorsten Moenig, *Preference Discovery*, 23 EXPERIMENTAL ECON. 694, 694 (2019) (demonstrating how consumers that discover preferences through use make consumption decisions).

204 *E.g.*, Margaret L. Westwater, Paul C. Flethcer & Hisam Ziauddeen, *Sugar Addiction: The State of the Science*, 55 EUR. J. NUTRITION 55, 56–58 (2016).

205 *See supra* Part I.

and general consumer knowledge represents a functionally hidden risk that disclosure can remedy. Manufacturers can disclose capture rates or other easily externalizable information about addiction risk to harmonize consumer information and scientific knowledge.

Knowing that the current regime is inconsistent with science and that there exists information that could promote better consumer decisions, this Article next considers whether it is reasonable to require manufacturers to do so as a matter of tort law. This Section sets aside the legal barriers of preemption and the common knowledge doctrine. Recall that the doctrine of failure-to-warn in torts is rooted in the concept of negligence.[206] Under a basic Hand Formula framework, a higher expected loss calls for more extensive burdens to be taken to avoid that loss. In line with this concept, in the context of products liability claims, "[w]hen possible harm is severe, quite specific information may be required."[207]

Both on an individual and a societal level, harm from addiction is, indeed, quite severe. Addiction causes seriously increased morbidity and mortality and, in the case of alcohol and opioids, serious problems on a social, familial, and career level. And on a societal level, approximately 700,000 people die in the United States each year from addictive products and millions more suffer from addiction.[208] The magnitude of harm attributable to addiction is staggering. It accordingly justifies significant care on the part of manufacturers, particularly through specific disclosure. And yet, the current regime requires essentially no disclosure, even though a negligence framework suggests that no other product calls for precautions as extensive.[209]

Courts have generally not examined the appropriate level of disclosure due to the common knowledge doctrine. In considering the common knowledge doctrine, this Article notes that the commentary to the Restatement (Third) of Torts: Products Liability specifies that warnings of obvious risks "*in most instances* will not provide an effective additional measure of safety."[210] In contrast, manufacturers can reduce addiction risks by providing more specific information. The risk is complicated and often misunderstood, and consumers are likely to act as if they are excessively optimistic about it.[211] In other failure-to-warn contexts, courts have held that warning consumers a risk exists may be

206 *See supra* Part II.

207 DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, THE LAW OF TORTS § 465 (2d ed. 2024).

208 *See supra* note 1.

209 *See supra* Parts I–II.

210 RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. j (AM. L. INST. 1998) (emphasis added).

211 *See supra* Section III.A.

insufficient if a manufacturer does not provide information about likely rates of injury.[212]

Of course, manufacturers cannot be required to disclose a particular consumer's precise risk of addiction to a particular substance because that probability is unknowable based on the current state of science. However, certain characteristics of the substance itself, patterns of use, and the consumer are predictive of addiction. For instance, smoking a cigarette one time presents a significantly lower risk of addiction from smoking one pack of cigarettes per day for an entire month. Ensuring that consumers are aware of when standard use has crossed into risky use is important to allow informed consumer decision-making. Equally important is informing consumers about the relative addictive propensities of the substance they are using.

Any regulation should also consider the distribution of responsibility between manufacturers and consumers. The commentary of the Restatement (Third) of Torts: Products Liability explains that part of achieving optimal safety involves "requiring individual users and consumers to bear appropriate responsibility for proper product use."[213] Of course, one can argue that the millions of individuals who become addicted to alcohol, nicotine, or opioids in any given year have not "borne appropriate responsibility" for the use of these addictive products. And the state of the law suggests that is the determination that has been made.[214] But, as argued throughout this Article, consumers' ability to bear appropriate responsibility hinges on knowledge of information that is currently unavailable to them or difficult to access. Furthermore, to the extent society would benefit from expanding understanding of addiction through research, the cost is currently borne by the public in general, rather than the manufacturers that profit from addiction and are likely to have more relevant information than the scientific community. It is accordingly likely that it would cost manufacturers less to determine capture rates and similar information for their products than the public.

Lawmakers should seriously consider whether, under the current disclosure regime, consumers have the necessary information to make informed choices and to bear appropriate responsibility as to their consumption of addictive products. In sum, when deciding whether to take up use of an addictive substance, or cut back on current substance use, a variety of information could be helpful. While none is perfect, as

212 *See* Cisson v. Bard, No. 11-cv-00195, 2013 WL 5700513, at *7 (S.D. W. Va. 2013) (summarizing cases).

213 RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. j (AM. L. INST. 1998).

214 *See supra* Parts I–II.

everyone's risk factors are unknowable, they at least provide significantly more information than the baseline binary "addictive" or "not addictive."

IV. ADDICTION RISK REFORM

This Part provides our proposal for reforming addiction risk disclosures. Section IV.A details our proposed framework and explains how it solves the problems with the current regime discussed above. Section IV.B considers alternative approaches and determines that they are less desirable.

A. *Two-Pronged Risk Disclosure*

As discussed above, optimal addiction risk disclosure must exhibit several characteristics.[215] First, and perhaps most importantly, it should provide consumers with the material information necessary to choose whether to consume an addictive product. Second, decisions regarding what products require addiction risk disclosure, what information manufacturers should provide, and how they should disclose those risks should reflect contemporary scientific expertise on the addictive product and effective information disclosure. Third, it should impose the costs of generating addiction risk information on manufacturers rather than the public. Finally, the system should provide both retrospective relief by compensating individuals who have been addicted following inadequate disclosure and prospectively induce information disclosure.

This Article proposes a two-pronged system of addiction risk disclosure regulation, which combines regulatory and private law tools to incentivize businesses to sufficiently inform disclosure. First, agencies with relevant regulatory authority, such as the FDA, the Bureau of Alcohol, Tobacco, and Firearms,[216] or the Consumer Products Safety Commission, should promulgate regulations requiring manufacturers of products that are known or should be known to be addictive to label their products with sufficiently detailed information about addiction and abuse.[217] Agencies should also pair the disclosure requirement with an

215 *See supra* Part III.

216 27 C.F.R. §§ 5.1–5.236 (2022).

217 To be sure, there is a meaningful possibility that the various agencies with authority over addictive products would adopt inconsistent standards for addiction disclosure. It does not undermine the thrust of our argument if, for example, alcohol disclosure includes an extreme level of detail while cigarette manufacturers merely disclose capture rates. Indeed, the current regime includes significant inconsistency by product. *See supra* Sections II.A–III.A.

obligation to investigate the addictive propensities of their products whenever a reasonable manufacturer would suspect their product is addictive. Second, state courts should hold a manufacturer liable in tort under a failure-to-warn products liability theory if the manufacturer fails to adequately warn consumers about material addiction risks of which the manufacturer knew or should have known. The two-pronged approach accomplishes the goals this Article has identified.

Regulatory requirements that manufacturers of addictive products disclose all material information regarding addiction risks does not require disclosure of all relevant data but should require manufacturers to disclose high-level quantitative information about addiction risks.[218] The disclosure of quantitative information is critical because reasonable consumers could make very different consumption decisions based on differing quantitative assessments.[219] As discussed above, nicotine products currently bear a label stating, "WARNING: This product contains nicotine. Nicotine is an addictive chemical."[220] If a consumer already knows that nicotine is addictive—as most of the public does[221]—a mere binary statement that nicotine is addictive will not cause any shift in the estimated risk of nicotine addiction.[222]

But informing consumers that the risk is much larger than they intuit may well matter. A far more useful label could read "WARNING: More than two-thirds of people who try cigarettes become daily

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218 *Cf.* Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972) ("[A] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significant to the risk or cluster of risks in deciding whether or not to forego the proposed therapy." (quoting Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U. L. REV. 628, 630–35 (1970))).

219 Viscusi & Hakes, *supra* note 12, at 50 tbl. 2 (showing that cigarette consumption varies with risk information).

220 *See supra* Section I.B.

221 *E.g.*, *New APA Poll Finds Americans Rate Cigarettes as Most Unsafe, Addictive Substance Among Options Surveyed*, AM. PSYCHIATRIC ASS'N (June 8, 2023), https://www.psychiatry.org/news-room/news-releases/new-apa-poll-finds-americans-rate-cigarettes-as-mo [https://perma.cc/FTB3-U5FC] (presenting poll in which eighty-seven percent of respondents said cigarettes are very or somewhat addictive).

222 Economists and psychologists often model learning about risk using a Bayesian learning model. *See, e.g.*, Mahmoud A. El-Gamal & David M. Grether, *Are People Bayesian? Uncovering Behavioral Strategies*, 90 J. AM. STAT. ASS'N 1137, 1142–43 (1995). Under such a model, individuals have prior risk beliefs which they update in response to new information. *See, e.g.*, Jacob P. Byl & W. Kip Viscusi, *Experimental Study of Consumer Responses to Difference Sources of Information about Prescription Drugs*, 186 J. ECON. BEHAV. & ORG. 754, 765–67 (2020) (showing that survey respondents updated their risk beliefs based on whether they viewed pharmaceutical advertisements that made a drug seem safe or attorney advertisements that made a drug seem dangerous). If consumers already know that addictive products present a risk of addiction, a disclosure that the risk exists at all provides no new information and will not induce an update.

smokers."[223] Similarly, physicians or their patients may be willing to set aside a warning that opioids present an amorphous risk of addiction and abuse but may pause if labels informed them that one out of three users who receive a thirty-day prescription are still using opioids a year later.[224] The quantitative information allows customers to make consumption decisions on the basis of updated and more accurate risk beliefs, rather than their preexisting notions.

Materiality is a manageable standard for agencies to administer and courts to interpret. Indeed, tort law has long required physicians to provide their patients with the material risks of treatment under-informed consent law.[225] Under the doctrine, physicians who do not inform patients about a material risk of a recommended treatment can be liable if the risk manifests and the patient is harmed.[226] To determine whether a risk is material, courts consider the magnitude of the risk and the degree of harm that occurs if the risk manifests.[227] Our proposed approach similarly requires agencies and courts to identify the information that would be material to individual decision-making and require its disclosure. If the risk of addiction is sufficiently large that it may affect an individual's choice of whether to consume a product, then agencies should require manufacturers to prominently disclose that risk on the product, and courts should hold defendants liable if they fail to do so.

Agency involvement increases the likelihood that disclosure regulations reflect current scientific consensus. Part III explored in depth the ways in which addiction science and our understanding of effective risk disclosure are complicated and evolving. Agency staff can employ scientific expertise to make sure that current approaches reflect best practices. For example, current research indicates that while graphic pictures on cigarette packages may prompt consumers to reflect more on cigarette risks, they often fail to change users' perceived likelihood and severity of harm.[228] In contrast, presenting statistical risk information in

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223 Max Birge, Stephen Duffy, Joanna Astrid Miller & Peter Hajek, *What Proportion of People Who Try One Cigarette Become Daily Smokers? A Meta-Analysis of Representative Surveys*, 20 NICOTINE & TOBACCO RSCH. 1427, 1427–28 (2018).

224 Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—Untied States, 2006–2015*, 66 MORBIDITY & MORTALITY WKLY. REP. 265, 266–68 (2017).

225 Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972).

226 *Id.*

227 *See, e.g.*, Collins v. Juergens Chiropractic, PLLC, 467 P.3d 126, 135–36 (Wash. Ct. App. 2020) (explaining that a risk must be sufficiently serious and likely to require disclosure).

228 Seth M. Noar, Jacob A. Rohde, Joshua O. Barker, Marissa G. Hall & Noel T. Brewer, *Pictorial Cigarette Pack Warnings Increase Some Risk Appraisals But Not Risk Beliefs: A Meta-Analysis*, 46 HUM. COMMC'N RSCH. 250, 251–52 (2020).

pictorial format, rather than numerical, significantly increases comprehension.[229] But not all graphs are created equal, and expert input may be necessary to determine the optimal method for communicating a particular risk to different types of consumers.[230] Indeed, whether a particular product presents addiction risks at all will, in some cases, require expertise. Beyond expertise, agencies are nimbler than courts or legislatures and better able to incorporate new risk information or new techniques into product labels.

While agencies' subject matter expertise enables them to incorporate contemporary scientific understanding, they still might not do so without a complementary tort regime. The current regime for prescription drugs would permit the FDA to require drug manufacturers to label their products with quantitative information regarding addiction; but the FDA does not do so, presumably because it does not believe that the additional quantitative detail for which this Article calls is necessary for providers and patients to determine whether patients should have a particular prescription. Tort lawsuits concerning whether a particular warning is adequate would provide the FDA with information about whether reasonable consumers view a particular view as adequate. Moreover, the discovery process can reveal fully hidden risks to the public and the FDA that otherwise would not come to light.[231]

Finally, the two-pronged approach serves to ensure that harmed consumers can get relief and businesses have adequate incentives to disclose addiction risks prior to suit. If the agencies appropriately calibrate their regulations, manufacturers of addictive products will be required to disclose all reasonably known material risks before selling their products. If the agency requirements work as intended, then in theory, firms would never actually fail to adequately disclose addiction risks. But agencies may make mistakes and occasionally require too little disclosure, the consequences of not disclosing may be too small, or addiction risks may not become known until after a substantial population of consumers have become addicted. In those cases, tort law serves as a backstop to ensure that companies have a financial incentive to discover and disclose risks.[232] The tort component also serves to ensure

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229 *E.g.*, Melanie Price, Rachel Cameron & Phyllis Butow, *Communicating Risk Information: The Influence of Graphical Display Format on Quantitative Information Perception—Accuracy, Comprehension and Preferences*, 69 PATIENT EDUC. & COUNSELING 121, 125–26 (2007).

230 Jessica S. Ancker, Yalini Senathirajah, Rita Kukafka & Justin B. Starren, *Design Features of Graphs in Health Risk Communication: A Systematic Review*, 13 J. AM. MED. INFORMATICS ASS'N 608, 610–14 (2006) (reviewing evidence that different types of graphical evidence are more useful in conveying risks).

231 Wyeth v. Levine, 555 U.S. 555, 579 (2009) ("State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.").

232 *See supra* Part II.

that consumers who were harmed can recover for their losses. Combining prospective and retrospective relief contributes to an ideal outcome.

The mirrored nature of the two-pronged approach also ensures that there is minimal risk of overregulation. As discussed, the same standard—disclosure of material risks—would apply to both agency regulations and failure-to-warn suits. The mirrored approach stands in stark contrast to the preemption approach that exists now,[233] which as explored above, results in substantial under-disclosure of alcohol and tobacco risks. Having the same approach apply in both legal contexts should result, on average, in the same incentives for defendants.

B. *Alternatives Examined*

This Section briefly considers two possible alternative reforms to our proposal. Section IV.B.1 considers whether regulation and tort intervention are necessary at all, given that public health campaigns can inform consumers about the magnitude of addiction risks. While public health campaigns could potentially reveal information to consumers, they are likely more expensive than manufacturer disclosure and require the public to bear a cost that manufacturers should bear. Section IV.B.2 considers whether self-regulation is possible, concluding that it is unlikely to achieve desirable outcomes.

1. Public Health Campaigns

Instead of requiring manufacturers to disclose information about addiction risks, federal agencies and state governments could use public health campaigns to broadly inform consumers about addiction risks. This Article uses the term "public health campaign" broadly, referring to any initiative from federal, state, or local governments to inform citizens about the risks of addiction and its consequences, or behaviors that combat addiction. Currently, the federal government, through the Department of Health and Human Services, sponsors numerous public health campaigns, including several to reduce drug abuse, alcohol abuse, and tobacco use.[234] Likewise, the Substance Abuse and Mental Health Services Administration maintains a national helpline that anyone can

233 *See supra* Parts I–II.

234 *See Public Health Campaigns*, NAT'L INST. HEALTH, https://prevention.nih.gov/research-priorities/dissemination-implementation/nih-public-health-campaigns [https://perma.cc/UFD3-7D8Y] (identifying several public health campaigns that the federal government funds).

call for treatment referral or general information on addiction.[235] The state governments are also very actively engaged in public health campaigns. The New York State Department of Health, for example, launched an overdose prevention campaign in July 2023 to encourage the public to carry naloxone, a drug used to reverse ongoing opioid overdoses.[236] Likewise, Virginia recently expanded its "Right Help, Right Now" campaign, committing $500 million to help address substance abuse disorder in the state through treatment and information.[237]

Unlike the regulatory and litigatory reform this Article proposes, there are few legal constraints on public health campaigns as a method of disclosing information risks. Such campaigns are generally an exercise of the federal or state governments' spending powers.[238] Under the federal Constitution, Congress may engage in public health campaigns if they are in pursuit of the general welfare, do not coerce states into participating, and do not run afoul of an independent constitutional provision, such as prohibitions on racial discrimination.[239] State authority will generally be a question of state law, but unless a state law or another legal authority prohibits a particular kind of campaign, states will be free to spend money on public health campaigns as they see fit. [240]

The real constraints on public health campaigns then are political and financial. Entities must allocate funds, but helping individuals suffering from addiction is not generally a popular political position due to stigma associated with addiction, as discussed in Part III.[241]

The core problem with a publicly financed approach to addiction risk disclosure is that public health authorities are unlikely to be the lowest cost disclosers of risk information. Manufacturers of addictive products have often engaged in extensive research about the risks of those products and are significantly better situated to discover further

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235 *SAMHSA's National Helpline*, SUBSTANCE ABUSE MENTAL HEALTH SERV. ADMIN., https://www.samhsa.gov/find-help/national-helpline [https://perma.cc/9UBE-5GC2].

236 *New York State Department of Health Launches Campaign Emphasizing Importance of Carrying Naloxone*, N.Y. STATE DEP'T. OF HEALTH (July 12, 2024), https://www.health.ny.gov/press/releases/2023/2023-07-12naloxone.htm [https://perma.cc/JM92-RVEP].

237 Press Release, Office of the Governor Glenn Youngkin, *Governor Glenn Youngkin Unveils Youth Mental Health Strategy on the One-Year Anniversary* (Dec. 14, 2023), https://www.governor.virginia.gov/newsroom/news-releases/2023/december/name-1019004-en.html [https://perma.cc/W2F-2ZG8].

238 *See, e.g.*, Dobkin v. Johns Hopkins Univ., 1995 WL 45789, at *2 (D. Md. Jan. 19, 1995) (noting that a program that provided funding for public health research and publication support was "an exercise by the federal government of its authority under the spending power to bring about a public policy goal" (quoting United States v. Vanhorn, 20 F.3d 104, 112 (4th Cir.1994))).

239 South Dakota v. Dole, 493 U.S. 203, 207–08 (1987).

240 U.S. CONST. amend. X.

241 *See supra* Part III.

information and convey that information to the public than state governments.[242] Regulation would require manufacturers to disclose that existing research, whereas a public health campaigns approach would require the state to fund research into addiction instead. The costs of generating information regarding risks is at least duplicated, and potentially more, if the manufacturers experience returns to scale in their research.

Beyond generating unnecessary costs, shifting the burden of funding addiction research and disclosure onto the public is unfair and inefficient. If public health campaigns are the primary method of disclosing risks, then the public effectively subsidizes the addictive products. In other words, selling addictive products creates an externality[243] that the public bears, rather than forcing manufacturers to internalize the costs of creating sufficient addiction information.

Regulatory and private law duties to disclose addiction risks, in turn, compel manufacturers to bear the costs of addiction risks, rather than the public. Under the current regime, the public must bear at least two kinds of costs: the public health costs from addiction and the costs of discovering risk and disseminating information in public health campaigns. This Article's proposal reduces the first set of costs and causes manufacturers to bear the second. Because manufacturers will be held strictly liable in products liability cases if they do not adequately disclose material risks, they will do so, assuming that disclosure is cheaper than the damages they would incur from failing to disclose.[244] Manufacturers will then include the costs of disclosure, including researching risks in their products as necessary, and increasing the price to reflect the total social cost of the product, including disclosed information. Consumers

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242 U.S. FDA, ASSESSMENT OF ABUSE POTENTIAL OF DRUGS, *supra* note 23 (providing guidance on when manufacturers of drugs should investigate addiction risks).

243 An externality exists whenever someone other than the manufacturer or consumer of a product bears a cost associated with the product's manufacture or consumption. Relatedly, the literature sometimes refers to negative "internalities"—when present consumption imposes a cost on one's future self. *See, e.g.*, Brian Galle, *The Problem of Intra-Personal Cost*, 18 YALE J. HEALTH POL'Y, L., & ETHICS 1, 6 (2018).

244 Joseph A. Page, *Generic Product Risks: The Case Against Comment K and For Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 884–85 (1983) ("Indeed, assuming that manufacturers foresee that, under negligence principles, not every injured plaintiff will recover full damages for harm from a particular design feature or warning, the application of strict liability to all generic hazards, known and unknown, will increase the prospect of full recovery, encouraging safety expenditures and accident avoidance."). This is generally true. The manufacturer's costs from disclosure would include research costs, which may be expensive but are unlikely to exceed the social costs of excess addiction due to uninformed consumers, and lost profits from consumers who choose not to purchase upon learning true addiction risks. But a manufacturer cannot argue that it should not need to warn consumers about risky products because they might lose business—that would undermine the very purpose of failure-to-warn law.

will demand less of the product at any price in response to the new information. Eventually, the market will reach a new equilibrium where the company makes fewer sales to only those consumers who are willing to tolerate the known addiction risks, and the company has lost profits representing the cost of disclosing information about its own addictive profits. Such an arrangement is preferable to the public bearing those costs as a matter of fairness and total social welfare.

2. Self-Regulation

Another possible approach to the problem of addiction disclosure would be deregulation, permitting competitive forces to incentivize firms to disclose their own addiction risks so that consumers prefer their products to the products of their competitors. If addictive compounds exhibited substantial heterogeneity between manufacturers, and consumer demand responded adequately to disclosure of the differences between manufacturers, then self-regulation could be an adequate alternative to the more expensive and interventionist proposal that this Article offers.[245]

However, contemporary efforts to self-regulate disclosure among manufacturers of addictive products suggest such efforts would fail. For example, consider the guidelines that major alcohol trade associations have adopted. The Beer Institute, the Wine Institute, and the Distilled Spirits Council of the United States have all adopted self-imposed advertising and marketing guidelines.[246] One major focus of the codes is to ensure advertising does not intentionally target underage drinkers.[247] However, the codes all have very little to say about health disclosure.[248] Indeed, the strongest provisions only mimic the requirements of the TTB, prohibiting scientifically unsubstantiated or misleading health claims.[249]

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245 A. Mitchell Polinsky & Steven Shavell, *Mandatory Versus Voluntary Disclosure of Product Risks*, 28 J.L. ECON. & ORG. 360, 362–65 (2010) (proposing a model of product risk disclosure in which firms choose what risks to disclose).

246 BEER INST., ADVERTISING & MARKETING CODE (2023), https://www.beerinstitute.org/policy-responsibility/responsibility/advertising-marketing-code [https://perma.cc/TW4H-PH89]; WINE INST., WINE INSTITUTE'S CODE OF ADVERTISING STANDARDS (2011), https://wineinstitute.org/our-work/responsibility/social/ad-code [https://perma.cc/UL5K-87LB]; DISTILLED SPIRITS COUNCIL OF THE U.S., CODE OF RESPONSIBLE PRACTICES FOR BEVERAGE ALCOHOL ADVERTISING AND MARKETING (2023), https://www.distilledspirits.org/wp-content/uploads/2023/06/DISCUS_CodeofResponsiblePractices_2023.pdf [https://perma.cc/J5F9-HTM6].

247 *See supra* note 246.

248 *Id.*

249 *Compare* 27 C.F.R. § 4.39 (2024) (prohibiting practices for labeling wine), *with* 27 C.F.R. § 5.129 (2024) (distilled spirits), *and* 27 C.F.R. § 7.129 (2024) (malt beverages—includes beer).

None of the codes make any mention of the addictive properties of alcohol.[250]

Historical competition between tobacco manufacturers further indicates that self-regulation is unlikely. First, while it is possible to manufacture cigarettes that are more or less addictive,[251] tobacco manufacturers have not historically competed by marketing products that are healthier than their competitors' products. Accordingly, it is unlikely that a deregulatory approach to addiction risk disclosure would successfully resolve the information gaps identified above.

V. CONCLUSION

The addiction crisis in the United States continues, aided by a regulatory regime that does not require manufacturers to disclose addiction risks and does not hold them civilly liable for failing to do so. As a result, the public bears the cost of consumer misperceptions of addiction risks, including death and other health injuries, while manufacturers enjoy the implicit subsidy that information gaps between them and consumers create. Contemporary medical understanding of addiction confirms that the current outdated legal approach is premised on a misunderstanding of how addiction works and how accurate consumer perceptions of addiction risks are.

Accordingly, substantial reform is necessary. This Article has argued that an ideal system of disclosure would require manufacturers to disclose all material information about addiction risks, including addiction rates and patterns of use correlated with increased addiction risk. Regulation and tort law should both play a role in that system to give manufacturers sufficient incentive to disclose risks and to mutually reinforce the advantages of both approaches.

250 *See supra* note 246.

251 *E.g.*, Eric C. Donny & Cassidy M. White, *A Review of the Evidence on Cigarettes with Reduced Addictiveness Potential*, 99 INT'L J. DRUG POL'Y 1, 2 (2022).