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Time to Bite the Bullet? How an Emboldened FDA Could Take Aim at the Firearms Industry

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Time to Bite the Bullet? How an Emboldened FDA Could Take Aim at the Firearms Industry

LARS NOAH

Firearms continue to cause tremendous losses in the United States, prompting increasingly frustrated calls for a public health response to this endemic problem. Although Congress has legislated repeatedly on the issue over the last century, it has not managed to do anything remotely comprehensive in the aggregate. This Article offers a radical new approach that has gone entirely unnoticed. Much as it tried to do a quarter of a century ago in asserting jurisdiction over tobacco products, the U.S. Food and Drug Administration (FDA) could try to use its “device” authority to rein in companies that manufacture firearms and accessories with far too little oversight at present. Device jurisdiction brings with it a wide range of powers that would give the agency tremendous flexibility in designing various ways of making guns and ammunition less hazardous to the community. Such an initiative would confront serious political hurdles, of course, to say nothing of an undoubtedly skeptical response by the federal judiciary on both statutory and constitutional grounds. Nonetheless, as happened with the FDA’s ultimately unsuccessful tobacco product rulemaking, simply making the effort might generate some much-needed momentum for seriously addressing this scourge.

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Time to Bite the Bullet? How an Emboldened FDA Could Take Aim at the Firearms Industry

LARS NOAH*

I often think we should have tattooed on the back of whatever hand we use to shoot or write, "I might be wrong."

– Louise Penny, *A Fatal Grace* (2007)

INTRODUCTION

Twenty-five years ago, the U.S. Food and Drug Administration (FDA) promulgated a rule premised on its novel assertion of authority over tobacco products.¹ Four years later, the industry's challenge reached the Supreme Court, and the agency's controversial effort came within one vote of succeeding.² Even in failure, the FDA's high-profile but short-lived initiative apparently had a lasting impact on public attitudes about the responsibility of the tobacco industry,³ ultimately prompting Congress to delegate explicit though more limited regulatory authority to the agency.⁴

I have long railed against the FDA's seemingly lawless behavior.⁵ You know what they say: if you can't beat them, join them. In the course of

* Chesterfield Smith Eminent Scholar and Professor of Law, University of Florida; author, *Law, Medicine, and Medical Technology* (Foundation Press 5th ed. 2022). For my interview about this project, hosted by the Center for Firearms Law at Duke University as part of its scholarship highlight series, see <https://firearmslaw.duke.edu/2021/01/scholarship-highlight-interview-noah-on-fda-gun-regulation/>.

¹ See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,615–18 (Aug. 28, 1996) (codified at 21 C.F.R. pt. 897 (1997)).

² See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); see also *infra* Part II.B (discussing the Court's decision at length).

³ See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2161 (2000) (“[T]he FDA first broke the story concerning the internal tobacco industry records and witnesses as a prelude to its rulemaking effort in this area. The lawyers who later capitalized on these disclosures might never have uncovered the documents or whistleblowers without the agency's initiative.” (footnote omitted)).

⁴ See Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, Div. A, tit. I, 123 Stat. 1776, 1783–842 (codified as amended in scattered sections of 21 U.S.C.); see also Eric N. Lindblom, *What Is “Appropriate for the Protection of the Public Health” Under the U.S. Tobacco Control Act?*, 74 FOOD & DRUG L.J. 523, 524–33 (2020) (summarizing the legislation and the agency's limited initial attempts at implementation); *id.* at 584 (“[I]n those first ten years, FDA has not implemented a single substantive rule to produce major reductions in the ongoing toll of unnecessary death, disease, and disability caused by smoking.”).

⁵ See, e.g., Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 122–24, 138 (2014); Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 924 (2008) (“[O]ver the course of a century of struggling to protect the public health with its limited statutory powers and often inadequate resources, the FDA evidently has institutionalized a practice of cavalierly ignoring legal constraints.”).

criticizing the agency's tobacco rulemaking and imagining a parade of horrors, I wondered in passing whether it might next turn its sights on guns.⁶ In retrospect, that no longer strikes me as such a crazy idea, though I have searched in vain for anyone else previously having made such a proposal,⁷ so this Article attempts to construct a serious case for targeting manufacturers of firearms and ammunition.⁸ As happened with the FDA's astonishing effort to tackle tobacco products in the mid-1990s, such an initiative likely would fail in the end, but it nonetheless might usefully move the national conversation too long dominated by friends of the industry in a more constructive direction that paid greater attention to the public health consequences of our national obsession with guns.

Obviously, the previous occupant of the White House would never have tolerated such a move,⁹ and even the moderate Democrat who replaced him might hesitate before getting behind what paranoid gun owners would view as an assault on their precious Second Amendment rights.¹⁰ Nevertheless,

⁶ See Lars Noah, *Snuffing out the FDA's Tobacco Restrictions*, HEALTH L. NEWS, Sept. 2000, at 7.

[W]hat if this ever entrepreneurial agency decided to pursue what the CDC has identified as one of our latest public health scourges—namely, guns and ammunition? It's less far-fetched than one might imagine: handguns clearly are intended to affect the structure or function of the body, though FDA officials have reassured Congress that the agency would not utilize its authority over medical devices in order to restrict the sale of such products.

Id. at 15; see also Lars Noah, *Regulating Cigarettes: (Non)sense and Sensibility*, 22 S. ILL. U. L.J. 677, 691 & n.63 (1998) (concluding that “the Agency should not be free to ignore the outer boundaries of its delegated authority in pursuit of a well-meaning crusade against a public health problem,” and citing the FDA's previously expressed position that it would not attempt to regulate firearms).

⁷ See *infra* note 14.

⁸ In contrast, I have elaborated on other crazy ideas entirely in jest. See, e.g., Lars Noah, “*Go Sue Yourself!*” *Imagining Intrapersonal Liability for Negligently Self-Inflicted Harms*, 70 FLA. L. REV. 649, 649 n.* (2018) (“Just to be absolutely clear, I do not advocate allowing injured persons to file lawsuits against themselves; instead, this tongue-in-cheek Article represents something of a riff on the (il)logic and growing dysfunction of American tort law.”); see also Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1139 (2004) (wondering, among other things, whether an embryo “had the same moral status as an inflamed appendix”); *id.* at 1140 n.26 (citing a billboard); *id.* at 1152 (quoting Humpty Dumpty). Then again, once the deplorables start sending hate mail my way, I might come to regret such excessive candor. Cf. Neil MacFarquhar et al., *Assault Spawns New Rally Cry for Extremists*, N.Y. TIMES, Jan. 17, 2021, at A1 (“The storming of the [Capitol] building, several analysts said, could fuel a dangerous pushback against the incoming Biden administration and its agenda on gun control . . . and other issues by extremists who are not afraid to use violence to get their way.”).

⁹ See Beth Reinhard & Sari Horwitz, *With Little Fanfare, Gun Regulations Being Eased*, WASH. POST, Oct. 5, 2017, at A9; see also Katie Benner, *Sidestepping Washington, Barr Unveils Gun Initiative*, N.Y. TIMES, Nov. 14, 2019, at A22 (“Congress and the White House remain largely immobilized on the issue.”); Mike DeBonis, *Recent Shootings Haven't Deterred GOP Efforts to Loosen Firearm Laws*, WASH. POST, Oct. 3, 2017, at A11.

¹⁰ The election of President Barack Obama alongside Democratic Party majorities in both chambers of Congress brought similar enthusiasm—or, for those on the other side of the fence, paranoia—about the possibility of serious federal efforts at gun control. See, e.g., Allen Rostron, *Cease Fire: A “Win-Win” Strategy on Gun Policy for the Obama Administration*, 3 HARV. L. & POL'Y REV. 347, 348 (2009) (“While generating a quick surge in sales for the gun industry, . . . the 2008 election gave a much-needed boost to gun control advocates . . .”). In the end, such hopes (and fears) proved to be largely misplaced. See Allen Rostron, *A New State Ice Age for Gun Policy*, 10 HARV. L. & POL'Y REV. 327, 329–40 (2016)

needing to placate the increasingly powerful progressive wing of the Democratic Party,¹¹ President Biden eventually might decide to nominate a crusading spirit to serve as Commissioner of the FDA and tolerate (if not enthusiastically endorse) a measure of federal gun control imposed without endlessly waiting for congressional guidance. If the political winds align in the fashion imagined, this Article offers a basic blueprint for something worth trying; serious roadblocks would, of course, remain in Congress and the federal courts (whose current tilt to the right will linger long after the latest election¹²), but the experience with tobacco products suggests that simply making the effort might generate some much-needed momentum for seriously addressing this scourge.¹³

I. SHOOTING BLANKS? GETTING BEYOND FEDERAL IMPOTENCE

Firearms continue to cause tremendous losses in the United States, prompting increasingly frustrated calls for a public health response to this endemic problem. This Part sketches out a radical new approach that has gone entirely unnoticed,¹⁴ explaining how a federal agency tasked with

(recounting President Obama's initial reticence to confront the problem, coupled with congressional resistance when he finally did, prompting instead a series of fairly modest executive actions). The Democratic Party also had controlled both chambers of Congress during President Bill Clinton's first two years in office, which allowed for the enactment of a pair of significant gun control laws. *See infra* notes 47, 52, and accompanying text.

¹¹ *See* Michelle Goldberg, Opinion, *Better Than Progressives Are Fearing*, N.Y. TIMES, Apr. 21, 2020, at A27; *see also* Bobby Caina Calvan, *Biden Calls on Congress to Strengthen Gun Laws; President Marks Parkland School Shooting Anniversary*, BOS. GLOBE, Feb. 15, 2021, at A2 ("In addition to background checks and an assault-weapons ban, Biden is calling on Congress to outlaw high-capacity magazines and make gun manufacturers liable for the role their products play in violence."). Conversely, the National Rifle Association (NRA), which in the past represented a lobbying juggernaut, has fallen on hard times of late. *See* Danny Hakim, *N.R.A. Seeks Texas Reboot as It Declares Bankruptcy*, N.Y. TIMES, Jan. 16, 2021, at A20 ("Long the nation's most powerful gun lobby, the N.R.A. played a diminished role in the 2020 election, hampered by financial woes and a host of legal challenges."). Although less well known than the NRA, the National Shooting Sports Foundation (NSSF) serves as the gun industry's primary trade association. *See* Tiffany Hsu, *Gunmakers Fight "Trump Slump" with a Softer Sales Pitch*, N.Y. TIMES, Feb. 24, 2020, at B1.

¹² *See* John Wagner, *Divided Senate Confirms Trump's 200th Judicial Pick for Federal Bench*, WASH. POST, June 25, 2020, at A3.

¹³ *See* Lars Noah, *Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products*, 48 ALA. L. REV. 1, 37 (1996) ("The Agency may hope simply to prompt congressional action. . . . Imagine that [it] next decided to tackle handgun control. . . . secure in the knowledge that such an initiative might convince Congress to legislate a compromise but would never survive long enough to undergo careful judicial scrutiny."). For a retrospective penned by the FDA Commissioner who spearheaded the agency's assault on tobacco, *see* DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* (2001).

¹⁴ *See* Annie Karni, *White House Considers Three Executive Actions on Gun Control*, N.Y. TIMES, Mar. 25, 2021, at A15 (reporting active consideration of minor steps that numerous other agencies might take); *cf.* Dru Stevenson, *The Urgent Need for Legal Scholarship on Firearm Policy*, 67 BUFF. L. REV. 1449, 1497 (2019) (identifying "a dearth of scholarly commentary on administrative law issues related to firearm regulation"). The closest that I could find was a short law review article penned by a couple of faculty members at the Johns Hopkins University School of Public Health more than twenty years ago, but strangely they had looked to the Consumer Product Safety Commission (CPSC) and the National Highway Traffic Safety Administration (NHTSA) rather than the FDA for relevant guidance. *See* Jon S. Vernick & Stephen P. Teret, *A Public Health Approach to Regulating Firearms as Consumer Products*,

protecting the public health could invoke its existing authority in a manner that would allow it to regulate manufacturers of firearms and ammunition in ways that might reduce the hazards associated with these products. Although Congress has legislated repeatedly on the issue over the last century, it has not managed to do anything remotely comprehensive in the aggregate.¹⁵ This arguably puts the onus on the Executive branch to take the initiative,¹⁶ but the small federal agency expressly empowered to deal with firearms has found itself hamstrung.¹⁷ Given this regulatory lacuna, the FDA could try to use its “device” authority to rein in companies that manufacture weapons and accessories with far too little oversight at present. Device jurisdiction brings with it a wide range of powers that would give the agency tremendous flexibility in designing various ways of making guns and ammunition less hazardous to the community.

A. *Gun-Related Injuries as a Public Health Menace*

Gun violence has become far too common in the United States. Private individuals possess an ever-growing number of firearms in this country,¹⁸

148 U. PA. L. REV. 1193, 1196, 1199 n.32, 1200, 1205 (2000); *see also id.* at 1203 (“Congress could choose to lift the restrictions it imposed on the CPSC and allow that agency to exercise regulatory authority over firearms. . . . Another regulatory option might be to create an entirely new agency, perhaps within the Department of Justice”); *cf.* David Hemenway, *The Public Health Approach to Reducing Firearm Injury and Violence*, 17 STAN. L. & POL’Y REV. 635, 646–49 (2006) (elaborating on the analogy to motor vehicle regulation).

¹⁵ *See* Katherine L. Record & Lawrence O. Gostin, *What Will It Take? Terrorism, Mass Murder, Gang Violence, and Suicides: The American Way, or Do We Strive for A Better Way?*, 47 U. MICH. J.L. REFORM 555, 557 (2014) (“[T]he country is in a state of political impasse. Despite public demand for reform, federal legislators have been unable to enact laws that would protect, at least in part, the public from gun violence.”); *id.* at 563–66 (listing dozens of unsuccessful gun control bills introduced in Congress just during 2013); Reid J. Epstein et al., *Despite Recent Advances, Obstacles Persist for Gun Control Advocates*, N.Y. TIMES, Aug. 5, 2019, at A14 (reporting that this pattern persists).

¹⁶ *See* Mary D. Fan, *Disarming the Dangerous: Preventing Extraordinary and Ordinary Violence*, 90 IND. L.J. 151, 159 (2015) (“Change by executive action is swifter and surer than change by seeking new laws—especially in the firearms context.”); *see also* Annie Karni, *Biden Moves to Curb Plague of Gun Crime*, N.Y. TIMES, Apr. 9, 2021, at A1 (“Even a modest step like addressing the issue of ghost guns . . . shows how paralyzed the politics surrounding gun control have become. . . . Given the wall of Republican opposition, supporters of more restrictive gun laws and regulations applauded even the modest moves that Mr. Biden announced”); *cf.* Philip J. Cook et al., *Gun Control After Heller: Threats and Sideshows from a Social Welfare Perspective*, 56 UCLA L. REV. 1041, 1050 (2009) (“[G]un regulation in the United States is almost entirely a product of legislation rather than rulemaking processes in administrative agencies.”).

¹⁷ *See infra* notes 49–50, 62, 66, and accompanying text (discussing the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)); *see also* Brian Freskos et al., *ATF Lets Problem Dealers off Hook; The Laws Are Lax, the Inspectors Lenient*, USA TODAY, May 27, 2021, at 1A; Glenn Thrush et al., *How the Firearms Lobby Hamstrings the A.T.F.*, N.Y. TIMES, May 3, 2021, at A1 (“In the 48 years since its mission shifted primarily to firearms enforcement, it has been weakened by relentless assaults from the N.R.A. that have, in the view of many, made the A.T.F. appear to be an agency engineered to fail.”). *See generally* WILLIAM J. VIZZARD, *IN THE CROSS FIRE: A POLITICAL HISTORY OF THE BUREAU OF ALCOHOL, TOBACCO AND FIREARMS* (1997).

¹⁸ *See* Christopher Ingraham, *Millions and Millions of Guns*, WASH. POST, Dec. 6, 2015, at B2 (reporting estimates “that there were as many as 357 million civilian firearms in circulation in 2013—more than one gun for every man, woman and child,” which means that “Americans own more guns per capita than people in any other country on Earth”).

and each year millions of new guns enter the civilian arsenal.¹⁹ Almost 40,000 Americans die each year from gunshot wounds,²⁰ and more than twice that number suffer serious injuries.²¹ The majority of these harms qualify as self-inflicted, primarily suicides.²² Among firearm homicides, domestic violence competes with other criminal uses,²³ while widely publicized mass shootings make a relatively minor contribution to the annual carnage.²⁴ Disaggregating the numbers in this fashion may help in assessing causality and designing possible solutions, but the exercise in no way changes the fact that the easy availability of guns has contributed to many

¹⁹ See Matthew Miller et al., *Firearm Acquisition Without Background Checks: Results of a National Survey*, 166 ANNALS INTERNAL MED. 233, 237 (2017) (noting that sixteen million firearms entered the U.S. market in 2013); Victoria M. Smith et al., *Broadening the Perspective on Gun Violence: An Examination of the Firearms Industry, 1990–2015*, 53 AM. J. PREVENTIVE MED. 584, 586 (2017) (“The number of firearms manufactured in the U.S. for domestic commerce ranged between 3 and 5 million per year between 1990 and 2005, but then grew . . . to a peak of 10.3 million in 2013.”); Dorothy R. Novick, Opinion, *Safe Gun Storage Could Prevent More Tragedies*, PHILA. INQUIRER, Feb. 5, 2021, at A13 (“Data from FBI background checks indicate that almost 40 million firearms were purchased across the United States in 2020. This is higher than any number on record for a single year.”).

²⁰ See Thomas Kaplan, *In Combating Gun Violence, Democrats Present a United Front*, N.Y. TIMES, Aug. 11, 2019, at A19; Sarah Mervosh, *Nearly 40,000 Deaths from Firearms in 2017*, N.Y. TIMES, Dec. 19, 2018, at A19 (“More people died from firearm injuries in the United States last year than in any other year since at least 1968, according to new data from the Centers for Disease Control and Prevention.”); see also Jason E. Goldstick et al., *US Firearm-Related Mortality: National, State, and Population Trends, 1999–2017*, 38 HEALTH AFFS. 1646, 1648 (2019) (“There were 114,683 firearm deaths in 2015–17 (11.8 per 100,000 person-years—a 13.8 percent increase from 1999–2014), of which 68,810 (60.0 percent) were suicides and 43,483 (37.9 percent) were homicides . . .”).

²¹ See Katherine Kaufer Christoffel, *Firearm Injuries: Epidemic Then, Endemic Now*, 97 AM. J. PUB. HEALTH 626, 627 fig.2 (2007); Faiz Gani et al., *Emergency Department Visits for Firearm-Related Injuries in the United States, 2006–14*, 36 HEALTH AFFS. 1729, 1729 (2017) (explaining that “the clinical burden of nonfatal firearm-related injuries [is] estimated to be approximately three times that of fatal injuries”); Bindu Kalesan et al., *The Hidden Epidemic of Firearm Injury: Increasing Firearm Injury Rates During 2001–2013*, 185 AM. J. EPIDEMIOLOGY 546, 550 (2017).

²² See David M. Studdert et al., *Handgun Ownership and Suicide in California*, 382 NEW ENG. J. MED. 2220, 2221 (2020) (“In 2018, 24,432 suicides by firearm occurred in the United States.”); Garen J. Wintemute, *The Epidemiology of Firearm Violence in the Twenty-First Century United States*, 36 ANN. REV. PUB. HEALTH 5, 6 (2015) (“Most deaths from firearm violence are suicides, not homicides—60.5%, on average, over the decade ending in 2012.”). The accidental discharge of firearms causes far fewer injuries and deaths, though typically the victims are young children. See Aaron E. Carroll, *Study Shows How the Way a Gun Is Stored Can Potentially Save the Life of a Child*, N.Y. TIMES, May 14, 2019, at A17 (“In the last decade, guns killed more than 14,000 American children. A startling number of those deaths—more than a third—were classified as suicides, and around 6 percent as accidents. Many more children were injured.”); Ryan Foley et al., *Accidental Shootings Put Kids in Early Graves; Minors Die at Pace of One Every Couple of Days Because Weapons Are Mishandled*, USA TODAY, Oct. 14, 2016, at 1A (reporting that the CDC’s numbers represent a significant undercount).

²³ See Sarah Mervosh, *Gun Ownership Tied to Domestic Homicides, Not Other Killings, Study Finds*, N.Y. TIMES, July 23, 2019, at A16; see also Mark Berman et al., *A Burst of Bloodshed in Major Cities*, WASH. POST, July 7, 2020, at A1 (reporting that a number of children recently died as bystanders to gun violence on the streets of urban areas); Jon Hilsenrath, *Homicide Spike Hits Most Large U.S. Cities*, WALL ST. J., Aug. 3, 2020, at A1 (“Shootings and gun violence also rose, even though many other violent crimes such as robbery fell.”).

²⁴ See Ali Rowhani-Rahbar et al., *Long-Lasting Consequences of Gun Violence and Mass Shootings*, 321 JAMA 1765, 1765 (2019) (“[T]he frequency of mass shooting events in the United States has been on the rise over the past 2 decades, with an increasing number of injuries and deaths . . . [though they] comprise less than 1% of all firearm related mortality in the United States each year.”).

of these individually tragic outcomes.²⁵ Lastly, these ceaseless casualties inflict staggering economic costs that everyone shares.²⁶

A growing chorus of commentators view gun violence in the United States as a public health crisis.²⁷ Unfortunately, their pleas for gun control have largely fallen on deaf ears, so we have seen little in the way of a public health (i.e., population-based, prevention-oriented) response.²⁸ Moreover, the federal and state legislation that does exist reflects an excessive preoccupation with the “who” and “where” of gun possession rather than the “what” of firearm production—call it a focus on the retail as opposed to the wholesale level.²⁹ Just as we have witnessed some movement away from a law enforcement emphasis in tackling the abuse of controlled substances to more of a public health approach,³⁰ a similar change in perspective might

²⁵ See Charles C. Branas et al., *Investigating the Link Between Gun Possession and Gun Assault*, 99 AM. J. PUB. HEALTH 2034, 2037 (2009) (“[G]un possession by urban adults was associated with a significantly increased risk of being shot in an assault. On average, guns did not seem to protect those who possessed them from being shot in an assault.”); Michael Siegel et al., *The Relationship Between Gun Ownership and Firearm Homicide Rates in the United States, 1981–2010*, 103 AM. J. PUB. HEALTH 2098, 2103 (2013) (“[S]tates with higher levels of gun ownership had disproportionately large numbers of deaths from firearm-related homicides.”); *infra* note 63 (citing comparable studies).

²⁶ See Monica Kalra, *A Ricochet of Pain—The Long Echo of Gun Violence*, 381 NEW ENG. J. MED. 1704, 1705 (2019) (“For the almost 85,000 people in the United States who were injured by firearms in 2015 . . . an estimated \$900 million was spent for medical care and hospitalizations.”); *id.* (“Some experts believe that firearm misuse costs the U.S. economy more than \$200 billion each year in lost wages, medical bills, and increased taxes to pay for law enforcement.”); Sarabeth A. Spitzer et al., *Costs and Financial Burden of Initial Hospitalizations for Firearm Injuries in the United States, 2006–2014*, 107 AM. J. PUB. HEALTH 770, 774 (2017); Wintemute, *supra* note 22, at 13 (“The societal costs of firearm suicides and homicides occurring in 2010, estimated at \$164.6 billion, approximated 1.1% of the US gross domestic product that year.”).

²⁷ See Howard Bauchner et al., Editorial, *Death by Gun Violence—A Public Health Crisis*, 318 JAMA 1763 (2017); Philip J. Cook, Editorial, *Expanding the Public Health Approach to Gun Violence Prevention*, 169 ANNALS INTERNAL MED. 723 (2018); David Hemenway & Matthew Miller, *Public Health Approach to the Prevention of Gun Violence*, 368 NEW ENG. J. MED. 2033 (2013); Steven E. Weinberger et al., *Firearm-Related Injury and Death in the United States: A Call to Action from 8 Health Professional Organizations and the American Bar Association*, 162 ANNALS INTERNAL MED. 513 (2015); Jane Gross, *New Group Joins Battle over Guns: Physicians*, N.Y. TIMES, Nov. 16, 1993, at A18 (“The turning point, experts agree, was the publication in June 1992 of a special issue of [JAMA] devoted to the public health consequences of violence.”); Tracy Jan, *Frustration Mounts on Gun Research Curb*, BOS. GLOBE, July 5, 2016, at A1 (reporting that the American Medical Association had just adopted a formal resolution declaring gun violence a “public health crisis”).

²⁸ See Renee Butkus et al., *Reducing Firearm Injuries and Deaths in the United States: A Position Paper from the American College of Physicians*, 169 ANNALS INTERNAL MED. 704, 707 (2018) (“The ACP has pressed for the adoption of policies to reduce the number of deaths and injuries related to firearms for more than 20 years and is disheartened by the lack of action to protect the American public.”); Nicholas Fandos & Thomas Kaplan, *Victims Vent Frustration as Lawmakers Show Inability to Act on Guns*, N.Y. TIMES, Feb. 16, 2018, at A19.

²⁹ See *infra* Part I.B. Focusing on the wholesale level may offer advantages. See Sam Kamin, *The Citizen’s Guide to Gun Control at 30*, 23 BERKELEY J. CRIM. L. 46, 68 (2018) (“Erecting barriers between individuals and their weapons—gun safes, trigger locks, etc.—may not only prevent accidents but may also give a suicidal person sufficient time and space to rethink their decision to end their life.”); Smith et al., *supra* note 19, at 589 (“The finding that firearm manufacturing is highly concentrated among a small number of companies is important because it suggests that the market may be driven by the practices of just a handful of companies. Therefore, changes in firearm design, safety, and marketing by these few companies could substantially affect the entire gun supply.”).

³⁰ See Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 757.

help us respond sensibly to the consequences associated with the widespread availability of firearms.

A quarter of a century ago, at the very same time that the FDA turned its focus to tobacco, the Commonwealth of Massachusetts pioneered just such a strategy. An inventive attorney general (AG), with the backing of a politically moderate governor,³¹ proposed rules that took aim primarily at firearm manufacturers rather than downstream retailers or purchasers.³² In the absence of legislation specifically delegating any power to do so, the AG found the requisite authority in an old and entirely generic consumer protection statute that prohibited unfair or deceptive acts and practices.³³ Issued in 1997, the final rules mandated trigger locks and other child safety features, loaded chamber indicators or magazine safety disconnects, tamper-resistant serial numbers, and safety instructions; they also prohibited the sale of handguns constructed from poor quality materials.³⁴

While a challenge filed by the industry wound its way through the courts, the Massachusetts legislature acted to endorse and embellish upon these rules.³⁵ Ultimately, the state's high court sustained most of the regulations, holding that they passed muster even under the old consumer protection statute.³⁶ Obviously, the political culture in the Commonwealth of Massachusetts differs from that found in other parts of the country (and reflected in our national legislature and federal courts), and one state can do little to protect its citizens from noncompliant firearms entering from more permissive nearby markets, but the White House might find that this effort offers a handy roadmap for pursuing an initiative to adopt nationally uniform product standards that would stand a greater chance of guarding against gun violence.³⁷ Although the experience in Massachusetts suggests that the

³¹ See Meg Vaillancourt, *Weld Supports AG's Strategy Against Pistols*, BOS. GLOBE, Dec. 12, 1996, at B13.

³² See Fox Butterfield, *Massachusetts to Enforce Strict Gun Safety Laws*, N.Y. TIMES, Apr. 3, 2000, at A12 ("The rules are the first consumer protection regulations in the country to concentrate on handgun safety . . ."); Mary McGrory, *Disarming*, WASH. POST, Apr. 9, 2000, at B1 ("The genius of the Massachusetts solution is that it simply bypasses all the obstacles the gun lobby habitually throws in the way of attempts to limit gun sales . . . by decreeing that guns are consumer products like all others, and must meet certain safety standards. Credit for this breakthrough concept goes to hard-charging Scott Harshbarger, the state's former attorney general . . .").

³³ See Glenn Kaplan & Chris Barry Smith, *Patching the Holes in the Consumer Product Safety Net: Using State Unfair Practices Laws to Make Handguns and Other Consumer Goods Safer*, 17 YALE J. ON REG. 253, 324–25 (2000); Pierre Thomas, *Massachusetts Aims Safety Rules to Hit Handguns on Bottom Line*, WASH. POST, Nov. 26, 1996, at A3; see also Andrew Ross Sorkin, *Suit over Ad Could Shake Gun Industry*, N.Y. TIMES, Mar. 3, 2021, at B1 (discussing the New Jersey AG's use of that state's consumer protection statute to unearth incriminating records related to promotional practices).

³⁴ See 940 MASS. CODE REGS. ch. 16 (2020); Pamela Ferdinand, *Massachusetts's Gun Laws Take Heavy Toll on Sales; Licensed Dealers Dwindle as More Controls Are Proposed*, WASH. POST, Jan. 24, 2001, at A3.

³⁵ See Pamela Ferdinand, *Mass. to Enforce Toughest Handgun Rules in U.S.*, WASH. POST, Apr. 4, 2000, at A15 ("They were issued in 1997—one year before Massachusetts legislators passed the nation's strictest gun control law, which includes many similar quality and safety provisions.").

³⁶ See *Am. Shooting Sports Council v. Att'y Gen.*, 711 N.E.2d 899, 902–08 (Mass. 1999).

³⁷ See Benjamin Bejar, Note, *Wielding the Consumer Protection Shield: Sensible Handgun Regulation in Massachusetts: A Paradigm for a National Model?*, 7 B.U. PUB. INT. L.J. 59, 85 (1998)

Federal Trade Commission (FTC) could employ its identical authority over unfair or deceptive business practices,³⁸ the FDA has the relevant public health expertise and, as explained below, arguably already enjoys clearer jurisdiction to regulate firearms and ammunition.

B. *Congress Has Responded in a Chaotic Fashion*

Federal firearm laws have gradually expanded over the last century. In 1918, Congress imposed a 10% excise tax on weapons and ammunition;³⁹ in 1927, it prohibited the shipment of pistols, revolvers, and other concealable firearms through the U.S. mails.⁴⁰ In 1934, Congress responded to Prohibition Era violence by requiring the registration of owners—and imposing a \$200 tax on transfers to private individuals—of machine guns, short barrel (sawed-off) shotguns, silencers and the like in the hopes of making them inaccessible to gangsters.⁴¹ Four years later, it required the licensing of manufacturers, importers, and dealers of guns and ammunition shipped in interstate commerce, prohibited these licensees from knowingly selling such items to certain criminals, and required dealers to maintain records of transactions.⁴²

(“Without uniform federal regulations, however, the burden will remain on each state to protect its citizens from these dangerous consumer products.”); Daniel LeDuc, *Marching for Uniform Gun Laws; “Million Mom” Organizers Want Congress to Set National Standards*, WASH. POST, May 12, 2000, at A1; see also Hemenway, *supra* note 14, at 651 (“[A] crucial first step would seem to be to create a new agency or provide an existing agency with the power to regulate firearms as a consumer product.”).

³⁸ See 15 U.S.C. § 45(a)(1) (2018); see also Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 U. KAN. L. REV. 209, 211–16, 242–43 (2016) (discussing some of the similarities and differences between federal and state laws in this area, though focusing on enforcement actions rather than rulemaking); cf. Jon S. Vernick et al., *Regulating Firearm Advertisements That Promise Home Protection: A Public Health Intervention*, 277 JAMA 1391 (1997) (explaining that the FTC had received citizen petitions from public interest organizations alleging that industry ads extolling the defensive benefits of handgun ownership qualified as unfair and deceptive).

³⁹ See Revenue Act of 1918, Pub. L. No. 65-254, § 900(10), 40 Stat. 1057, 1122 (1919); see also Frances Stead Sellers, *Hunting Is Declining, Creating a Crisis for Conservation*, WASH. POST, Feb. 3, 2020, at A3 (referencing “the 1937 passage of the Pittman-Robertson Act, which imposed an 11 percent excise tax on the sale of firearms that is apportioned annually to state agencies for conservation”). The excise tax remained at 10% for pistols and revolvers. See Internal Revenue Code of 1954, Pub. L. No. 83-591, 68A Stat. 3, 490 (codified at 26 U.S.C. § 4181 (2018)); see also 16 U.S.C. § 669b(a)(1) (2018) (earmarking proceeds for state wildlife restoration projects).

⁴⁰ See Pub. L. No. 69-583, 44 Stat. 1059, 1060 (1927) (codified as amended at 18 U.S.C. § 1715) (exempting shipments to “bona fide dealers”).

⁴¹ See National Firearms Act, Pub. L. No. 73-474, §§ 3(a), 5(a), 48 Stat. 1236, 1237–38 (1934) (codified as amended at 26 U.S.C. §§ 5801–5872 (2018)); see also *United States v. Miller*, 307 U.S. 174, 178 (1939) (rejecting a Second Amendment challenge to convictions for the interstate movement of an unregistered short-barreled shotgun); *Sonzinsky v. United States*, 300 U.S. 506, 511–14 (1937) (rejecting a challenge to the separate \$200 annual license tax on dealers of covered firearms); cf. *Haynes v. United States*, 390 U.S. 85, 96–100 (1968) (holding that the registration requirement conflicted with the Fifth Amendment’s privilege against self-incrimination). Two years earlier, Congress had prohibited the possession of any firearm that “shoots automatically or semiautomatically more than twelve shots without reloading” in the District of Columbia. See Pub. L. No. 72-275, §§ 1, 14, 47 Stat. 650, 654 (1932) (codified as amended at D.C. CODE §§ 22-4501, 22-4516).

⁴² See Federal Firearms Act, Pub. L. No. 75-785, §§ 2–3, 52 Stat. 1250, 1250–52 (1938) (repealed by the Omnibus Crime Control and Safe Streets Act of 1968, Pub. L. No. 90-351, § 906, 82 Stat. 197,

After a three-decade lull, and prompted by a pair of high-profile assassinations, Congress decided to enhance existing gun control measures. In 1968, it limited, among other things, the interstate transfers of handguns and raised the minimum handgun purchase age to twenty-one, and it enhanced the requirements for licensing sellers while barring a broader range of individuals from purchasing weapons (adding, for instance, minors, the mentally ill, and drug abusers).⁴³ With limited exceptions for wholly intrastate activities, only those persons with a federal firearms license could produce or sell guns.⁴⁴ As it had done earlier in the century when imposing taxes, Congress delegated the power to regulate licensees to the Department of Treasury.⁴⁵ In addition, it barred the importation of guns unless certified by the agency as “particularly suitable for . . . sporting purposes.”⁴⁶

Twenty-five years later, the Brady Act inaugurated a national system of background checks to better enforce the restrictions on persons allowed to purchase firearms.⁴⁷ In order to implement this law, the Federal Bureau of Investigation (FBI) established the National Instant Criminal Background Check System (NICS).⁴⁸ The Bureau of Alcohol, Tobacco, Firearms & Explosives (ATF), however, represents the federal agency that enjoys the clearest delegated authority over guns. Previously just denominated as the

234); *see also* Franklin E. Zimring, *Firearms and Federal Law: The Gun Control Act of 1968*, 4 J. LEGAL STUD. 133, 143 (1975) (“Congress got pretty much what it wanted in the F.F.A.: a symbolic denunciation of firearms in the hands of criminals, coupled with an inexpensive and ineffective regulatory scheme that did not inconvenience the American firearms industry or its customers.”).

⁴³ *See* Gun Control Act of 1968, Pub. L. No. 90-618, § 102, 82 Stat. 1213, 1214–26 (codified as amended at 18 U.S.C. §§ 921–931 (2018)); *see also id.* § 102, 82 Stat. at 1214 (codified as amended at 18 U.S.C. § 921(a)(4)(B)) (defining as a “destructive device” any weapon whose barrel has a bore greater than half an inch in diameter except for shotguns found to be “generally recognized as particularly suitable for sporting purposes”). *But see* Hirschfeld v. ATF, 5 F.4th 407, 452 (4th Cir.) (invalidating the age restriction under the Second Amendment), *vacated as moot*, 14 F.4th 322 (4th Cir. 2021).

⁴⁴ *See* Keersten Heskin, Note, *Easier Than Obtaining a Driver’s License: The Federal Licensing of Gun Dealers*, 46 FLA. L. REV. 805, 825–34 (1994).

⁴⁵ *See* 18 U.S.C. § 926; *see also* Zimring, *supra* note 42, at 150 (“The regulation of interstate traffic (in the Act and its regulations) was stronger than under the Federal Firearms Act, but there were, of course, opportunities for evasion. The [intrastate] sale of guns by nondealers was, from the beginning, outside of any record-keeping requirement of the Act.”).

⁴⁶ 18 U.S.C. § 925(d)(3); *see also* Zimring, *supra* note 42, at 154–56, 163–67 (discussing questions about the operation of this provision).

⁴⁷ *See* Brady Handgun Violence Prevention Act of 1993, Pub. L. No. 103-159, § 102, 107 Stat. 1536, 1536–41 (codified as amended at 18 U.S.C. § 921). The law initially applied only to handgun purchases, but, after a five-year interim period, the background check requirement would become applicable to other firearms (i.e., long guns) as well. *See id.* §§ 102(a)–(b), 103(b). Three years after passage, the Lautenberg amendment added to the list of prohibited purchasers’ certain individuals convicted of domestic violence. *See* Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, § 658, 110 Stat. 3009, 3009–371 (1996); *see also* Voisine v. United States, 136 S. Ct. 2272, 2278–82 (2016) (broadly construing this restriction).

⁴⁸ *See* National Instant Criminal Background Check System Regulation, 63 Fed. Reg. 58,303, 58,307 (Oct. 30, 1998) (codified as amended at 28 C.F.R. pt. 25). It does not, however, apply to private sales. *See* Richard A. Oppel, Jr. & Adeel Hassan, *Simple Way for Abusers, Felons and Fugitives to Buy a Weapon*, N.Y. TIMES, Aug. 14, 2019, at A14 (“Transactions between private sellers and buyers do not require a background check. That used to typically just mean sales at gun shows, or through listings found in classified ads. But that was before the internet made it as easy as a few mouse clicks to find a gun for sale from a private seller on an online marketplace or through social media.”).

Bureau of Alcohol, Tobacco & Firearms, and housed within the Department of Treasury to reflect its focus on collecting revenue from these otherwise little-regulated products,⁴⁹ ATF acquired its current designation when it moved to the Department of Justice in 2003.⁵⁰

In 1994, Congress enacted a pair of significant measures related to firearms. First, it reinforced the federal age restriction by prohibiting handgun possession by and sale to persons under 18 years of age.⁵¹ Second, and more controversially, Congress enacted a prohibition on the possession and sale of newly manufactured “assault weapons” and large-capacity magazines.⁵² The legislation sunset after ten years, however, when congressional efforts to extend the ban failed.⁵³

On occasion, and wholly apart from the excise tax that it had imposed in 1918, Congress has focused on ammunition. In 1986, after banning (rather than just taxing) private possession of newly manufactured machine guns,⁵⁴ it barred the sale of “cop killer” bullets.⁵⁵ This prohibition got expanded in

⁴⁹ See Zimring, *supra* note 42, at 157 (explaining that the Commissioner of Internal Revenue had created this division in 1942 to implement federal firearm laws and that thirty years later the Treasury Department reorganized ATF as a separate bureau); Fox Butterfield, *Bill Would Subject Guns to Federal Safety Controls*, N.Y. TIMES, Mar. 3, 1999, at A10.

⁵⁰ See Homeland Security Act of 2002, Pub. L. No. 107-296, § 1111, 116 Stat. 2135, 2274 (codified at 6 U.S.C. § 531) (splitting off ATF’s revenue collection function into a new unit that remained within the Treasury Department); *see also* 28 U.S.C. § 599A(b)(1) (2018).

⁵¹ See Violent Crime Control and Law Enforcement Act of 1994, Pub. L. No. 103-322, § 110201(a), 108 Stat. 1796, 2010–11 (codified at 18 U.S.C. § 922(x)) (also known as the Youth Handgun Safety Act).

⁵² See *id.* tit. XI(A), 108 Stat. at 1996–2010 (codified at 18 U.S.C. §§ 921(a), 922(v)–(w), appendix, 923(i)); *see also* Allen Rostron, *High-Powered Controversy: Gun Control, Terrorism, and the Fight over .50 Caliber Rifles*, 73 U. CIN. L. REV. 1415, 1434–35 (2005).

⁵³ See Pub. L. No. 103-322, § 110105(2), 108 Stat. at 2000; Sheryl Gay Stolberg, *Effort to Renew Weapons Ban Falters on Hill*, N.Y. TIMES, Sept. 9, 2004, at A1. Subsequent efforts to resurrect the law in the wake of the Sandy Hook massacre failed as well. See Jonathan Weisman, *Gun Control Drive Blocked in Senate; Obama, in Defeat, Sees “Shameful Day,”* N.Y. TIMES, Apr. 18, 2013, at A1; *see also* John J. Phelan IV, Note, *The Assault Weapons Ban—Politics, the Second Amendment, and the Country’s Continued Willingness to Sacrifice Innocent Lives for “Freedom,”* 77 ALB. L. REV. 579, 598–603 (2014) (suggesting ways of tightening the expired federal ban); John Donohue & Theodora Boulouta, Opinion, *That Assault Weapon Ban Worked*, N.Y. TIMES, Sept. 5, 2019, at A27 (“[D]ata from the 15 years following the ban’s expiration now provide stronger evidence that permitting the gun industry to flood the market with increasingly powerful weapons that allow for faster killing has facilitated exactly that outcome.”). In contrast, our neighbors to the north recently managed to adopt such a law. See Ian Austen, *After Nova Scotia Killings, Canada Bans Assault Rifles*, N.Y. TIMES, May 2, 2020, at A19.

⁵⁴ See Firearms Owners’ Protection Act, Pub. L. No. 99-308, § 102, 100 Stat. 449, 453 (1986) (codified at 18 U.S.C. § 922(o)); *see also* Demko v. United States, 216 F.3d 1049, 1051–53 (Fed. Cir. 2000) (rejecting a challenge to the ATF’s refusal to exempt a particular large caliber semiautomatic shotgun from statutory restrictions); Rostron, *supra* note 52, at 1428–34 (discussing other changes inaugurated by these amendments); *id.* at 1466 (summarizing “the additional rules and restrictions accompanying classification as an NFA weapon, including more thorough background checks, a significant waiting period, law enforcement discretion over access to the weapons, and a comprehensive system of registration”). ATF recently amended its rules to treat “bump stocks” as machine guns. See *Bump-Stock-Type Devices*, 83 Fed. Reg. 66,514, 66,553–54 (Dec. 26, 2018) (codified at 27 C.F.R. §§ 447.11, 478.11, 479.11); *see also* Guedes v. ATF, 920 F.3d 1, 35 (D.C. Cir. 2019) (affirming the denial of a preliminary injunction); Aposhian v. Barr, 958 F.3d 969 (10th Cir.) (same), *vacated for en banc rehrg.*, 973 F.3d 1151 (10th Cir. 2020), *reinstated sub nom.* Aposhian v. Wilkinson, 989 F.3d 890 (10th Cir. 2021) (en banc).

⁵⁵ See Pub. L. No. 99-408, 100 Stat. 920 (1986) (codified as amended at 18 U.S.C. § 921(a)(17)(B)); Reagan Signs Ban on Armor-Piercing “Cop-Killer” Bullets, L.A. TIMES, Aug. 29, 1986, at A4. A couple

1994 to cover other armor-piercing, metal-alloy ammunition.⁵⁶ Aside from these narrowly focused bans, coupled with the decade-long prohibition on large-capacity magazines, federal legislation has largely disregarded the types of ammunition sold to civilians.

During much of this same period, Congress demonstrated equal interest in preventing other entities from taking action. In 1976, for instance, the Toxic Substances Control Act (TSCA), which the Environmental Protection Agency (EPA) implements, excluded guns and ammunition.⁵⁷ That same year, Congress expressly barred the Consumer Product Safety Commission (CPSC) from restricting the sale of firearms and ammunition,⁵⁸ even though the statute creating the Commission just four years earlier already appeared to exclude these products from its jurisdiction.⁵⁹ In 1986, Congress enacted the Firearms Owners' Protection Act,⁶⁰ which amended several sections of the Gun Control Act of 1968 to, among other things, preempt state or local laws that would prevent the interstate transportation of an unloaded and

of years later, Congress outlawed firearms designed to evade metal detectors or x-ray machines. *See* Undetectable Firearms Act of 1988, Pub. L. No. 100-649, § 2(a), 102 Stat. 3816 (codified as amended at 18 U.S.C. § 922(p)).

⁵⁶ *See* Pub. L. No. 103-322, § 110519, 108 Stat. at 2020 (codified at 18 U.S.C. § 921(a)(17)). A couple of years later, Congress called for a study on the quantities and uses of ammunition. *See* Antiterrorist and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, § 809, 110 Stat. 1214, 1311.

⁵⁷ *See* Pub. L. No. 94-469, § 3, 90 Stat. 2003, 2004 (1976) (codified as amended at 15 U.S.C. § 2602(2)(B)(v)) (cross-referencing the firearms excise tax provision); *cf.* Felicity Barringer, *Groups Seek Ban on Lead in Sporting Ammunition*, N.Y. TIMES, Aug. 3, 2010, at A15 (discussing a petition filed with the EPA). This has left other agencies, primarily the U.S. Fish & Wildlife Service (FWS), to address concerns about environmental contamination from lead shot on a piecemeal basis. *See* 50 C.F.R. § 20.108 (2020) (banning its use for hunting waterfowl effective 1991); *see also id.* § 20.134 (creating a mechanism for approval of nontoxic types of shot and coatings); Darryl Fears, *Endangered Species Act Is Itself Endangered*, WASH. POST, Mar. 28, 2017, at E5 ("One of the first things the Interior Department did under its new secretary, Ryan Zinke, was rescind an Obama administration regulation that [would have more broadly] outlawed hunting with lead shot.").

⁵⁸ *See* Consumer Product Safety Commission Improvements Act of 1976, Pub. L. No. 94-284, § 3(e), 90 Stat. 503, 504 ("The [CPSC] shall make no ruling or order that restricts the manufacture or sale of firearms, firearms ammunition, or components of firearms ammunition, including black powder or gunpowder for firearms."). This provision did not, for instance, appear designed to address a jurisdictional dispute that had arisen over stun guns. *See* Craig S. Lerner & Nelson Lund, *Heller and Nonlethal Weapons*, 60 HASTINGS L.J. 1387, 1400 (2009) ("When Tasers were first developed, the [CPSC] claimed jurisdiction in 1975, followed by the [ATF] in 1976; these agencies meddled with sales to the public, and even banned them for a time." (footnotes omitted)); *cf.* Eugene Volokh, *Nonlethal Self-Defense, (Almost Entirely) Nonlethal Weapons, and the Rights to Keep and Bear Arms and Defend Life*, 62 STAN. L. REV. 199, 211 n.44 (2009) (explaining that, at the time of ATF's 1976 ruling, Tasers used gunpowder to fire their barbs, only later switching to compressed nitrogen).

⁵⁹ *See* Consumer Product Safety Act, Pub. L. No. 92-573, § 3, 86 Stat. 1207, 1208 (1972) (codified as amended at 15 U.S.C. § 2052(a)(5)(E)) (excluding from the definition of "consumer product" any article subject to the tax imposed under 26 U.S.C. § 4181, which had imposed an excise tax on firearms, shells, and cartridges); *cf.* Bejar, *supra* note 37, at 61 n.13 (noting that the original Senate bill would have granted the CPSC jurisdiction over firearms); Erik Larson, *Wild West Legacy: Ruger Gun Often Fires If Dropped, but Firm Sees No Need for Recall*, WALL ST. J., June 24, 1993, at A1 (reporting that, in 1991, the General Accounting Office urged Congress to delegate authority over firearms to the CPSC). The statute also excludes from the CPSC's jurisdiction "devices" as defined under the FDA's enabling statute. *See* 15 U.S.C. § 2052(a)(5)(h).

⁶⁰ Pub. L. No. 99-308, 100 Stat. 449 (1986); *see also* David T. Hardy, *The Firearms Owners' Protection Act: A Historical and Legal Perspective*, 17 CUMB. L. REV. 585, 627-80 (1987) (offering a comprehensive assessment of this complex legislation).

inaccessible firearm,⁶¹ and to prevent the ATF from taking or sharing dealer records and from creating a system to register firearms or owners.⁶²

In 1996, responding to a pair of prominent studies funded by the U.S. Centers for Disease Control and Prevention (CDC),⁶³ an appropriations rider known as the Dickey Amendment limited that agency's ability to underwrite research on gun violence,⁶⁴ a restriction that remains in place more than two decades later.⁶⁵ In 2003, Congress used an appropriations measure to prevent

⁶¹ Pub. L. No. 99-308, § 107, 100 Stat. at 460 (codified at 18 U.S.C. § 926A).

⁶² *Id.* § 106, 100 Stat. at 459 (codified at 18 U.S.C. § 926(a)); see also Jeanne Marie Laskas, *Inside the Federal Bureau of Way Too Many Guns*, GQ (Aug. 30, 2016), <https://www.gq.com/story/inside-federal-bureau-of-way-too-many-guns> (reporting how these restrictions have hamstrung the ATF).

⁶³ See Arthur L. Kellermann et al., *Gun Ownership as a Risk Factor for Homicide in the Home*, 329 NEW ENG. J. MED. 1084, 1087 (1993) (“Although firearms are often kept in homes for personal protection, this study shows that the practice is counterproductive.”); Arthur L. Kellermann et al., *Suicide in the Home in Relation to Gun Ownership*, 327 NEW ENG. J. MED. 467, 471 (1992) (“The ready availability of firearms appears to be associated with an increased risk of suicide in the home.”). In a comprehensive review of the literature conducted two decades later, these two studies counted among only sixteen that satisfied the criteria for inclusion. See Andrew Anglemeyer et al., *The Accessibility of Firearms and Risk for Suicide and Homicide Victimization Among Household Members: A Systematic Review and Meta-Analysis*, 160 ANNALS INTERNAL MED. 101, 102 & tbl.1 (2014); see also *id.* at 109 (“[W]e found the association between firearm availability and homicide to be more modest than that between firearm availability and completed suicide.”).

⁶⁴ See Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, 110 Stat. 3009, 3009-244 (1996) (“[N]one of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control.”); see also Michael Luo, *Sway of N.R.A. Blocks Studies, Scientists Say*, N.Y. TIMES, Jan. 26, 2011, at A1. Fifteen years later, the National Institutes of Health (NIH) faced a similar prohibition when the language of this rider was expanded to cover other units in the Department of Health and Human Services (HHS). See Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, Div. F, tit. II, § 218, 125 Stat. 786, 1085 (2011) (“None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.”); see also Arthur L. Kellermann & Frederick P. Rivara, *Silencing the Science on Gun Research*, 309 JAMA 549, 549-50 (2013) (explaining that the publication of a study funded by a component of the NIH had prompted this move).

⁶⁵ See Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 210, 133 Stat. 2534, 2579 (2019). Although the FDA resides within HHS and represents a part of the Public Health Service alongside the CDC and NIH, its appropriations appear in an entirely different part of the budget legislation (in Division B, Title VI, alongside the Department of Agriculture, which had housed the agency until 1940, rather than in Division A, Title II). Thus, the FDA would never have had to abide by this rider. Moreover, when included in 2018, an accompanying report explained that the rider would not bar support of research into the causes of gun violence. See Allen Rostron, Editorial, *The Dickey Amendment on Federal Funding for Research on Gun Violence: A Legal Dissection*, 108 AM. J. PUB. HEALTH 865, 866 (2018); see also Sheryl Gay Stolberg, *With C.D.C. Funds, Gun Violence Researchers Seek Path Around Politics*, N.Y. TIMES, Mar. 29, 2021, at A17 (reporting that starting in 2019, with an annual appropriation of \$25 million earmarked for this purpose though split with NIH, the CDC “is once again funding research into gun violence after a nearly 25-year hiatus imposed by Congress”).

the ATF from disclosing its gun trace data;⁶⁶ one year later, another rider required the destruction of background check records within 24 hours.⁶⁷

In 2005, Congress acted to displace most tort litigation against the gun industry,⁶⁸ which arguably makes the need for serious regulatory scrutiny that much more pressing.⁶⁹ At the same time, it required that makers and sellers of handguns provide secure storage or other child safety devices such as trigger locks and incentivized their use by owners.⁷⁰ In 2009, Congress loosened a pair of restrictions related to carrying loaded weapons on federal property.⁷¹ One year thereafter, the Affordable Care Act included a special provision designed to safeguard the Second Amendment rights of patients.⁷²

In short, Congress has acted sporadically, addressing only limited facets of gun violence and largely ignoring the possibility of imposing controls at the manufacturer level.⁷³ Instead, it has focused its attention on the retail

⁶⁶ See Consolidated Appropriations Resolution, 2003, Pub. L. No. 108-7, Div. J, § 644, 117 Stat. 11, 473; see also Colin Miller, *Lawyers, Guns, and Money: Why the Tiahrt Amendment's Ban on the Admissibility of ATF Trace Data in State Court Actions Violates the Commerce Clause and the Tenth Amendment*, 2010 UTAH L. REV. 665, 676-82 (discussing the origin and subsequent changes to this recurring rider); Erica Goode & Sheryl Gay Stolberg, *Legal Curbs Said to Hamper A.T.F. in Gun Inquiries*, N.Y. TIMES, Dec. 26, 2012, at A1; Ali Watkins, *How the N.R.A. Uses Its Influence to Hobble Federal Gun Regulators*, N.Y. TIMES, Feb. 23, 2018, at A12 (reporting that the gun lobby has “pushed Congress to enact restrictions on how the bureau spends money to curtail its ability to regulate firearms and track gun crimes”).

⁶⁷ See Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, Div. B, § 617(a)(2), 118 Stat. 3, 95.

⁶⁸ See Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, §§ 2-4, 119 Stat. 2095, 2095-99 (2005) (codified at 15 U.S.C. §§ 7901-7903); see also *City of New York v. Beretta U.S.A. Corp.*, 524 F.3d 384, 392-98 (2d Cir. 2008) (rejecting various constitutional objections to this statute).

⁶⁹ See Andrew J. McClurg, *The Second Amendment Right to Be Negligent*, 68 FLA. L. REV. 1, 7-8 (2016) (“Because no federal gun safety design regulations exist, the absence of a threat of tort liability leaves gun manufacturers with little incentive to implement safer gun designs” (footnote omitted)); Jon S. Vernick et al., *Availability of Litigation as a Public Health Tool for Firearm Injury Prevention: Comparison of Guns, Vaccines, and Motor Vehicles*, 97 AM. J. PUB. HEALTH 1991, 1996 (2007) (“[T]he lack of both regulation and litigation as public health tools for firearm injury prevention is a potentially dangerous combination for the public’s health.”); *id.* at 1995 (complaining that this statute “simply eliminates litigation’s feedback mechanism without providing an alternative means to ensure the safe design and distribution of firearms”); *id.* at 1994 (“[U]nlike the case with virtually every other consumer product in the United States, no federal agency has the authority to regulate the safe design of firearms.”).

⁷⁰ See Child Safety Lock Act of 2005, Pub. L. No. 109-92, § 5, 119 Stat. 2095, 2099-101 (codified as amended at 18 U.S.C. §§ 922(z), 924(p)). This legislation largely codified what the industry had promised to do almost a decade earlier. See James Bennet, *Gun Makers Agree on Safety Locks*, N.Y. TIMES, Oct. 9, 1997, at A1.

⁷¹ See Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, § 4, Div. A, tit. I, 123 Stat. 3034, 3061 (2009) (calling for guidance to allow transportation of guns in checked baggage on Amtrak); Credit Card Accountability Responsibility and Disclosure Act of 2009, Pub. L. No. 111-24, § 512, 123 Stat. 1734, 1764 (codified at 16 U.S.C. § 1a-7b) (overriding rules that banned carrying loaded guns on national parkland); see also Department of Homeland Security Appropriations Act of 2007, Pub. L. No. 109-295, § 557, 120 Stat. 1355, 1391 (2006) (codified at 42 U.S.C. § 5207) (barring confiscation of guns during a disaster or emergency).

⁷² See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 10101(e)(2), 124 Stat. 119, 884-85 (codified at 42 U.S.C. § 300gg-17(c)).

⁷³ See Stevenson, *supra* note 14, at 1455 (“No other product on the market causes as many deaths of both consumers and innocent bystanders while having no federal regulations requiring safety features, warning labels, or manufacturing specifications.”); Vernick & Teret, *supra* note 14, at 1196 (“Noticeably absent in the United States, however, are laws governing the design, manufacture, and marketing of

level, while at the same time legislating to insulate the industry from unwelcome scrutiny and to expand the freedom enjoyed by lawful gun owners. Insofar as Congress has demonstrated that it cannot muster the courage to lead on this issue, the Executive branch should take a stab at regulating firearms under already broad delegations of authority to a public health agency.

C. *Characterizing Guns and Ammo as “Devices”*

In tandem with significant legislative milestones related to firearms and ammunition, Congress has delineated a seemingly broad category of so-called “devices” subject to the FDA’s control. In 1938, the same year that it passed the Federal Firearms Act, Congress enacted the federal Food, Drug, and Cosmetic Act (FDCA),⁷⁴ which for the first time granted the FDA jurisdiction over devices. In 1976, the same year that it reiterated the CPSC’s lack of any authority over firearms and excluded the EPA from exercising any comparable powers under TSCA,⁷⁵ Congress greatly expanded the FDA’s authority to regulate devices.⁷⁶

Pursuant to the FDCA, “drug” means “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . [or] intended to affect the structure or any function of the body of man or other animals.”⁷⁷ The 1938 statute included parallel language to define a different product category: “The term ‘device’ . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.”⁷⁸ Thus, Congress had delegated to the FDA jurisdiction to regulate products

firearms. . . . [N]o federal agency has the authority to establish standards for their safe design.”). Even more so than vehicles, of course, the existing supply of guns turns over at a slow rate. *See* United States v. Singer, 943 F.2d 758, 763 (7th Cir. 1991) (“[F]irearms, unlike drugs, are durable goods useful to their owners for long periods of time.”). This means that fixes imposed at the manufacturer level will take far longer to make a difference than efforts targeting possession, though restrictions on allowable forms of ammunition would have a more immediate impact. *Cf.* Ron Berler, Opinion, *Keep the Guns, Just Get Rid of the Bullets*, PHILA. INQUIRER, Nov. 13, 2019, at A14 (“[H]ere’s what would happen if the manufacture of today’s standard-size rounds were outlawed, and .23, .39 and .46-caliber rounds took their place: Eventually, gun owners would run out of the old ammo, and their weapons would become paperweights. . . . To use the recalibrated rounds, people would have to purchase new weapons to fire them.”); Sam Roberts, *Controlling Guns: One Idea Starts with the Bullets*, N.Y. TIMES, Dec. 6, 1990, at B1 (discussing a proposal by Senator Patrick Moynihan (D-N.Y.) to ban bullets for .25- and .32-caliber and 9-millimeter semiautomatic weapons).

⁷⁴ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331–397). Senator Royal Copeland (D-N.Y.) had served as the principal author of both of these statutes.

⁷⁵ *See supra* notes 57–58 and accompanying text.

⁷⁶ Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 540 (codified as amended in scattered sections of 21 U.S.C.).

⁷⁷ 21 U.S.C. § 321(g)(1) (2018). Until 1990, the last clause of this definitional section included the proviso that the term “does not include devices or their components, parts, or accessories.”

⁷⁸ 21 U.S.C. § 321(h) (1974).

intended to serve diagnostic or therapeutic purposes as well as products intended to affect the structure or function of the body.⁷⁹ Courts sometimes struggled in trying to distinguish drugs and devices,⁸⁰ prompting Congress in 1976 to add the proviso that a device “does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and . . . is not dependent upon being metabolized for the achievement of any of its principal intended purposes.”⁸¹

The “intended use” of a product plays a central role in defining the reach of the FDA’s authority.⁸² Typically the agency looks to labeling and any other promotional claims made by the seller.⁸³ A regulation governing labeling requirements for devices provides, however, that intended use also “may be shown by the circumstances surrounding the distribution of the article.”⁸⁴ Indeed, the FDA relied on the latter when it asserted regulatory jurisdiction over tobacco products, a contested issue that the U.S. Supreme Court ultimately left unresolved when it invalidated that initiative.⁸⁵

⁷⁹ When it created a tax deduction for the costs of “medical care” four years later, Congress defined that phrase using language identical to these clauses from the drug and device definitions. *See* Revenue Act of 1942, Pub. L. No. 77-753, § 127(a), 56 Stat. 798, 825–26 (codified as amended at 26 U.S.C. § 213(d)(1)(A)). Because the deduction covers only *medical* expenses, however, the clauses may operate somewhat more narrowly than those used in the FDCA.

⁸⁰ *See, e.g.,* *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798–801 (1969) (sustaining an FDA decision to classify antibiotic sensitivity discs as drugs rather than devices); *AMP Inc. v. Gardner*, 389 F.2d 825, 829–31 (2d Cir. 1968) (same, for a ligature product that used nylon suture material to tie off blood vessels).

⁸¹ *See* Pub. L. No. 94-295, § 3(a)(1)(A), 90 Stat. at 575 (codified as amended at 21 U.S.C. § 321(h)(3) (2018) (replacing, for instance, both uses of the term “principal” with the term “primary”)). Congress also expanded the diagnostic use clause to cover “conditions” in addition to diseases, and it dropped the use of plural forms in the original introductory clause (“instruments, apparatus, contrivances” and such) while further broadening that list to include the following items: “implement, machine, . . . implant, in vitro reagent, or other similar or related article.”

⁸² *See* Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 55–56 n.112 (2011).

⁸³ *See, e.g.,* *United States v. Article of Drug Designated B-Complex Cholinols Capsules*, 362 F.2d 923, 925–26 (3d Cir. 1966) (radio broadcasts); *Nature Food Ctrs., Inc. v. United States*, 310 F.2d 67, 70 (1st Cir. 1962) (public lectures); *United States v. Gen. Nutrition, Inc.*, 638 F. Supp. 556, 563–64 (W.D.N.Y. 1986) (oral representations made by authorized sales distributors).

⁸⁴ *See* 21 C.F.R. § 801.4 (2020) (“This objective intent may . . . be shown . . . by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.”); *see also* Regulations Regarding “Intended Uses,” 86 Fed. Reg. 41,383, 41,401 (Aug. 2, 2021) (amending this rule); *United States v. Travia*, 180 F. Supp. 2d 115, 118–19 (D.D.C. 2001) (allowing for the prosecution of defendants for selling balloons filled with nitrous oxide (laughing gas) outside of a rock concert even though they had made no representations that these products would affect the structure or function of the body); *id.* at 119 (“This case is obviously unique in that, if the government’s allegations are true, the sellers did not need to label or advertise their product, as the environment provided the necessary information between buyer and seller.”).

⁸⁵ *See* *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 131–32 (2000) (declining to address the industry’s argument that only claims made to consumers could provide the basis for finding an intended drug or device use). In contrast, after giving the issue close scrutiny, four members of the Court unreservedly endorsed the FDA’s broad interpretation of this statutory language as entitled to deference. *See id.* at 170–74 (Breyer, J., dissenting); *id.* at 170 (“[E]ven in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product.”); *see also id.* at 172 (“Although in recent decades cigarette manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the

The FDA has, however, twice seemingly disavowed enjoying any authority over firearms. While testifying at a Senate subcommittee hearing that focused on the dangers of products such as “Chemical Mace” self-defense spray in 1969 (one year *after* fairly exhaustive legislative activity on firearms), the Commissioner and Chief Counsel of the FDA made some remarks about the agency’s lack of authority over firearms.⁸⁶ In 1996, in the preamble to its final rule asserting jurisdiction over tobacco products, the FDA answered public comments imagining a slippery slope by explaining that the rule would not serve as precedent for treating guns as

companies no longer need to express—that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.”).

⁸⁶ See *Public Sale of Protective Chem. Sprays: Hearing Before the Consumer Subcomm. of the Sen. Comm. on Commerce*, 91st Cong. 37 (1969) (statement of William W. Goodrich, FDA Chief Counsel) (“I suppose that pistols and bullets are intended to affect the function or structure of the body in the same way these [self-defense chemical sprays] are, but we concluded that the products could not properly be classified as drugs under the definition in the [FDCA].”). This came in response to a question from Senator Moss (D-Utah), chairman of the subcommittee, about “a premarketing clearance approach,” *id.*, which in that era only classification as a “new drug” would have accomplished. *Cf. id.* at 44 (testimony of Paul R. Dixon, FTC Chairman) (noting that the FDA “has ruled that these chemical sprays do not meet the definition of a ‘drug’”). To the extent that officials from the FDA who testified at the hearing discussed guns rather than chemical sprays, they focused on devices used to propel canisters of tear gas (a.k.a. lacrymating agents). See *id.* at 28–29 (testimony of Herbert L. Ley, FDA Commissioner); *id.* at 26–27 (explaining FDA labeling regulation pursuant to the Federal Hazardous Substances Act (FHSA)); *id.* at 39, 41 (describing the nature of injuries reported from this type of dispenser). The Commissioner did speak briefly about traditional firearms, though expressing his views about wise policy rather than the scope of the agency’s potential regulatory jurisdiction:

We also require, for example, in the labeling of shotgun shells, which fall under the same act [i.e., the FHSA], the statement that this box contains shotgun shells. We do not go into the details and principles of the proper handling of a shotgun. I believe that the consumer education in the use of firearms and other weapons is not an appropriate area for FDA to function in. This is a weapon.

Id. at 35; see also *id.* at 35–36 (responding to Senator Moss’s follow-up question about “authority to go further” by again focusing on the lacrymating agents, though alluding to earlier testimony [referenced on p.7] about asserting drug jurisdiction as “the most drastic approach”); *id.* at 37 (same, but again without ruling it out as theoretically possible); *id.* at 41–43 (same, in responding to Senator Cotton’s questions). Even the official statement on the narrower question of exercising drug jurisdiction over chemical sprays used for law enforcement seemed to equivocate. See *id.* at 61 (letter from William H. Stewart, Surgeon General, U.S. Public Health Service) (“While ‘Chemical Mace’ and related formulations . . . do not fit, in our opinion, within the definition of ‘drugs’ under the purview of the [FDA] we plan to encourage further studies, particularly to determine possible chronic effects. As additional information is available, we will revise our recommendations as necessary.”).

In short, the testimony from the FDA officials at this hearing never once mentioned the potential reach of the agency’s device jurisdiction, declined to extend its drug jurisdiction over chemical self-defense sprays, though without entirely dismissing the possibility of doing so in the future, and made passing references to more traditional weapons, conceding that such products intend to affect the structure or function of the body, though preferring to steer clear of that subject altogether. For a discussion on how such testimony might impact judicial review of statutory objections, see *infra* notes 204–12 and accompanying text. Although he did not address firearms in particular, Mr. Goodrich’s immediate successor as Chief Counsel famously staked out a far broader conception of the FDA’s regulatory jurisdiction, believing that it extended to anything consistent with promoting the public health unless explicitly prohibited by Congress. See Noah, *The Little Agency That Could*, *supra* note 5, at 918–19 (summarizing and critiquing this position espoused by Peter Barton Hutt).

devices.⁸⁷ Although such a reassurance might qualify as a general statement of policy deserving some respect,⁸⁸ the agency ventured this remark exactly a quarter of a century ago in connection with a rulemaking process that had related to an entirely different subject. In fact, the U.S. Supreme Court has roundly disparaged similar sorts of dicta that the FDA has sprinkled into other rulemaking preambles.⁸⁹

A good deal more clearly than tobacco products, firearms and ammunition represent “instruments, apparatus, and contrivances, including their components, parts, and accessories intended . . . to affect the structure or any function of the body of man or other animals.” Their lack of any therapeutic use or other medical application would have surprisingly little bearing on the question. In the original FDCA, Congress had opted to use the unadorned term “device,” and sweeping amendments enacted decades later generally continued to do so even while the titles of the newer legislation made reference to “medical” devices.⁹⁰

⁸⁷ In response to comments that feared this use of the structure-or-function clause “might provide precedent for applying the provision to a wide range of products that have effects on the structure or function of the body—including guns and other weapons,” the FDA explained that it “has never construed the structure-function provision to include products such as guns, airbags, and chemical sprays, and applying the structure-function provision to nicotine-delivering tobacco products will not provide any precedent for doing so.” *Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination*, 61 Fed. Reg. 44,619, 44,684–85 (Aug. 28, 1996). Historically accurate as a descriptive matter but otherwise unilluminating. The agency did, however, elaborate by attempting to distinguish the cases as follows:

[T]here are fundamental distinctions between these products and nicotine-delivering tobacco products. Cigarettes deliver a pharmacologically active dose of the drug nicotine to the body through inhalation. Smokeless tobacco delivers a pharmacologically active dose of the same drug through buccal absorption. Collectively, tobacco products achieve their effects on the structure and function of the body through nicotine’s pharmacological effects. These include sedation, stimulation, weight control, and maintenance of addiction. Tobacco products are thus indistinguishable from products that the Agency has traditionally regulated as drugs and devices. In contrast, guns, airbags, and chemical sprays are markedly different and distinguishable from such products.

Id. at 44,685. True but utterly meaningless—a tobacco product may represent a drug-device combination, and, as its primary mechanism of action is pharmacological, should face regulation as a drug rather than a device. *See* Noah, *supra* note 13, at 23–27. Most conventional devices do not come prefilled with or otherwise deliver pharmacological agents and therefore plainly qualify as unadorned devices. I agree that the contorted jurisdictional analysis characterizing tobacco products as devices fails to set any precedent for doing so with guns, and not simply because the courts subsequently rebuffed it—perhaps that analysis would help if trying to squeeze tranquilizer darts into the device box, but firearms and ammunition literally satisfy the structure-or-function clause of the statutory definition so much more clearly!

⁸⁸ *See* 21 C.F.R. § 10.85(d)(1) (2020). The rule emphasized that the agency remained entirely free to subsequently revisit a previously announced policy. *See id.* § 10.85(d)–(h); *see also* Lars Noah, *The FDA’s New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113 (1997) (discussing a proposal to revoke this rule).

⁸⁹ *See* *Wyeth v. Levine*, 555 U.S. 555, 575–81 (2009). No such language had appeared in the preamble to the proposed rule, 60 Fed. Reg. 41,314 (Aug. 11, 1995), or the accompanying jurisdictional statement, 60 Fed. Reg. 41,453 (Aug. 11, 1995), so this assertion of general policy did not itself get subjected to notice-and-comment procedures.

⁹⁰ *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539, 540; Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4520. Subsequent legislation began to include the

Contrary to the frequent assumption that Congress intended to delegate jurisdiction over only those devices having some medical application, the FDA has classified as devices a number of products lacking any intended therapeutic use.⁹¹ It also has persuaded courts that it could use its device authority to regulate plainly nonmedical items.⁹² For instance, the FDA treats sunlamps and other indoor tanning equipment, which serve primarily cosmetic purposes, as devices,⁹³ and it recently has increased the rigor of its requirements in response to concerns about malignant melanoma and other skin cancers.⁹⁴ Even hypodermic needles and syringes, which plainly qualify as devices,⁹⁵ may get put to non-therapeutic uses such as recreational drug abuse or lethal injection.

adjective “medical” to modify the term “device” in the statutory text as well. *See, e.g.*, Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 102, 116 Stat. 1588 (codified as amended at 21 U.S.C. §§ 379i–379j). These amendments made no alteration, however, to the FDCA’s definitional section or core provisions governing devices.

⁹¹ For instance, the FDA has asserted authority to regulate certain devices useful primarily in law enforcement. *See* 21 C.F.R. § 862.3050 (breathalyzer); *id.* § 866.5800 (rape test kit); *id.* § 882.1540 (machines sometimes used as lie detectors); Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical “Devices” from Medical “Devices” Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 832 n.165 (1993) (The FDA “declared in a May 1990 Compliance Policy Guide that kits promoted for the testing of hair for the presence of drugs by employers and law enforcement officers are unapproved medical devices.”); *id.* at 853–54 (elaborating on devices used in such contexts); *see also id.* at 811–12 & n.34, 832–36 (questioning the FDA’s assertion of jurisdiction over merely assistive devices intended for use by persons with disabilities); *id.* at 815 (“Because most of the [device classification] regulations have gone unnoticed and unchallenged, their validity is untested.”); *id.* at 824 & n.117 (same); *cf.* Matthew Avery & Makenzi Galvan, *Animal-Based Medical Diagnostics: A Regulatory Problem*, 75 FOOD & DRUG L.J. 370, 397–99 (2020) (explaining that the FDA has classified maggots and leeches as devices when used for wound healing, and forecasting that it will do the same with disease-sniffing dogs); Rebecca Robbins, *Will Akili’s Prescription Video Game Be a Winner?*, BOS. GLOBE, June 25, 2020, at C1 (reporting that the FDA cleared the online game EndeavorRx for use in children with ADHD). The FDA reconsidered its position with regard to at least one assistive device, deciding that NHTSA enjoyed primary jurisdiction instead. *See* Physical Medicine Devices; Revocation of the Classification of Mechanical Automobile Hand and Foot Driving Control, 58 Fed. Reg. 29,535 (May 21, 1993).

⁹² *See, e.g.*, *United States v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026, 1028–29 (10th Cir. 1994) (empty glass specimen containers used to transport saliva or urine to a clinical laboratory to conduct testing solely for insurance underwriting purposes); *United States v. Article of Device*, 731 F.2d 1253, 1255–58 (7th Cir. 1984) (chiropractic instrument that supposedly detected low levels of electromagnetic radiation emanating from the body); *United States v. 23, More or Less, Articles*, 192 F.2d 308, 309 (2d Cir. 1951) (phonograph record purporting to induce sleep); *see also* *United States v. 25 Cases, More or Less, of an Article of Device*, 942 F.2d 1179, 1182 (7th Cir. 1991) (“The FDA has consistently interpreted ‘device’ in a very expansive manner.”); *cf.* *Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940, 943–46 (D.C. Cir. 2012) (affirming dismissal for lack of finality challenges to FDA warning letters that had treated homeopathic “ear candles” as devices).

⁹³ *See* Medical Devices; Classification of 70 Electromedical Devices, 55 Fed. Reg. 48,436, 48,440 (Nov. 20, 1990) (codified as amended at 21 C.F.R. § 878.4635). The FDA had separately classified UV lamps used for treating dermatological conditions. *See* General and Plastic Surgery Devices; General Provisions and Classifications of 51 Devices, 53 Fed. Reg. 23,856, 23,876 (June 24, 1988) (codified as amended at 21 C.F.R. § 878.4630). The agency enjoys distinct authority over radiation-emitting electronic products. *See* Radiation Control for Health and Safety Act of 1968, Pub. L. No. 90-602, 82 Stat. 1173 (codified as amended at 21 U.S.C. §§ 360hh–360ss).

⁹⁴ *See infra* notes 137–38.

⁹⁵ *See* 21 C.F.R. § 880.5570(a) (“A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.”); *cf. id.* § 812.3(k) (distinguishing between “noninvasive” and invasive diagnostic devices based on whether they “by design

The fact that most guns never get fired (serving only as a threat) should present no obstacle. After all, courts have rejected the argument that a product incapable of actually doing what it claims would escape device jurisdiction.⁹⁶ Consider in this respect automated external defibrillators (AEDs), which plainly qualify as (therapeutic) devices.⁹⁷ Although now fairly ubiquitous in public places,⁹⁸ these resuscitation devices rarely, if ever, get used for treating ventricular fibrillation.⁹⁹ AEDs may, of course, get discharged periodically as part of routine maintenance checks or when training individuals how to use them, which might be viewed as akin to target practice. The FDA also has authorized the sale of these devices for home use,¹⁰⁰ but in practice this appears to serve as little more than a security blanket given the even lower likelihood of use in this setting.¹⁰¹

If the relative infrequency of use for wounding presented an obstacle to asserting device jurisdiction over firearms, then the agency could focus instead on ammunition as satisfying the structure-or-function clause of the definition and treat guns as accessories to such devices, designed as systems for delivering the ammunition.¹⁰² After all, an unloaded firearm could not affect the structure or function of anyone's body, unless used for purposes

or intention . . . [p]enetrates or pierces the skin or mucous membranes of the body," though "simple venipuncture is considered noninvasive"). The agency also has treated instruments used to pierce ears as devices. *See* FDA, Compliance Policy Guide § 320.100 (1987), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-320100-ear-piercing-devices>; *see also* Studex Ear Piercing Guns, 510(k) Premarket Notification (1986), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K860622>.

⁹⁶ *See, e.g.,* United States v. Bowen, 172 F.3d 682, 686 (9th Cir. 1999) ("[T]he only question . . . is whether the *intended use* of the product is to prevent disease, not whether the product *actually* prevents disease."); Church of Scientology of Cal. v. Richardson, 437 F.2d 214, 217 (9th Cir. 1971) (holding that a Scientology "E-meter" was a device, even though the plaintiff admitted that "the devices are ineffective for any medical therapeutic purpose"); *see also* Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 105 (1989) (explaining that Congress had added the device definition in 1938 to ensure that the FDA could act against quack devices).

⁹⁷ *See* 21 C.F.R. § 870.5310 (2020).

⁹⁸ *See, e.g.,* Lars Noah, *Turn the Beat Around?: Deactivating Implanted Cardiac-Assist Devices*, 39 WM. MITCHELL L. REV. 1229, 1234 & n.21 (2013).

⁹⁹ *See* Dianne L. Atkins, Editorial, *Public Access Defibrillation: Where Does It Work?*, 120 CIRCULATION 461 (2009). In this sense, they have become a bit like fire extinguishers.

¹⁰⁰ *See* Barnaby J. Feder, *Do It Yourself: The Home Heart Defibrillator*, N.Y. TIMES, May 3, 2005, at C1.

¹⁰¹ *See* Gust H. Bardy et al., *Home Use of Automated External Defibrillators for Sudden Cardiac Arrest*, 358 NEW ENG. J. MED. 1793, 1802 (2008) ("[T]he low event rate and the neutral outcome with respect to death from any cause suggest that the placement of AEDs in homes would be an inefficient strategy in public health terms, despite the value to patients who are fortunate enough to have the event witnessed and the AED applied.").

¹⁰² A similar debate has arisen in public health circles over whether to characterize the gun as an injurious "agent" or instead as a "vector" (akin to a mosquito) that transmits the immediately injurious "agent" (namely, ammunition). *See* Smith et al., *supra* note 19, at 585 ("Regardless of how the model is applied, its value lies in the articulation of a broad range of proximal and distal contributing factors that provide potential leverage at multiple levels to achieve injury prevention goals."); *see also* Peter Applebome, *Conversations/David Satcher: CDC's New Chief Worries as Much About Bullets as About Bacteria*, N.Y. TIMES, Sept. 26, 1993, at A7.

of inflicting blunt trauma, while bullets that enter “the body of man or other animals” plainly intend to affect its structure or function.

Guns come in all shapes and sizes—from toys that shoot foam projectiles or water,¹⁰³ and equipment used in athletic competitions such as starter guns or pistols and rifles fired at targets, to a variety of long guns used primarily for hunting and handguns designed largely for personal protection. Technological improvements that initially focused on military and law enforcement uses quickly spread into the civilian market—thus, among handguns, semiautomatic pistols have taken the place of revolvers, and self-loading features have become the norm among long guns as well.¹⁰⁴ Of course, sellers of toy guns do not intend to affect the structure or function of the body, even if some of these products (i.e., BB and paintball guns) may cause eye injuries or worse.¹⁰⁵ If accidental harms sufficed to trigger device jurisdiction, then the FDA implausibly could regulate all manner of potentially injurious consumer goods such as lawn mowers and toasters. In short, the statutory term “intended” must represent an antonym of inadvertent. Similarly, pistols that fire blanks or high-powered air guns that fire pellets for use in marksmen competitions (e.g., biathlon) need not detain us. Shotguns and the like used primarily for hunting would, however, fit the definition of device insofar as their intended use is to affect the structure or function of the body of animals.

Weapons and ammunition designed to inflict wounding force on humans even more clearly satisfy the structure or function clause. Responsible users will, of course, train to use these guns at shooting ranges, and they will hope to never actually fire them at another person;¹⁰⁶ similarly, irresponsible users may brandish weapons solely to threaten others without planning to discharge them. None of this changes the fact that manufacturers have designed such products to cause bodily harm and that guns accomplish this purpose with great regularity.¹⁰⁷ Relatively inexpensive small caliber

¹⁰³ See Esther B. Fein, *Violent Playthings: Parents Ponder Choices*, N.Y. TIMES, Dec. 23, 1993, at B1.

¹⁰⁴ See James B. Jacobs, *Why Ban “Assault Weapons”?*, 37 CARDOZO L. REV. 681, 686 (2015) (“Practically all modern rifles, pistols, and shotguns are semiautomatics; non-semiautomatic long guns include bolt action, slide action, and breach loaders; non-semiautomatic pistols [nowadays] are called revolvers.”); C.J. Chivers, *The Tools of Modern Terror*, N.Y. TIMES, Aug. 5, 2016, at A12 (discussing the Cold War origins of the Russian AK-47 and the American AR-15/M-16 rifles); Ali Watkins et al., *Once Banned, “America’s Rifle” Is Fiercely Loved and Loathed*, N.Y. TIMES, Mar. 3, 2018, at A1 (discussing the growing popularity of semiautomatic versions of the AR-15).

¹⁰⁵ See Margaret Jones et al., *Nonpowder Firearm Injuries to Children Treated in Emergency Departments*, 144 PEDIATRICS e20192739 (2019); Sabrina K. Presnell, Comment, *Federal Regulation of BB Guns: Aiming to Protect Our Children*, 80 N.C. L. REV. 975, 979–91, 1002–28 (2002) (discussing the increasing power of such guns and accumulating evidence of serious harm, concluding that the CPSC should regulate these products more aggressively).

¹⁰⁶ Cf. David Hemenway & Sara J. Solnick, *The Epidemiology of Self-Defense Gun Use: Evidence from the National Crime Victimization Surveys 2007–2011*, 79 PREVENTIVE MED. 22, 25 (2015) (“Self-defense gun use is a rare event.”).

¹⁰⁷ See Andrew Jay McClurg, *In Search of the Golden Mean in the Gun Debate*, 58 HOW. L.J. 779, 798 n.112 (2015) (“[G]uns, at least handguns, are the only legal product for which the intended purpose

handguns lack any utility for hunting or target shooting, while newer firearms include various features such as increased caliber size for the sole purpose of making them still more lethal.¹⁰⁸ The FDA could, however, also assert device jurisdiction over nonlethal weapons, such as stun guns,¹⁰⁹ and nonpenetrating ammunition, such as rubber bullets.¹¹⁰

When gunshot victims assert products liability claims against manufacturers, the defendants invariably respond by pointing out that their weapons performed exactly as designed.¹¹¹ Moreover, the marketing of

and primary utility is to kill or injure human beings. Thus, comparisons to other dangerous products, such as automobiles, alcohol, or baseball bats, are inapt because their primary purposes and utilities are, respectively, transportation, recreation, and the national pastime.”); Vernick & Teret, *supra* note 14, at 1194 (“[F]irearms are specifically designed to injure or kill.”); Michael S. Obermeier, Comment, *Scoping out the Limits of “Arms” Under the Second Amendment*, 60 U. KAN. L. REV. 681, 701 (2012) (“All weapons are dangerous. If a particular weapon was not dangerous, then there would be little use for it in the first place.”); Eliza Sydnor Romm, Opinion, *Gun Makers Must Do More*, N.Y. TIMES, Apr. 6, 2018, at A23 (“[G]un manufacturers . . . create products designed to kill human beings.”).

¹⁰⁸ See Smith et al., *supra* note 19, at 589 (finding “a large increase, especially since 2005, in the share of firearms produced that are of higher caliber and therefore greater lethality”).

¹⁰⁹ See Cheryl W. Thompson & Mark Berman, *Stun Guns: “There Was Just Too Much Use,”* WASH. POST, Nov. 27, 2015, at A1 (“Tasers are best known for their ability to incapacitate individuals while used in ‘probe mode,’ when they fire two barbs that deliver an electric current along wires, causing the muscles to lock up. When placed against a person’s body in ‘drive stun’ mode, . . . Tasers do not incapacitate but cause localized pain that can be used to control dangerous individuals.”). Although they do not qualify as firearms (lacking both gun powder and wounding projectiles), stun guns—also known as “conducted electrical devices” (or “electroshock weapons”)—operate in a fashion vaguely similar to AEDs, see *supra* notes 97–101 and accompanying text, though obviously without intending to serve any sort of therapeutic purpose. Nonetheless, an instrument designed to discharge enough voltage to inflict pain or trigger momentary muscle paralysis plainly would satisfy the structure-or-function clause; after all, the agency has regulated as devices other products that resemble cattle prods. See Judge Rotenberg Educ. Ctr., Inc. v. FDA, 3 F.4th 390, 396–40 (D.C. Cir. 2021) (invalidating the agency’s ban on electrical stimulation devices to treat aggressive or self-injurious behavior); see also *United States v. Universal Mgmt. Servs.*, 191 F.3d 750, 754–55 (6th Cir. 1999) (sustaining an FDA enforcement action against the seller of electric gas grill igniters marketed for analgesic purposes). If the FDA preferred an incremental approach, then it could start by tackling stun guns notwithstanding the lack of carnage associated with such weapons. Cf. Kate Mather, *Trouble with Tasers; One of the LAPD’s Preferred Weapons to Help Officers Avoid Shootings Often Doesn’t Work*, L.A. TIMES, Apr. 3, 2016, at A1; *supra* note 58 (referencing jurisdictional jockeying by the CPSC and the ATF over early versions of the Taser); *infra* note 230 and accompanying text (explaining that in 2016 the U.S. Supreme Court extended Second Amendment protection to stun guns).

¹¹⁰ See Knavul Sheikh & David Montgomery, *It’s “Nonlethal,” but It Maims, and Also Kills*, N.Y. TIMES, June 13, 2020, at A1 (“Rubber bullets, one of the most common crowd-control munitions, are more than four times the diameter of typical bullets and weigh more than five times as much. They are usually fired from military grenade launchers Since they are cylinder-shaped, without the pointy tips of regular bullets, they are not designed to penetrate the body.”); *id.* (“A 2017 analysis published in the British Medical Journal of several decades of the use of rubber bullets, beanbag rounds and other projectiles during arrests and protests found that 15 percent of people who were injured were left with permanent disabilities and 3 percent of those who were injured died.”).

¹¹¹ See, e.g., *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1158 (Md. 2002) (rejecting a design defect claim against the manufacturer of a semiautomatic pistol because “it worked exactly as it was designed and intended to work and as any ordinary consumer would have expected it to work”); *id.* at 1153 (pointing out that “a handgun does not malfunction when it shoots a bullet into a person in whose direction it is fired”); see also Timothy D. Lytton, *Negligent Marketing: Halberstam v. Daniel and the Uncertain Future of Negligent Marketing Claims Against Firearms Manufacturers*, 64 BROOK. L. REV. 681, 682 (1998) (“While well-made firearms that function precisely as designed might be dangerous, they are not defective.”); Note, *Handguns and Products Liability*, 97 HARV. L. REV. 1912, 1912 (1984)

some firearms and accessories amply confirms this intended use,¹¹² and sales to civilians of weapons designed for professionals belie any suggestion of a function other than the capacity to cause personal injury.¹¹³ Outside of products liability, tort law routinely characterizes firearms as inherently dangerous instrumentalities, which may have consequences for users' standard of care and owners' obligations when entrusting them to others.¹¹⁴

Although at best only a minor facet of the overall problem, exotic ammunition offers a stark illustration of the broader difficulty. Consider this advertisement directed to gun enthusiasts:

Officially called the Supreme Expansion Talon, SXT, the Black Talon represents the latest step up in hollow-point bullet performance. . . . The Talon expands to expose razor-sharp reinforced jacket petals. These cut tissue in the wake of the penetrating core. Toward the end of the bullet travel, the Talon bullet typically turns sideways. . . . From this point on, it penetrates soft tissue like a throwing star—very nasty; very effective; a real improvement in handgun ammo.¹¹⁵

(criticizing attempts “to hold manufacturers liable for making available a product that performs exactly as it is intended to perform”).

¹¹² See, e.g., *Prescott v. Slide Fire Solutions, LP*, 410 F. Supp. 3d 1123, 1140 (D. Nev. 2019) (referencing allegations that the defendant had “promoted the bump stock device for its high rate-of-fire capabilities”); *id.* at 1129 (“Plaintiffs also point to statements made by Slide Fire’s inventor . . . which suggest that bump stocks are intended for consumers who seek a firearm that mimics a fully automatic weapon.”); *Merrill v. Navegar, Inc.*, 28 P.3d 116, 119–20, 132–33 (Cal. 2001) (discussing efforts to market the TEC-DC9 in ways designed to appeal to criminals, but ultimately rejecting the tort claims); *id.* at 136–39 (Werdegar, J., dissenting) (elaborating on the design and marketing of these semiautomatic pistols and their 32 round detachable magazines); *Soto v. Bushmaster Firearms Int’l*, 202 A.3d 262, 325 (Conn. 2019) (allowing only unfair trade practice claims based on allegedly unlawful marketing of the assault rifle used in the Sandy Hook Elementary School mass shooting).

¹¹³ See *Ileto v. Glock Inc.*, 349 F.3d 1191, 1204 (9th Cir. 2003) (“Plaintiffs allege that Glock’s marketing and distribution strategy includes the purposeful oversupply of guns to police departments and the provision of unnecessary upgrades and free exchange of guns with police departments to create a supply of post-police guns that can be sold through unlicensed dealers without background checks to illegal buyers at a profit.”); Dru Stevenson, *Smart Guns, the Law, and the Second Amendment*, 124 PENN ST. L. REV. 691, 716 (2020) (“[G]un makers advertise products to the civilian market as the same guns used by the Army, Marines, or major urban police departments.”); see also James William Gibson, Opinion, *Guns Today Are Combat-Ready*, L.A. TIMES, June 25, 2019, at A11 (“[B]uyers find the power of combat weapons seductive. Paramilitary consumers crave adrenaline, and the weapons are designed and advertised to appeal to warrior fantasies.”).

¹¹⁴ See, e.g., *Kitchen v. K-Mart Corp.*, 697 So. 2d 1200, 1206–08 (Fla. 1997); *Wood v. Groh*, 7 P.3d 1163, 1168–69 (Kan. 2000); *Est. of Strever v. Cline*, 924 P.2d 666, 671 (Mont. 1996); *Herland v. Izatt*, 345 P.3d 661, 666–68, 672–75 (Utah 2015).

¹¹⁵ *Bull of a Bullet*, HOUS. CHRON., Aug. 17, 1993, at A2 (quoting from the November 1992 issue of *Handguns for Sport & Defense*); see also Ronald Smothers, *A Tax Debate Focuses on Destruction Science*, N.Y. TIMES, Nov. 7, 1993 (§ 1), at 22 (“Marketed under names like Black Talon, Starfire and Hydro-Shok, the ammunition is touted in the advertising for its ‘unsurpassed stopping power’ and its ‘knockdown power.’ Those attributes have made it popular with handgun owners who say their main reason for keeping a weapon is self-defense rather than target practice or hunting.”). Manufacturers of other exotic types of ammunition have engaged in similar types of marketing:

Distributors advertise their wares with a variety of lethal claims. In most states, it is possible to mail-order Blammo Ammo, which explodes upon impact into hundreds of

By not exiting their intended target, barbed hollow-point bullets work to limit risks to bystanders. Nonetheless, after the Black Talon ammunition featured in a pair of mass shootings in 1993,¹¹⁶ physicians began expressing alarm about removing such sharp projectiles from the mangled viscera of victims.¹¹⁷ A prominent member of the U.S. Senate proposed taxing this class of ammunition into oblivion,¹¹⁸ and some commentators advocated imposing direct restrictions on the sale of bullets more generally.¹¹⁹ Although these proposals never gained traction, and products liability claims

small shards—“naturally, life threatening trauma and shock occur immediately.” The Bolo delivers little balls, connected by piano wire, that whirl around inside—“it slices, it dices.” Dragon’s Breath ignites miniature magnesium fireballs—“also known as the three-second flamethrower. . . . Will not harm your shotgun barrel.”

Judy Pasternak, *Taking Aim at Exotic Bullets*, L.A. TIMES, Jan. 11, 1994, at A1.

¹¹⁶ See Robert Gunnison & Susan Sward, *Highrise Killer Used Mushrooming Bullets in Attack*, S.F. CHRON., July 13, 1993, at A17; Jonathan Rabinovitz, *Sadness and Hope for Family of Victims of Train Shooting*, N.Y. TIMES, Dec. 14, 1993, at B5.

¹¹⁷ See Rene Sanchez, *Brutal Message in Bullet’s Hollow Point; Growing Use of Black Talon Ammunition Causes Alarm in D.C.*, WASH. POST, Jan. 10, 1994, at D1 (“[S]ome medical groups have complained that the Black Talon’s sharp, curling edges pose risks during surgery because they are more likely to tear a surgeon’s gloves and expose the surgeon and victim to infection during an attempt to remove the bullet.”).

¹¹⁸ See Adam Clymer, *Moynihan Asks Big Tax Increase on Ammunition*, N.Y. TIMES, Nov. 4, 1993, at A1 (reporting that the chairman of the Senate Finance Committee advocated an increase in the excise tax to 10,000%); see also *id.* (“Mr. Moynihan’s proposal would raise the current 11 percent tax on the wholesale price of handgun ammunition to 50 percent in most [other] cases. It would not raise the tax on .22-caliber ammunition typically used for target shooting.”); Scott D. Dailard, *The Role of Ammunition in a Balanced Program of Gun Control: A Critique of the Moynihan Bullet Bills*, 20 J. LEGIS. 19, 23 n.31 (1994) (noting that the proposal to increase the excise tax to 50% on centerfire ammunition with a cartridge case shorter than 1.3 inches would reach all ammunition used for handguns, apart from the .22 caliber rimfire type preferred for target shooting and sports competition, while entirely excluding rifles); *cf. id.* at 24–34 (discussing shortcomings in related proposals to prohibit the sale of a more limited subset of handgun ammunition, doubting that this underinclusive approach would quickly render such firearms obsolete). Senator Moynihan’s proposed massive tax hike on the 9 mm Black Talon cartridge also would have applied to .50 caliber “Desert Eagle” ammunition. See *id.* at 23, 27; see also Daniel Patrick Moynihan, Opinion, *Guns Don’t Kill People. Bullets Do.*, N.Y. TIMES, Dec. 12, 1993 (§ 4), at 15.

¹¹⁹ See Katherine Kaufer Christoffel, *Toward Reducing Pediatric Injuries from Firearms: Charting a Legislative and Regulatory Course*, 88 PEDIATRICS 294, 300 (1991) (“Because ammunition is a consumable product, modification of ammunition may have more promise as a rapid means to reduce the severity of injuries from firearms than modification of the weapons themselves.”); *id.* at 301 (“The destructiveness of available bullets could be reduced by regulating the amount of gunpowder, the shape of the tip, and/or jacketing. Such regulation might reduce the severity of nonfatal injury fairly quickly.”); Brendan J. Healey, *Plugging the Bullet Holes in U.S. Gun Law: An Ammunition-Based Proposal for Tightening Gun Control*, 32 J. MARSHALL L. REV. 1, 18–34 (1998) (proposing to require background checks and recordkeeping for the purchase of ammunition and stricter licensing of dealers); Scott Shuger, Opinion, *A Prescription for Ammo; Why Are Killer Bullets as Easy to Buy as Aspirin?*, WASH. POST, Dec. 26, 1993, at C1 (“Let’s treat handgun bullets as a controlled substance.”); see also *supra* note 73 (referencing other proposals to limit ammo); *cf.* Michael Corkery, *Walmart Enters Gun Debate, Curtailing Ammunition Sales*, N.Y. TIMES, Sept. 4, 2019, at A1.

against the Black Talon manufacturer failed,¹²⁰ the company decided to cease selling these bullets to civilians.¹²¹

Even entirely mundane types of ammunition merit closer scrutiny. Higher muzzle velocities and higher energy rounds cause greater tissue damage that surgeons may then find harder to isolate.¹²² Moreover, the vast majority of the billions of bullets produced every year contain lead.¹²³ Unlike copper, lead evidently “helps bullets maintain consistent trajectories . . . [and] ensures maximum damage when a target is hit.”¹²⁴ Apart from their greater potential for causing lethal injury, such bullets may become lodged in the body of survivors and later cause dangerous lead poisoning.¹²⁵ Thus, even though they represent the very antithesis of therapeutic products, guns and ammunition literally fit within the FDA’s regulatory jurisdiction over devices because these products unmistakably intend to affect the structure or function of the body.¹²⁶

¹²⁰ See, e.g., *McCarthy v. Olin Corp.*, 119 F.3d 148, 154–57 (2d Cir. 1997); *Leslie v. United States*, 986 F. Supp. 900, 909–13 (D.N.J. 1997), *aff’d mem.*, 178 F.3d 1279 (3d Cir. 1999); *Downs v. R.T.S. Sec., Inc.*, 670 So. 2d 434, 439 (La. Ct. App. 1996). As with the unsuccessful products liability claims brought against gun manufacturers, these courts held that the ammunition had functioned precisely as intended. See, e.g., *McCarthy*, 119 F.3d at 155.

¹²¹ See Ronald Smothers, *Manufacturer to Withdraw Controversial Ammunition*, N.Y. TIMES, Nov. 23, 1993, at B9 (adding, however, that “there are still 20 to 25 other types of high-performance handgun ammunition of similar type on the market”); see also *Lethal New Ammunition Penetrates a Federal Ban*, N.Y. TIMES, Dec. 27, 1994, at A10 (reporting on “plans to market two types of destructive handgun ammunition that escape a Federal ban on such fragmenting rounds because they are made of carbon-based plastics called polymers, rather than metal. . . . [T]he bullets break into thousands of razorlike fragments when they strike human flesh, the fragments becoming lethal shrapnel”); *id.* (“As deadly as hollow points [such as Black Talon and its still marketed imitators] can be, they pale in comparison to the new [Rhino] ammunition because a much larger proportion of it fragments upon impact.”).

¹²² See AMA Council Sci. Affs., *Assault Weapons as a Public Health Hazard in the United States*, 267 JAMA 3067, 3068 (1992) (“High-velocity bullets may set up shock waves and cause cavitation effects, resulting in unpredictable damage at sites far from the wound tract.”); Daniel W. Webster et al., *Epidemiologic Changes in Gunshot Wounds in Washington, DC, 1983–1990*, 127 ARCHIVES SURGERY 694, 697–98 (1992) (suggesting that a shift in weaponry toward high-capacity, semiautomatic handguns accounted for the increase in patients presenting with multiple thoracic wounds); Margot Sanger-Katz & Quoc Trung Bui, “Type of Weapon Matters”: *Linking Caliber Size to Death Rate*, N.Y. TIMES, Mar. 28, 2019, at A16 (“Over recent decades, the size of bullets fired by the typical handgun has increased. Changes in design have made it easier to fire big [and more lethal] bullets from concealable weapons, and manufacturers have marketed more powerful [semiautomatic] guns as better tools for self-defense.”); see also *id.* (“There are no serious current proposals to regulate or limit the sale of handguns by caliber size.”). For the classic reference volume on different types of ammunition, see FRANK C. BARNES, *CARTRIDGES OF THE WORLD* (W. Todd Woodward ed., 16th ed. 2019).

¹²³ See Melissa Chan, *The Poison in Their Blood: They Survived Mass Shootings, but the Bullets Could Still Kill Them*, TIME, July 8, 2019, at 40, 42 (“Of the 9 billion ammunition rounds produced in the U.S. or imported into the country each year, 95% contain lead, according to the National Shooting Sports Foundation, a gun trade group.”).

¹²⁴ *Id.*

¹²⁵ See *id.* at 40 (discussing “a lesser-known side effect of gun violence: lead poisoning” caused by unremoved bullet fragments); see also Debora Weiss et al., *Elevated Blood Lead Levels Associated with Retained Bullet Fragments—United States, 2003–2012*, 66 MORBIDITY & MORTALITY WKLY. REP. 130, 130 (2017) (calling it “an infrequently reported, but important, cause of lead toxicity; symptoms are often nonspecific and can appear years after suffering a gunshot wound”); cf. *supra* note 57 (discussing limited efforts to address environmental contamination caused by lead shot used when hunting).

¹²⁶ See *Gamerman*, *supra* note 91, at 834 n.177 (conceding that “manufacturers [of guns] plainly intend that their products affect a function of the body”).

D. *Applying the Tools Used for Device Regulation*

The FDA enjoys a range of powers over sellers of devices, and it can use these to promote technological changes that enhance safety and to inhibit those that make products more hazardous. The various statutory provisions governing devices provide flexible options for sensibly controlling the production and sale of guns and ammunition, including measures such as imposing a minimum age for purchasing any type of firearm from any class of seller, demanding clearer instructions related to conscientious use and storage, mandating the adoption of magazine disconnects and other risk reduction features, and altogether prohibiting particularly hazardous classes of guns, ammunition, or other accessories.

It violates federal law to sell an “adulterated” or “misbranded” device.¹²⁷ Adulteration relates primarily to flaws in the process of manufacturing,¹²⁸ while misbranding connotes some shortcoming in labeling,¹²⁹ but the FDCA enumerates several more particular ways that a seller might violate each of these prohibitions. For instance, it would misbrand a device to make false or misleading claims about its performance or fail to reveal dangers associated with its use.¹³⁰ Similarly, if a device must abide by a performance standard or requires the filing of an application for premarket approval, the failure by the seller to do so would render the product adulterated.¹³¹

Devices introduced before May 28, 1976, or that are “substantially equivalent” to devices marketed before that date, may remain on the market. Class III devices, defined to include those products that pose “a potential unreasonable risk of illness or injury,”¹³² may take advantage of this abbreviated route to market until the FDA issues a regulation that requires the filing of an application for premarket approval (PMA) for a particular type of device. A person wishing to introduce a new device but asserting that it qualifies as substantially equivalent to a previously marketed (a.k.a. predicate) device must file a premarket notification (PMN) under § 510(k) of the FDCA to advise the agency.¹³³ The PMN must demonstrate that the device has the same intended use and that any changes in its technological characteristics would raise no new safety or effectiveness questions.¹³⁴ This

¹²⁷ See 21 U.S.C. §§ 331(a)–(c), 351–352 (2018).

¹²⁸ See *id.* § 351(a); see also *United States v. 789 Cases, More or Less, of Latex Surgeons’ Gloves, an Article of Device*, 799 F. Supp. 1275, 1285–94 (D.P.R. 1992).

¹²⁹ See 21 U.S.C. § 352(a); 21 C.F.R. pt. 801 (2020).

¹³⁰ See 21 U.S.C. §§ 321(n), 352(a)(1), 352(f); see also *United States v. Two Units, More or Less, of an Article or Device, Consisting of a Power Unit & a Chair*, 49 F.3d 479, 482 (9th Cir. 1995); *United States v. An Article of Device . . . “Toftness Radiation Detector,”* 731 F.2d 1253, 1259 (7th Cir. 1984) (“[T]he device has to work—if it does not work, it is misbranded.”); *United States v. One Device, Intended for Use as a Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947) (sustaining misbranding action against the “tox-eliminator”).

¹³¹ See 21 U.S.C. § 351(e), (f)(1).

¹³² *Id.* § 360c(a)(1)(C)(ii)(II).

¹³³ See *id.* § 360(k); 21 C.F.R. pt. 807(E).

¹³⁴ See 21 U.S.C. § 360c(i); 21 C.F.R. § 807.100; see also *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 927–28 (D.C. Cir. 2013).

has become the primary mechanism for FDA review of new devices,¹³⁵ but, unlike the far more rigorous PMA process, it does not provide any real assessment of product safety and effectiveness.¹³⁶

If devices need not (yet) secure full approval, the FDA may impose “special controls” such as postmarket surveillance duties or performance standards.¹³⁷ In addition, the agency can designate devices as “restricted” in order to limit their distribution,¹³⁸ which would also give it the power to regulate any advertising for such products.¹³⁹ If a device presents “an unreasonable risk of substantial harm to public health,” the FDA may require notification of this hazard to device users and others.¹⁴⁰ The agency can ban particularly hazardous devices,¹⁴¹ which it has done just a handful of times,¹⁴² though a call for the filing of PMAs for a device can accomplish the same thing.¹⁴³ If it chose to do so for firearms, then manufacturers would find it difficult to demonstrate the safety of their products.

Device sellers must register with the FDA and face periodic inspections of their facilities and records.¹⁴⁴ Sellers also must submit reports of bad outcomes experienced with certain devices.¹⁴⁵ If necessitated by newly

¹³⁵ See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (“Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.”).

¹³⁶ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–80, 493–94 (1996).

¹³⁷ See 21 U.S.C. §§ 351(e), 360c(a), 360d(a), 360f; 21 C.F.R. pts. 822, 861; see also *General and Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, Henceforth to Be Known as Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products*, 79 Fed. Reg. 31,205, 31,213–14 (June 2, 2014) (codified at 21 C.F.R. § 878.4635) (moving sunlamps and related equipment used for indoor tanning from Class I to Class II and imposing as special controls disclosure requirements to caution against underage usage and warn of risks). For an example of a performance standard, see 21 C.F.R. pt. 898 (implanted leads). Although the statute called for such special controls only in connection with Class II devices, the FDA could make them applicable to Class III devices not yet subject to PMA requirements as well. See *infra* note 143.

¹³⁸ See 21 U.S.C. § 360j(e); see also *General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products*, 80 Fed. Reg. 79,493, 79,503–05 (Dec. 22, 2015) (to be codified at 21 C.F.R. § 878.4635) (proposing to use this authority in order to ban all use of tanning beds by minors and require that adults first sign a risk acknowledgment form).

¹³⁹ See 21 U.S.C. § 352(q)–(r). Otherwise, the FTC exercises authority over device advertising. See 15 U.S.C. § 52 (2018); see also *FTC v. QT, Inc.*, 512 F.3d 858, 862–64 (7th Cir. 2008) (affirming judgment for the Commission on charges that analgesic claims in advertising for an “ionized” brass bracelet lacked substantiation).

¹⁴⁰ See 21 U.S.C. § 360h(a)(1)–(2).

¹⁴¹ See *id.* § 360e(e).

¹⁴² See 21 C.F.R. pt. 895(B) (listing only prosthetic hair fibers, powdered medical gloves, and electrical stimulation devices for self-injurious or aggressive behavior).

¹⁴³ See Duff Wilson, *F.D.A. Panel Is Split on Electroshock Risks*, N.Y. TIMES, Jan. 29, 2011, at B7 (reporting about fears that electroconvulsive therapy (ECT) may disappear if the agency demands that manufacturers of these devices secure PMAs); see also *Neurological Devices; Reclassification of Electroconvulsive Therapy Devices; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy Devices for Certain Specified Intended Uses*, 83 Fed. Reg. 66,103, 66,123–24 (Dec. 26, 2018) (codified at 21 C.F.R. § 882.5940) (finessing this concern by reclassifying ECT devices for only a limited set of uses and calling for the submission of PMNs to demonstrate adherence to newly issued special controls).

¹⁴⁴ See 21 U.S.C. §§ 360(h)(2), 374(a), 374(e); *In re Establishment Inspection of Medtronic, Inc.*, 500 F. Supp. 536, 538–40 (D. Minn. 1980).

¹⁴⁵ See 21 U.S.C. § 360i(a); 21 C.F.R. pt. 803; *United States v. Laerdal Mfg. Corp.*, 73 F.3d 852,

discovered hazards, the agency can order the recall of a device.¹⁴⁶ The FDA also can require that sellers track devices in order to facilitate such forms of postmarket surveillance and corrective action.¹⁴⁷

The violation of any of these requirements would allow the FDA to pursue a variety of enforcement actions. It could impose an administrative detention order or civil fines,¹⁴⁸ subject to judicial review, or it could initiate prosecution in the federal courts seeking an order condemning any seized inventory of the product,¹⁴⁹ broad forms of injunctive relief,¹⁵⁰ or even criminal sanctions.¹⁵¹ In short, unlike the ATF's fairly tepid requirements and limited enforcement powers, the FDA's assertion of device jurisdiction would confront the firearms industry with a powerful regulatory body. Conversely, if the FDA imposed specific requirements on sellers of guns and ammunition, then it likely would preempt state and local laws addressing the same subjects.¹⁵²

As it did in the case of tobacco products, however, the agency could opt to use only a subset of its possible device powers, and it might prefer a reactive rather than proactive stance initially—for instance, responding to any dangerous malfunctions by ordering a recall. Basic recordkeeping and reporting requirements would allow it to learn more about what sorts of issues require vigilance. The agency could mandate that purchasers receive instructions and safe storage recommendations. It might designate some or all of these products as restricted devices, which would allow the FDA to impose various conditions on their sale: age restrictions, quantity limits, screening purchasers more carefully than done under existing background

855–56 (9th Cir. 1995).

¹⁴⁶ See 21 U.S.C. § 360h(e); 21 C.F.R. pt. 810.

¹⁴⁷ See 21 U.S.C. §§ 360i(e), 360j(j); 21 C.F.R. pt. 821.

¹⁴⁸ See 21 U.S.C. §§ 333(f), 334(g); 21 C.F.R. § 800.55.

¹⁴⁹ See 21 U.S.C. § 334(a); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1295–98 (D.P.R. 1992); *United States v. An Article . . . Acu-dot*, 483 F. Supp. 1311, 1316–17 (N.D. Ohio 1980).

¹⁵⁰ See 21 U.S.C. § 332(a); *United States v. Diapulse Corp.*, 457 F.2d 25, 31 (2d Cir. 1972) (affirming an injunction against the continued marketing of misbranded devices); see also *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 761–64 (6th Cir. 1999) (affirming an equitable order of restitution to purchasers of an adulterated device).

¹⁵¹ See 21 U.S.C. § 333(a); see also *United States v. Caputo*, 456 F. Supp. 2d 970, 982–83, 985 (N.D. Ill. 2006) (ordering several years in jail for two officers of a small company that had violated numerous FDCA provisions in the course of selling a sterilizer for surgical instruments), *aff'd in relevant part*, 517 F.3d 935, 940–43 (7th Cir. 2008); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1517 (E.D.N.Y.) (involving a criminal conviction for device adulteration and misbranding), *aff'd mem.*, 751 F.2d 373 (2d Cir. 1984).

¹⁵² See 21 U.S.C. § 360k(a); see also *Comm. of Dental Amalgam Mfrs. v. Stratton*, 92 F.3d 807, 813 (9th Cir. 1996) (holding that the FDA's general requirements governing fillings for cavities did not preempt a state warning requirement); *METX, LLC v. Wal-Mart Stores Texas, LLC*, 62 F. Supp. 3d 569, 573 (E.D. Tex. 2014) (holding that federal hearing aid requirements preempted more restrictive state rules related to dispensing). States can apply for waivers. See 21 U.S.C. § 360k(b); 21 C.F.R. pt. 808. An FDA assertion of device jurisdiction also might provide the basis for a preemption defense to tort claims depending on the rigor of controls it then chose to impose, see *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–25 (2008), but that would matter little as Congress already has granted the firearms industry fairly sweeping immunity, see *supra* note 68 and accompanying text.

checks, or authorizing their distribution only to law enforcement or military agencies. Under its authority to require device tracking, the agency could collect detailed information about where firearms and ammunition end up.¹⁵³ Under its authority to require unique device identifiers,¹⁵⁴ the FDA might demand tamper-resistant serial numbers on weapons as well as bullets.¹⁵⁵

If the agency sought to drive more ambitious modifications in product designs, then it could promulgate performance standards, perhaps akin to those adopted in Massachusetts.¹⁵⁶ Standards could address problems such as the ease of gun use by children,¹⁵⁷ unauthorized use by adults,¹⁵⁸ and semiautomatic weapons firing even after the removal of the magazine,¹⁵⁹ and

¹⁵³ For more on the potential benefits of systematically collecting such information, see Philip J. Cook & Anthony A. Braga, *Comprehensive Firearms Tracing: Strategic and Investigative Uses of New Data on Firearms Markets*, 43 ARIZ. L. REV. 277 (2001).

¹⁵⁴ See 21 U.S.C. § 360i(f); 21 C.F.R. pts. 801(B), 830. This represents one of the few operative provisions of the FDCA, however, that refers more narrowly to “medical devices,” which suggests that it would have no application to guns and ammunition.

¹⁵⁵ Cf. Hemenway, *supra* note 14, at 652 (“The regulatory agency should have the power to ensure that every gun has a unique identifier, that the serial number is virtually impossible to obliterate and that bullets can be readily traced to a particular gun.”). Federal law already requires serial numbers on firearms but does not dictate tamper-resistance. See 18 U.S.C. §§ 922(k), 923(i) (2018); 27 C.F.R. §§ 478.92(a)(1)(i), 479.102(a)(1) (2020) (requiring only that a “serial number must be placed in a manner not susceptible of being readily obliterated, altered, or removed,” though more recently specifying a minimum depth of engraving); Identification Markings Placed on Firearms, 66 Fed. Reg. 40,596, 40,599 (Aug. 3, 2001) (conceding “that all markings can be removed by someone who wishes to make a deliberate effort to remove the markings,” focusing instead on the tendency to wear off from normal handling); see also *United States v. Marzzarella*, 614 F.3d 85, 93–101 (3d Cir. 2010) (rejecting Second Amendment challenge to a conviction for possession of a handgun with an obliterated serial number). In responding to the opioid crisis, the FDA similarly encouraged drug manufacturers to introduce abuse-resistant formulations of their prescription narcotics. See Noah, *supra* note 30, at 771.

¹⁵⁶ See *supra* note 34 and accompanying text; see also Butkus et al., *supra* note 28, at 706 (“The American College of Physicians recommends that guns be subject to consumer product regulations regarding access, safety, and design.”); John S. Milne et al., *Effect of Current Federal Regulations on Handgun Safety Features*, 41 ANNALS EMERGENCY MED. 1, 9 (2003) (“It might be possible . . . to develop effective performance-based handgun safety standards, similar to the safety standards for automobiles, that could result in a significant decrease in firearm-related injuries.”); *id.* at 5–7 (discussing the use of features such as a grip safety, firing pin block, loaded chamber indicator, and magazine safety).

¹⁵⁷ Cf. Hemenway, *supra* note 14, at 652 (“The agency should have the power to require safety and crime detection measures for all firearms manufactured or sold in the United States. For example, guns should not fire when dropped and should be made child-proof (a toddler should not be able to fire any gun).”). Some newer handguns have become easier for a child to fire. See Jeff Leen, *Weapon of “Simplicity” Finds Success*, WASH. POST, Nov. 18, 1998, at A23 (reporting that the popular Glock semiautomatic pistols have “light triggers,” which means that it takes half the normal force to fire the first round).

¹⁵⁸ Cf. Philip J. Cook & Jens Ludwig, *Principles for Effective Gun Policy*, 73 FORDHAM L. REV. 589, 612 (2004) (“While trigger locks are widely distributed and would be sufficient for this purpose [namely, guarding against unauthorized use after theft or by children] if they were actually used, an internal keyed lock is more convenient and hence likely to be more widely used by owners.”); *id.* (“Several manufacturers already sell models with internal locks, and Maryland now requires that all new handguns be equipped with integrated mechanical locking devices.” (footnotes omitted)). “Smart” guns incorporate biometric security or other technologies. See Stevenson, *supra* note 113, at 698–718 (discussing types of personalized guns and their limitations); *id.* at 740 (“It may be worth encouraging the development of the technology to save a few hundred lives per year, but advocates (and politicians) should not overpromise what the technology could achieve.”).

¹⁵⁹ See Jon S. Vernick et al., *“I Didn’t Know the Gun Was Loaded”: An Examination of Two Safety Devices That Can Reduce the Risk of Unintentional Firearm Injuries*, 20 J. PUB. HEALTH POL’Y 427,

they might even limit muzzle velocity or caliber size.¹⁶⁰ For some of these concerns, technological fixes already exist, while for others they remain on the drawing board. The FDA need not dictate particular modifications in design, but demanding attention to particular problems would put the onus on the gun industry to come up with feasible solutions. Without performance standards, however, the prospect of having to secure agency clearance before marketing novel redesigns might inhibit safety-enhancing innovation by manufacturers even though the FDA undoubtedly would allow it.

In theory, the premarket review provisions would mean demanding that sellers of these Class III devices file applications for PMA that demonstrate their safety and effectiveness; in practice, the FDA would only require that sellers of new guns and ammunition file PMNs to demonstrate their substantial equivalence to older models.¹⁶¹ At a minimum, this should block the introduction of still more dangerous versions,¹⁶² while it would allow technological innovations that enhance product safety. For instance, had the FDA exercised device jurisdiction over ammunition in 1992, Black Talon bullets presumably would never have entered the market.

If the agency did not content itself with freezing the state of the art in this industry, then it could call for the filing of futile PMAs while exempting certain preferred relatively safer models. If it did not care about subtlety or shouldering the burden of proof, then the agency could accomplish such an end even more directly by issuing an order banning certain excessively hazardous types of guns or accessories such as large-capacity magazines.¹⁶³

433 (1999) (discussing the initially limited adoption of loaded chamber indicators and magazine safeties in semiautomatic pistols).

¹⁶⁰ See Dailard, *supra* note 118, at 35 (“Congress might reasonably decide to suppress the manufacture and sale of the high-velocity, high-energy handgun cartridges that tend to create the most massive wounds in shooting victims. . . . [S]uch a ban would not be conceived as a restriction on specific calibers. Instead, Congress would simply determine a maximum threshold or a benchmark of ballistic performance measured in muzzle energy that no caliber could legally exceed.”); Judith S. Palfrey & Sean Palfrey, *Preventing Gun Deaths in Children*, 368 *NEW ENG. J. MED.* 401, 403 (2013) (“[T]he tissue-destruction capability of ammunition should be limited.”); Rostron, *supra* note 52, at 1462 (“If legislators want to impose tighter restrictions on extremely powerful firearms, they . . . should write laws that look to the amount of energy a firearm is capable of producing, rather than its caliber. For example, Congress could pass a measure imposing additional restrictions on firearms capable of achieving muzzle energy exceeding some specified threshold, such as 10,000 or 12,000 foot-pounds.”); *id.* at 1465 (“[M]uzzle energy is an attractive measure because it provides a good gauge of a firearm’s potency without undue complexity. Muzzle energy may not tell the whole story when it comes to comparing the power of firearms, but it provides a workable means of making distinctions far more sensible than those based entirely on caliber.”); *see also id.* at 1419–28 (distinguishing among various types of firearms, cartridges, ammunition, calibers, and muzzle velocity); *id.* at 1436–67 (discussing the debate about .50 caliber sniper rifles); Gina Kolata & C.J. Chivers, *A Clinical View of Assault Rifles and Their “Ghastly” Toll*, *N.Y. TIMES*, Mar. 6, 2018, at A14 (“The high energy bullet creates a blast wave around the bullet. And the yaw can contribute to the larger exit wound. Striking bone can also cause bone fragments that radiate outward, cutting tissue in each fragment’s path.”).

¹⁶¹ *See supra* notes 133–36 and accompanying text.

¹⁶² *Cf.* Hemenway, *supra* note 14, at 652 (“The [hypothetical] agency should also have the power to prevent the introduction into the civilian market of new firearm products that are more lethal, more concealable, or more conducive to crime than current firearms.”).

¹⁶³ *Cf.* Donald L. Flexner, *Why the Civilian Purchase, Use, and Sale of Assault Weapons and Semiautomatic Rifles and Pistols, Along with Large Capacity Magazines, Should Be Banned*, 20 *N.Y.U.*

Similarly, it could try to force a shift from lead to copper or other less toxic materials in ammunition. A still more ambitious strategy might seek to put an end to all sales of semiautomatic pistols to civilians.¹⁶⁴ Thus, the assertion of device jurisdiction over guns and ammunition would offer the FDA a variety of regulatory options, ranging from reactive to proactive and from incremental to extreme.¹⁶⁵ Political calculations may convince the agency to start off slowly, reserving its proverbial big guns for only the most egregious conduct by members of the firearms industry.

II. GOING BALLISTIC? DISARMING A BARRAGE OF RETURN FIRE

Even if the FDA decided to assert device jurisdiction over guns and ammunition, it would have to count on a skeptical response from all three branches of government. Without clearance from the White House, any such agency proposal would never see the light of day. Assuming that the President decided to play along, Congress would enjoy various opportunities to squelch the initiative. Lastly, even if the FDA survived these political checks, adversely affected parties surely would mount a legal challenge, giving our nominally apolitical judicial branch the last word. Any effort to regulate guns and ammunition as devices would encounter serious but hardly insurmountable statutory and constitutional objections in the federal courts. Long odds, to be sure, but still worth a try.

A. Political Roadblocks and Opportunities

As FDA officials have learned in the last few decades, the leadership at the cabinet-level department that houses it—namely, Health and Human

J. LEGIS. & PUB. POL'Y 593, 612–15 (2017); Louis Klarevas et al., *The Effect of Large-Capacity Magazine Bans on High-Fatality Mass Shootings, 1990–2017*, 109 AM. J. PUB. HEALTH 1754, 1761 (2019); Griff Witte, *Calls to Restrict Firearm Capacity*, WASH. POST, Aug. 19, 2019, at A1.

¹⁶⁴ Cf. Dailard, *supra* note 118, at 34–35 (“[C]ompared to its auto-loading counterpart, the revolver is slow and cumbersome to load, difficult to fire rapidly with accuracy, and has an inherently low ammunition capacity. These features translate to reduced firepower and, thus, to a reduced capacity to inflict multiple wounds or wound multiple victims.”); Kamin, *supra* note 29, at 71 (noting “the likely resistance to implementing another assault weapon ban (or the far greater pushback that could be expected in opposition to a plan to limit access to semiautomatic handguns)”). Law enforcement departments have come to rely on semiautomatic weapons. See Ashley Southall, *For Final Few Officers, the Era of the Revolver Is at an End*, N.Y. TIMES, June 1, 2018, at A20 (discussing the transition among law enforcement personnel to semiautomatic pistols); Watkins et al., *supra* note 104, at A1 (reporting that “police departments around the country started making AR-15s standard issue for officers”).

¹⁶⁵ Cf. Hemenway, *supra* note 14, at 652 (“The key point is not to prescribe exactly what the agency would or should do, but to create such an agency and invest it with the resources and power—including standard-setting, recall and research capability—for making reasonable decisions about firearms.”). Although it may lack the full panoply of powers found in the federal version, the uniform state FDCA uses a parallel definition of devices. See, e.g., CONN. GEN. STAT. § 21a-92(6)(B) (2020); MASS GEN. LAWS ch. 94, § 1 (2020); see also Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 860–61 (2017) (discussing widespread adoption but infrequent enforcement of this uniform law). Although Massachusetts had used entirely different statutory authority to regulate gun manufacturers, see *supra* notes 33–36 and accompanying text, this analysis suggests that agencies in other states could assert device authority if federal action does not materialize. Cf. *supra* note 152 and accompanying text (discussing the prospect of federal preemption).

Services (HHS)—might take issue with the agency’s decisions, perhaps at the behest of the White House.¹⁶⁶ Something like this happened with efforts to make an emergency contraceptive available without a prescription; in 2011, just one day after the FDA Commissioner had announced approval of full over-the-counter status, the Secretary of HHS overruled the agency, with the President soon thereafter publicly expressing his support for the latter decision.¹⁶⁷ After an exhaustive review of what had happened in this case, a federal district court invalidated the Secretary’s decision, remanding the case with instructions that the FDA authorize unrestricted marketing.¹⁶⁸

Even if the White House chose not to stand in the way, Congress would get an expedited opportunity to override a major regulation before it could take effect.¹⁶⁹ In 2016, the Social Security Administration promulgated a rule that would report to the National Instant Criminal Background Check System certain disability benefit recipients if premised on findings of mental illness.¹⁷⁰ A couple of months later, Congress adopted an override that the new occupant of the White House signed.¹⁷¹ If a controversial rule got issued earlier in a Presidential term, then the likelihood of a veto would prevent such a move unless Congress managed to muster super-majorities in both

¹⁶⁶ See Sheila Kaplan, *Health Chief Forbids Agencies Like F.D.A. to Issue Rules on Their Own*, N.Y. TIMES, Sept. 20, 2020, at A4 (calling a memorandum issued by HHS Secretary Azar that evidently was designed to rein in rulemaking initiatives by the FDA “a stunning declaration of authority”); see also Noah Weiland, *How the C.D.C. Lost Its Voice Under Trump*, N.Y. TIMES, Dec. 17, 2020, at A8 (“[P]olitical appointees at the health department repeatedly asked C.D.C. officials to revise, delay and even scuttle drafts they thought could be viewed, by implication, as criticism of President Trump.”).

¹⁶⁷ See Rob Stein, *Judge Rejects Plan B Challenge, May Review FDA Decision*, WASH. POST, Dec. 14, 2011, at A2 (“[I]n an unprecedented decision, [HHS Secretary Kathleen] Sebelius overruled [FDA Commissioner Margaret] Hamburg . . . , a decision endorsed the next day by President Obama.”); see also Lisa Heinzerling, *The FDA’s Plan B Fiasco: Lessons for Administrative Law*, 102 GEO. L.J. 927, 961 (2014) (explaining that “Obama himself disclaimed involvement (though he was quick to affirm support for Sebelius’s overruling of the FDA in 2011)”); Gardiner Harris, *White House and the F.D.A. Often at Odds*, N.Y. TIMES, Apr. 3, 2012, at A1 (discussing this and similar incidents during Obama’s first term). Obama’s successor in office perfected this technique. See, e.g., Sharon LaFraniere et al., *Stung by Trump, F.D.A. Authorizes Plasma Therapy*, N.Y. TIMES, Aug. 24, 2020, at A1 (reporting that Trump had made an “unfounded claim that the F.D.A. was deliberately holding up decision-making until after the election, this time citing a ‘deep state’”); Sheila Kaplan, *F.D.A. Chief Besieged by Politics at Key Moment*, N.Y. TIMES, Aug. 11, 2020, at A1 (suggesting that “the F.D.A. has never been pushed as hard as it is being pushed now”).

¹⁶⁸ See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 197–98 (E.D.N.Y. 2013); see also Michael D. Shear & Pam Belluck, *Obama to Drop Limit on Selling a Contraceptive*, N.Y. TIMES, June 11, 2013, at A1.

¹⁶⁹ See Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, tit. II, § 251, 110 Stat. 847, 857, 868–74 (1996) (codified at 5 U.S.C. §§ 801–808). Commonly referred to as the Congressional Review Act (CRA), it only recently has had much of an impact. See Coral Davenport, *Tool Wielded by Trump May Roll Back His Rules*, N.Y. TIMES, July 18, 2020, at A18 (reporting that, after the CRA got used only once during its first two decades, Republican lawmakers successfully deployed it fourteen times in 2017 to wipe out regulations promulgated late in the Obama administration). See generally Paul J. Larkin, Jr., *Reawakening the Congressional Review Act*, 41 HARV. J.L. & PUB. POL’Y 187 (2018).

¹⁷⁰ See Implementation of the NICS Improvement Amendments Act of 2007, 81 Fed. Reg. 91,702, 91,713–15 (Dec. 19, 2016) (to be codified at 20 C.F.R. pt. 421).

¹⁷¹ See Pub. L. No. 115-8, 131 Stat. 15 (2017); see also Implementation of the NICS Improvement Amendments Act of 2007, 82 Fed. Reg. 22,741 (May 18, 2017) (withdrawing the rule).

chambers.¹⁷² Alternatively, Congress could include a rider in the next appropriations bill that the President would find harder to veto—this would delay implementation of the rule and, if regularly added to subsequent appropriations measures, might block it indefinitely.¹⁷³

B. *Statutory Objections and Misconceptions*

As mentioned at the outset, just over twenty years ago the U.S. Supreme Court rejected the FDA's effort to regulate tobacco products as restricted devices.¹⁷⁴ Although the decision may have signaled a subtle shift in the judicial deference typically accorded to agency interpretations of statutory ambiguities, it hardly settled questions that a comparable effort to regulate guns and ammunition would raise. The *Brown & Williamson* majority spoke with a single voice—in an opinion authored by Justice O'Connor—as did the four dissenters in an opinion penned by Justice Breyer. The conservative members of the Court seemingly set aside their usual commitments to textualism,¹⁷⁵ not even prompting a brief concurring opinion from Justice Scalia to reiterate his strict views about the appropriate places to look for congressional intent,¹⁷⁶ while the Court's liberal wing largely hewed to the statutory text in dissent.¹⁷⁷ Even more striking than their contrasting approaches to the language appearing in various relevant statutes, or their broader views of comparative institutional competence, both sides labored under serious misapprehensions about the operation of the FDCA.¹⁷⁸ As a

¹⁷² Then again, political calculations might prompt a President unwilling to directly countermand the initiative of an agency housed within the Executive branch to allow a legislative override of a controversial rule to take effect.

¹⁷³ For examples involving gun violence, see *supra* notes 64–66 and accompanying text.

¹⁷⁴ See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

¹⁷⁵ *Cf. id.* at 132 (“In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.”); *id.* at 133 (“Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.”). The opinion, however, went rather far beyond such a contextual analysis. It even took seriously the views about the reach of the FDCA that a single member expressed during a floor debate leading to the passage of an entirely different piece of legislation. See *id.* at 154.

¹⁷⁶ See Lars Noah, *Divining Regulatory Intent: The Place for a “Legislative History” of Agency Rules*, 51 HASTINGS L.J. 255, 269 (2000) (“Except in rare cases to confirm that an apparently absurd result was not in fact what the legislature had intended, the adherents of this [textualist] approach, most notably Justice Scalia, adamantly refuse to consider a statute’s legislative history.” (footnote omitted)); see also John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2419–20 (2003) (noting the tension in his position and that of other textualists). The *Brown & Williamson* majority opinion never, however, invoked the “absurd result” justification for looking beyond the statutory text.

¹⁷⁷ See *Brown & Williamson*, 529 U.S. at 162–63, 167–68 (Breyer, J., dissenting); *id.* at 191 (“Previous FDA disclaimers of jurisdiction may have helped to form the legislative atmosphere out of which Congress’ own tobacco-specific statutes emerged. But a legislative atmosphere is not a law, unless it is embodied in a statutory word or phrase.”).

¹⁷⁸ In each of the next two Terms, the Court again demonstrated fundamental failures to understand the intricacies of the FDCA. See Noah, *supra* note 82, at 55 n.109 (noting that *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), “hardly represents the first time that members of the same

consequence, and putting aside for one moment the fact that the high Court's membership has become still more polarized on questions of these sorts in the intervening two decades, one can find surprisingly little meaningful guidance about how the Court might assess the hypothetical FDA initiative sketched out in Part I.

In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,¹⁷⁹ the Supreme Court famously held that, unless Congress had spoken clearly to the precise issue presented, judges must defer to reasonable agency interpretations of the latter's enabling statutes.¹⁸⁰ This position sprang in part from the view that Congress had intended to delegate interpretive authority to agencies rather than the courts.¹⁸¹ What, however, about novel agency claims of jurisdiction that it had never before exercised, which begged the question of congressional intent to delegate? The FDA's tobacco regulations offered the Court a golden opportunity to confront this question.¹⁸²

Both the majority and dissenting opinions in *Brown & Williamson* purported to apply the *Chevron* framework. Justice O'Connor concluded at "Step One" that Congress had spoken clearly to the question of whether the FDA had authority over tobacco products as conventionally marketed,¹⁸³ while Justice Breyer found ambiguity in the broad delegation of authority, which the agency reasonably could construe as reaching what it now had come to characterize as nicotine delivery devices.¹⁸⁴ The clarity discerned by the majority required some fancy footwork.

Justice O'Connor made much of the fact that, once it exercised device jurisdiction, the FDA would have no choice but to ban tobacco products,

Court entirely misunderstood the complicated operation of the FDCA and its many amendments," citing *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), as a prior instance of this tendency).

¹⁷⁹ 467 U.S. 837 (1984).

¹⁸⁰ See *id.* at 842–43.

¹⁸¹ See *id.* at 843–44. Relative expertise and electoral accountability offered additional rationales. See *id.* at 865–66.

¹⁸² See Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1466–67 (2000) ("[T]he nature of 'jurisdictional' questions, in administrative law as elsewhere, demands special attention from the courts. By granting the government's petition for certiorari to review the lower court's invalidation of the tobacco regulations promulgated by the FDA, the Supreme Court appears poised to tackle the question directly this Term." (footnote omitted)); *id.* at 1529 ("When it resolves the tobacco industry's challenge to the agency's novel assertion of regulatory jurisdiction later this Term, the Supreme Court will have an important opportunity to recalibrate the balance of power between the three branches of government.").

¹⁸³ See *Brown & Williamson*, 529 U.S. at 126 ("Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA."); *id.* at 132 ("[Even if] a product can be 'intended to affect the structure or any function of the body' absent claims of therapeutic or medical benefit, the FDA's claim to jurisdiction contravenes the clear intent of Congress."); *id.* at 133 ("Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products."); *id.* at 161 ("Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here.").

¹⁸⁴ See *id.* at 162–74 (Breyer, J., dissenting).

which would plainly contravene congressional intent.¹⁸⁵ The regulation promulgated in 1996 sought, however, only to restrict marketing to underage consumers, and the agency had explained at length why it decided against taking any more draconian steps. Nonetheless, the majority read the FDCA as forcing the agency's hand insofar as tobacco products could not possibly satisfy statutory safety requirements.¹⁸⁶ The prohibitions on various forms of adulteration and misbranding, which Congress made applicable to devices in 1938, may well have allowed the FDA to institute enforcement actions against tobacco product manufacturers, but, as Justice Breyer emphasized in dissent, these provisions did not obligate the agency to do so.¹⁸⁷ Indeed, in a significant 1985 decision cited by neither side, the Court had held that the FDA enjoyed largely unreviewable enforcement discretion in the face of complaints by death row inmates that the use of prescription drugs for lethal injection violated many of these same provisions.¹⁸⁸

Justice O'Connor also referenced the premarket review provisions as obligating the FDA to prohibit marketing of devices absent proof of safety and effectiveness.¹⁸⁹ No one doubts that the agency could have taken such an extreme step if so inclined,¹⁹⁰ but, as explained previously, it has long allowed the continued marketing of Class III devices without demanding that manufacturers file applications for premarket approval accompanied by evidence documenting a reasonable assurance of safety and effectiveness.¹⁹¹ Moreover, as Justice Breyer pointed out in dissent, if the sponsor of every

¹⁸⁵ See *id.* at 139 (majority opinion) (“[T]he collective premise of these [subsequently enacted tobacco-specific] statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.”).

¹⁸⁶ See *id.* at 135–36; see also *id.* at 142 (“What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA’s core objective of ensuring that every drug or device is safe and effective.”).

¹⁸⁷ See *id.* at 174–78 (Breyer, J., dissenting).

¹⁸⁸ See *Heckler v. Chaney*, 470 U.S. 821, 831–38 (1985). More recently, after uncovering evidence that, in response to domestic supply shortages, the FDA had cleared the importation of an unapproved version of a drug used for lethal injections, a group of death row inmates filed a successful lawsuit challenging the agency’s action. See *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (affirming an order that enjoined the agency from allowing further sales to state correctional departments of unapproved sodium thiopental from foreign manufacturers not registered with the FDA because the statutory provision governing drug importation unambiguously dictated refusal of entry under such circumstances).

¹⁸⁹ See *Brown & Williamson*, 529 U.S. at 136–37, 142–43; see also *id.* at 143 (“If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.”); *id.* (“[I]f tobacco products were within the FDA’s jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress’ clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA’s regulatory scheme.”).

¹⁹⁰ See *id.* at 159 (“[T]he FDA contends that, were it to determine that tobacco products provide no ‘reasonable assurance of safety,’ it would have the authority to ban cigarettes and smokeless tobacco entirely.”).

¹⁹¹ See *supra* Part I.D. The dissenting opinion failed to pick up on this point even though just four years earlier it had played a central role in a tort preemption decision involving an allegedly defective cardiac pacemaker. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996) (“[T]he § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market.”); *id.* at 493–94; *id.* at 513 (O’Connor, J., concurring in part and dissenting in part) (agreeing that premarket notification would not preempt a design defect claim).

new drug and device must demonstrate that these products can achieve a “therapeutic” purpose to offset any risks of harm, it would render the structure-or-function definitional clauses surplusage.¹⁹² To make this point more strongly, under the majority’s reading of the FDCA, prescription products and implants serving only cosmetic purposes that the FDA currently regulates as drugs or devices would become unlawful unless entirely benign, which is rarely the case.¹⁹³

Once the feared tobacco prohibition reveals itself as nothing more than a strawman argument, the supposed misfit under the FDCA evaporates, as does the apparent incompatibility with congressional design. Even if the FDCA only allowed but did not require banning cigarettes and so forth once treated as medical devices, Justice O’Connor viewed such a possibility as inconsistent with the intent of Congress as reflected in several pieces of tobacco-specific legislation coupled with the repeated statements of FDA officials disclaiming any such authority.¹⁹⁴ Preliminarily, she regarded these “subsequent” enactments as more telling than the broad delegation of authority to the FDA in 1938,¹⁹⁵ entirely ignoring the fact that Congress had made major amendments to the device provisions—including the all-important definition, grant of authority over the advertising of restricted devices, and criteria for regulating combination products—in 1976 and 1990,¹⁹⁶ indeed, to the extent that the premarket review provisions might have forced the agency to ban intrinsically unsafe devices, these arrived on the scene long after the most substantial tobacco-specific statutes that supposedly evidenced a congressional intent incompatible with the prospect of a prohibition.

Moreover, Justice O’Connor noted that Congress explicitly stripped the

¹⁹² See *Brown & Williamson*, 529 U.S. at 168 (Breyer, J., dissenting).

¹⁹³ See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 863–66 (2009).

¹⁹⁴ See *Brown & Williamson*, 529 U.S. at 144 (“Congress’ tobacco-specific statutes have effectively ratified the FDA’s long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products.”); *id.* at 156; *id.* at 157–58 (“Congress consistently evidenced its intent to preclude any federal agency from exercising significant policymaking authority in the area. Under these circumstances, we believe the appropriate inference—that Congress intended to ratify the FDA’s prior position that it lacks jurisdiction—is unmistakable.”). Writing two years before the Supreme Court’s decision, I called this “a fairly compelling historical record.” Noah, *Regulating Cigarettes*, *supra* note 6, at 682 (“The legislature’s failure to address the FDA’s role is notable but hardly surprising given the Agency’s own prior view that it lacked anything other than a limited authority to regulate tobacco products under its enabling statute.”); see also *id.* at 680–81 (summarizing this record). Nonetheless, I would have invalidated the assertion of jurisdiction over tobacco products on entirely other grounds. See *infra* note 217.

¹⁹⁵ See *Brown & Williamson*, 529 U.S. at 143; see also *id.* at 133 (“[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.”); *id.* at 137 (“Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965.”). The dissent found no evidence that these subsequent enactments reflected a congressional directive ousting the FDA from potentially exercising jurisdiction over tobacco products. See *id.* at 181–86 (Breyer, J., dissenting); see also *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011) (“Post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation.”).

¹⁹⁶ See *supra* note 90.

CPSC of tobacco product jurisdiction in 1976,¹⁹⁷ but it failed to do the same for the FDA even though the Medical Device Amendments passed that very same year would have offered a perfect vehicle for doing so. True, Congress had not previously enacted bills that would have explicitly authorized FDA regulation of tobacco products,¹⁹⁸ but, as Justice Breyer explained, it similarly had failed to pass proposed legislation that would have done the opposite.¹⁹⁹ Although the failure to deploy the then-new procedure for expedited congressional review, which only recently has come into regular use,²⁰⁰ to override the FDA's 1996 rule would hardly qualify as an endorsement by Congress that should impact judicial review of an agency's statutory authority, the dissent emphasized that sweeping amendments to the FDCA passed just one year later took care to remain noncommittal about the tobacco rule.²⁰¹

Justice O'Connor also explained that some of the tobacco-specific legislation that required health warnings had expressly preempted different state or federal requirements.²⁰² Although such provisions may well limit the application of some of the FDA's misbranding powers or else constrain its decisions about certain aspects of product labeling at the time of premarket review, that possibility hardly would have rendered the assertion of device jurisdiction somehow fundamentally incompatible with these narrower legislative mandates,²⁰³ and, of course, the particular regulation under scrutiny in no sense intruded on the already occupied domain.

Lastly, though a feature mentioned in the very first paragraph of the majority's opinion,²⁰⁴ Justice O'Connor repeatedly emphasized that the agency routinely had disavowed the authority that it now asserted.²⁰⁵ As she recounted, more than half a dozen officials over the years had expressed the

¹⁹⁷ See *Brown & Williamson*, 529 U.S. at 151. This had happened in tandem with reminding the Commission that it could not regulate firearms. See *supra* note 58 and accompanying text.

¹⁹⁸ See *Brown & Williamson*, 529 U.S. at 144, 146, 147; cf. *id.* at 155 ("We do not rely on Congress' failure to act—its consideration and rejection of bills that would have given the FDA this authority—in reaching this conclusion.").

¹⁹⁹ See *id.* at 183 (Breyer, J., dissenting).

²⁰⁰ See *supra* note 169 and accompanying text.

²⁰¹ See *Brown & Williamson*, 529 U.S. at 184, 191–92 (Breyer, J., dissenting); cf. *United States v. Rutherford*, 442 U.S. 544, 554 (1979) ("[D]eference is particularly appropriate where, as here, an [FDA] interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives.").

²⁰² See *Brown & Williamson*, 529 U.S. at 148–49, 154, 156.

²⁰³ See *id.* at 149 ("This is not to say that the FCLAA's pre-emption provision by itself necessarily foreclosed FDA jurisdiction.").

²⁰⁴ See *id.* at 125 (noting that the FDA had "expressly disavowed any such authority since its inception").

²⁰⁵ See, e.g., *id.* at 146 ("The FDA's disavowal of jurisdiction was consistent with the position that it had taken since the agency's inception. As the FDA concedes, it never asserted authority to regulate tobacco products as customarily marketed until it promulgated the regulations at issue here."); *id.* at 156 ("[T]he FDA repeatedly and consistently assert[ed] that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed."); *id.* at 157 ("When the FDA repeatedly informed Congress that the FDCA does not grant it the authority to regulate tobacco products, its statements were consistent with the agency's unwavering position since its inception, and with the position that its predecessor agency had first taken in 1914.").

position that the FDA did not enjoy jurisdiction over tobacco products unless accompanied by drug-like claims.²⁰⁶ The agency also twice during the Carter administration had denied citizen petitions asking that it assert authority over tobacco products.²⁰⁷

As Justice Breyer explained, agencies enjoy the opportunity to change their minds, so long as they offer an explanation—whether related to newly discovered information, intervening changes in the applicable legal standards, or even a revised political judgment.²⁰⁸ *Chevron* itself, of course, represented a striking about-face, with the EPA amending a rule promulgated at the end of the Carter administration just one year later after President Reagan took office, yet the Court credited the fact that the agency had consistently interpreted the disputed statutory term inconsistently.²⁰⁹ Thus, agencies remain free to revisit interpretations of their enabling statutes even after courts have endorsed the earlier views.²¹⁰ Surely the uncodified opinions expressed by officials many years (even decades) earlier does not somehow estop an agency,²¹¹ though it plainly troubled the majority that members of Congress detrimentally relied on contemporaneous statements by the FDA disclaiming any authority when they crafted tobacco-specific legislation.²¹²

In the two decades that followed, the Supreme Court has in various ways continued to narrow *Chevron*'s operation, and now some observers forecast

²⁰⁶ See *id.* at 145, 146, 151–52, 153, 154–55.

²⁰⁷ See *id.* at 152–53 (discussing the rejection of a pair of petitions filed by Action on Smoking & Health (ASH)).

²⁰⁸ See *id.* at 186–90 (Breyer, J., dissenting); see also *Action on Smoking & Health v. Harris*, 655 F.2d 236, 242 n.10 (D.C. Cir. 1980) (“Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . [H]owever, it must provide a reasoned explanation for its action.”).

²⁰⁹ See *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 857, 863 (1984).

²¹⁰ See Kenneth A. Bamberger & Peter L. Strauss, *Chevron's Two Steps*, 95 VA. L. REV. 611, 616 (2009) (“[A] judicial determination that an agency interpretation embodies one option within the zone of indeterminacy makes it possible for the agency to put forth a different interpretation at a later time.”); see also *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (“[I]f the agency adequately explains the reasons for a reversal of policy, change is not invalidating, since the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency.” (internal quotation marks omitted)).

²¹¹ See Noah, *supra* note 88, at 130–33.

²¹² See *Brown & Williamson*, 529 U.S. at 144 (“In adopting each statute, Congress has acted against the backdrop of the FDA’s consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer.”); *id.* at 147 (“[T]his intent is certainly relevant to understanding the basis for the FDA’s representations to Congress and the background against which Congress enacted subsequent tobacco-specific legislation.”); *id.* at 153 (“Against this backdrop, Congress enacted three additional tobacco-specific statutes over the next four years that incrementally expanded its regulatory scheme for tobacco products.”); *id.* at 156 (“Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA.”); *id.* at 159 (“This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy.”).

its imminent demise.²¹³ Commentators have dubbed *Brown & Williamson* as adopting the “major questions” exception,²¹⁴ even though that particular turn of phrase came only in the majority’s quotation from an article penned by then-Judge Breyer.²¹⁵ To be sure, O’Connor repeatedly opined that tobacco products occupied a central role in the economy and culture of the United States,²¹⁶ but that left what else might qualify as a major question very much in the eye of the beholder.²¹⁷ In 2013, however, the Court emphatically rejected efforts to treat jurisdictional questions as outside of *Chevron*’s rule of deference.²¹⁸

How does our hypothetical FDA initiative to regulate guns and ammunition as devices compare under the analysis crafted by the majority in *Brown & Williamson*? Tobacco products cause roughly ten times as many deaths as do firearms, and evidently all uses of the former contribute marginally to health risks while the latter have both safe and unsafe patterns of use. Unlike tobacco products, guns and ammunition do not amount to

²¹³ See, e.g., Kristin E. Hickman, *To Repudiate or Merely Curtail? Justice Gorsuch and Chevron Deference*, 70 ALA. L. REV. 733, 751–55 (2019); Cass R. Sunstein, *Chevron as Law*, 107 GEO. L.J. 1613, 1615–19, 1664–79 (2019); Justin Walker, *The Kavanaugh Court and the Schechter-to-Chevron Spectrum: How the New Supreme Court Will Make the Administrative State More Democratically Accountable*, 95 IND. L.J. 923, 947–62 (2020).

²¹⁴ For useful summaries of pertinent decisions and the scholarly debate, see Joshua S. Sellers, “Major Questions” Moderation, 87 GEO. WASH. L. REV. 930, 932–35, 939–48 (2019); and Daniel Hornung, Note, *Agency Lawyers’ Answers to the Major Questions Doctrine*, 37 YALE J. ON REG. 759, 760–66, 783–84, 788–99 (2020).

²¹⁵ See *Brown & Williamson*, 529 U.S. at 159 (quoting Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 370 (1986)). Like other efforts to critique colleagues for staking out contrary positions in a case before the Court, this reference comes across as more of a dig for hypocrisy than an intent to endorse the concept. The dissent, however, questioned the existence or wisdom of any such canon of construction. See *id.* at 190–91 (Breyer, J., dissenting).

²¹⁶ See *id.* at 133 (majority opinion) (“[W]e must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency.”); *id.* at 147 (“Given the economic and political significance of the tobacco industry at the time [i.e., 1938], it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter.”); *id.* at 159 (“Owing to its unique place in American history and society, tobacco has its own unique political history.”); *id.* at 160 (“[W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.”); see also *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (“When an agency claims to discover in a long-extant statute an unheralded power to regulate ‘a significant portion of the American economy,’ . . . we typically greet its announcement with a measure of skepticism.”); cf. *Gundy v. United States*, 139 S. Ct. 2116, 2142 (2019) (Gorsuch, J., dissenting) (“Although it is nominally a canon of statutory construction, we apply the major questions doctrine in service of the constitutional rule that Congress may not divest itself of its legislative power by transferring that power to an executive agency.”).

²¹⁷ To be entirely clear, I believe that the Court reached the correct result but for the wrong reasons. I would have treated jurisdictional questions as beyond *Chevron*’s reach. See Noah, *supra* note 182, at 1516–30; *id.* at 1467 (arguing that “*Chevron* deference should not extend to the review of jurisdictional questions”). In the alternative, I would not have allowed agencies to stack multiple claims for *Chevron* deference. See Noah, *Regulating Cigarettes*, *supra* note 6, at 686 (“[P]erhaps [the district court judge] recognized that each prior act of deference to the FDA’s statutory interpretation compounded the tenuous nature of the Agency’s overall assertion of jurisdiction, so much so that the final and seemingly easiest request for deference was more than he could permit.”). Insofar as the Court adopted neither one of those rationales and *Chevron* deference remains available, an FDA assertion of device jurisdiction over guns and ammunition may well deserve to get judicial deference.

²¹⁸ See *City of Arlington v. FCC*, 569 U.S. 290, 296–307 (2013).

drug-device combinations, so they seem to fit more readily within the device category. As far as I know, FDA officials only once disclaimed the power to regulate firearms (though only as drugs) in the course of testifying before Congress—and more than half a century ago at that—about an altogether different subject (and not in the course of proposing legislation on that subject, much less firearms).²¹⁹ Similarly, it never before has denied a citizen petition requesting such a move. Thus, the record related to the possibility of exercising device authority over guns and ammunition differs from the repeated expression of agency views that it lacked the authority to regulate tobacco products unless marketed with drug-like claims. Indeed, the apparent need to openly disavow having such authority itself demonstrates that this hardly represented a far-fetched idea, which might have served to alert Congress that it might want to explicitly bar any such effort.²²⁰

No one can doubt that the power of the FDA to regulate the firearms industry would qualify as a major question, even if the agency's initial assertion of such jurisdiction accompanied an extremely modest regulatory obligation. As far as I know, Congress has never considered bills that would have either specifically authorized or prohibited FDA jurisdiction to regulate firearms,²²¹ which again stands in stark contrast to the record with tobacco products. To be sure, congressional activity demonstrates a desire to leave firearm manufacturers as well as their customers relatively unencumbered, though the sole express preemption clause ousts only state common law.²²² In short, if the template reflected by the majority opinion in *Brown & Williamson* controls, then the FDA would stand a far better chance of skirting statutory objections to a rule asserting device jurisdiction over guns and ammunition.

²¹⁹ See *supra* note 86. The agency similarly once expressed doubts to Congress over its power to regulate whole organs without seeming to subsequently feel particularly constrained by such prior views. See Lars Noah, *Growing Organs in the Lab: Tissue Engineers Confront Institutional "Immune" Responses*, 55 JURIMETRICS 297, 311 (2015).

²²⁰ One commentator proposed a narrowing construction to exclude from the FDA's jurisdiction three different categories of "nonmedical" devices, including the following:

The third category, an area under section 201(h) into which FDA has not yet ventured, includes products used to prevent injury (for example, bicycle helmets and bullet-proof vests), cause injury (mace and guns), or prevent environmental threats (radon detectors and video display terminal shields). The primary rationale for excluding these items from FDA regulation is that already they are regulated competently by other federal agencies, such as CPSC, OSHA, or EPA, and FDA lacks the special expertise or the statutory mission to regulate these products.

Gameran, *supra* note 91, at 853. Notice that his stated rationale did not mention the ATF and referenced only statutory "mission" rather than the broad language that Congress selected in defining devices. *Cf. id.* at 851 (allowing that device jurisdiction would include products intended "invasively to alter a bodily function or structure").

²²¹ It would not surprise me, however, to find that at some point someone had introduced a bill that sought to make unmistakable the FDA's lack of authority.

²²² See *supra* note 68 and accompanying text. Although not framed in express preemption terms, Congress plainly meant to do so when in 1986 it granted narrow protection to the interstate transportation of unloaded and inaccessible weapons. See *supra* note 61 and accompanying text.

When Congress feared that other agencies might overstep their bounds, it expressly barred those initiatives; when Congress sensed that state law might unduly intrude on matters affecting interstate commerce, it expressly blocked those threats.²²³ Congress has not, however, limited the FDA's power to use its existing authority over devices to regulate manufacturers of firearms and bullets. As suggested in the previous section, it might well do so if confronted with such an initiative in the future, but that prospect hardly disables the agency under existing statutory arrangements.

C. *Second Amendment Rights and Wrongs*

A court inclined to invalidate an initiative to regulate guns as devices would hardly need to resort to constitutional analysis. If the agency managed to surmount the statutory obstacles, however, then it would have to confront objections based on the Second Amendment to the U.S. Constitution. Even so, device regulation by the FDA might offer some intriguing ways of potentially skirting the federal right to bear arms as presently understood. Moreover, the unexpected retirement (or leftward drift) of a couple of the conservative members of the high Court could lower both the statutory and constitutional hurdles that would otherwise stand in the way of the agency.

In 2008, a closely divided U.S. Supreme Court decided *District of Columbia v. Heller*.²²⁴ The Court's five conservative members struck down the District's longstanding prohibition on the possession of handguns and a requirement for securing other loaded firearms with trigger locks. Writing for the majority, Justice Scalia held that the Second Amendment protected an individual right to keep and bear arms for self-defense in the home.²²⁵ The four liberal members of the Court joined in a pair of dissenting opinions.²²⁶ Two years later, in *McDonald v. City of Chicago*,²²⁷ a slightly more fractured Court held that the Fourteenth Amendment incorporated this same right as against the states.²²⁸ These decisions left many questions unanswered and have prompted a lively academic commentary.²²⁹ So far,

²²³ See *supra* Part I.B.

²²⁴ 554 U.S. 570 (2008).

²²⁵ See *id.* at 635.

²²⁶ See *id.* at 636 (Stevens, J., dissenting); *id.* at 681 (Breyer, J., dissenting).

²²⁷ 561 U.S. 742 (2010).

²²⁸ See *id.* at 791 (plurality opinion). The author of the majority opinion in *Heller* filed a concurrence for the sole purpose of more fully answering the approach offered by one of the dissenting Justices. See *id.* at 791 (Scalia, J., concurring). Another member of the *Heller* majority wrote separately to offer a somewhat different analysis of the incorporation issue. See *id.* at 805 (Thomas, J., concurring in part and concurring in judgment) (preferring to use the Fourteenth Amendment's privileges or immunities clause rather than its due process clause). The same four members of the Court dissented, though they did not all join in the pair of opinions. See *id.* at 858 (Stevens, J., dissenting) (for himself alone); *id.* at 912 (Breyer, J., dissenting) (joined by Ginsburg and Sotomayor).

²²⁹ See, e.g., JOSEPH BLOCHER & DARRELL A. H. MILLER, THE POSITIVE SECOND AMENDMENT: RIGHTS, REGULATION, AND THE FUTURE OF *HELLER* (2018); Lawrence Rosenthal, *The Limits of Second Amendment Originalism and the Constitutional Case for Gun Control*, 92 WASH. U. L. REV. 1187 (2015); Eric Ruben, *An Unstable Core: Self-Defense and the Second Amendment*, 108 CALIF. L. REV. 63 (2020);

however, apart from a short per curiam opinion subsequently explaining that stun guns also enjoy protection,²³⁰ the Supreme Court has not offered further clarification about the scope of the Second Amendment right.²³¹ What clues do these decisions offer about the constitutionality of an FDA assertion of device jurisdiction over guns and ammunition?

After a lengthy historical exegesis on the meaning of the Second Amendment, the majority in *Heller* equivocated on precisely what form of heightened scrutiny to apply.²³² In his opinion for the four dissenters, Justice Stevens offered a persuasive critique of the majority's historical analysis.²³³ Meanwhile, in his opinion for the four dissenters, Justice Breyer carefully undertook the sort of intermediate scrutiny or interest-balancing analysis entirely glossed over by the majority when it invalidated the District's handgun prohibition.²³⁴

The majority conceded that the Second Amendment hardly granted individuals an absolute right to possess arms.²³⁵ More interestingly, the majority summarily carved out some forms of gun control as permissible:

Eric Ruben & Joseph Blocher, *From Theory to Doctrine: An Empirical Analysis of the Right to Keep and Bear Arms After Heller*, 67 DUKE L.J. 1433, 1507–08 (2018); Symposium, *Heller at Ten*, 46 HASTINGS CONST. L.Q. 509 (2019); Symposium, *The Second Generation of Second Amendment Law and Policy*, 80 LAW & CONTEMP. PROBS., no. 2, 2017, at 1.

²³⁰ See *Caetano v. Massachusetts*, 577 U.S. 411, 412 (2016) (per curiam); see also *id.* at 412, 420 (Alito, J., concurring in judgment) (“While less popular than handguns, stun guns are widely owned and accepted as a legitimate means of self-defense across the country.”); *People v. Webb*, 131 N.E.3d 93, 98 (Ill. 2019); *Ramirez v. Commonwealth*, 94 N.E.3d 809, 814–15 (Mass. 2018); Adam Winkler, *Is the Second Amendment Becoming Irrelevant?*, 93 IND. L.J. 253, 254 (2018) (arguing that the unanimous per curiam opinion in *Caetano* “signals that *Heller* is secure as a precedent”).

²³¹ See Robert Barnes, *Court Declines to Take a Handful of Gun Rights Cases*, BOS. GLOBE, June 16, 2020, at A4 (“The court’s most conservative members at various times have expressed frustration that their colleagues have routinely turned down requests to evaluate laws that impose tough restrictions for permits to carry guns outside the home and ban certain types of weapons.”); see also Adam Liptak, *Court to Hear Case on Limit to Gun Rights*, N.Y. TIMES, Apr. 27, 2021, at A1 (reporting that the Court agreed to “review a longstanding New York law that imposes strict limits on carrying guns outside the home, setting the stage for its first major Second Amendment decision in more than a decade—and the first to be decided by the court’s newly expanded conservative majority”).

²³² See *Heller*, 554 U.S. at 628–29 & n.27 (applying some form of heightened scrutiny); *id.* at 634–35 (responding to the dissent’s criticism of its failure to elaborate on the standard of review, but rejecting an interest-balancing approach).

²³³ See *id.* at 640 (Stevens, J., dissenting) (finding it “abundantly clear that the Amendment should not be interpreted as limiting the authority of Congress to regulate the use or possession of firearms for purely civilian purposes”); *id.* at 679 (“Until today, it has been understood that legislatures may regulate the civilian use and misuse of firearms so long as they do not interfere with the preservation of a well-regulated militia.”).

²³⁴ See *id.* at 714 (Breyer, J., dissenting) (“The upshot is that the District’s objectives are compelling; its predictive judgments as to its law’s tendency to achieve those objectives are adequately supported; the law does impose a burden upon any self-defense interest that the Amendment seeks to secure; and there is no clear less restrictive alternative.”); *id.* (finding no undue burden in part because “[t]he law concerns one class of weapons, handguns, leaving residents free to possess shotguns and rifles, along with ammunition”); *id.* at 719–20 (criticizing the majority’s failure to put as much effort into trying to apply its newfound right to the facts before it); *id.* at 722 (“One cannot answer those questions by combining inconclusive historical research with judicial *ipse dixit*.”).

²³⁵ See *id.* at 626 (majority opinion) (“[T]he right secured by the Second Amendment is not unlimited. From Blackstone through the 19th-century cases, commentators and courts routinely explained that the right was not a right to keep and carry any weapon whatsoever in any manner

[N]othing in our opinion should be taken to cast doubt on longstanding prohibitions on the possession of firearms by felons and the mentally ill, or laws forbidding the carrying of firearms in sensitive places such as schools and government buildings, or laws imposing conditions and qualifications on the commercial sale of arms.²³⁶

If the FDA asserted device jurisdiction over guns and ammunition, then it would test the reach of the allowance for restrictions related to commercial sales.²³⁷ Obviously, a right to possess firearms implies that suppliers would enjoy some correlative right to sell these products.²³⁸

More importantly for present purposes, the *Heller* Court limited Second Amendment protection to commonly used weapons.²³⁹ It plainly did not

whatsoever and for whatever purpose.”); *cf. id.* at 635 (“The Second Amendment . . . elevates above all other interests the right of law-abiding, responsible citizens to use arms in defense of hearth and home.”).

²³⁶ *Id.* at 626–27; *see also id.* at 627 n.26 (“We identify these presumptively lawful regulatory measures only as examples; our list does not purport to be exhaustive.”); *id.* at 632 (“Nor, correspondingly, does our analysis suggest the invalidity of laws regulating the storage of firearms to prevent accidents.”); *id.* at 635 (“[F]or those regulations of the right that we describe as permissible . . . [,] there will be time enough to expound upon the historical justifications for the exceptions we have mentioned if and when those exceptions come before us.”); *cf. id.* at 688 (Breyer, J., dissenting) (“[T]he majority implicitly, and appropriately, rejects [strict scrutiny] by broadly approving a set of laws—prohibitions on concealed weapons, forfeiture by criminals of the Second Amendment right, prohibitions on firearms in certain locales, and governmental regulation of commercial firearm sales—whose constitutionality under a strict-scrutiny standard would be far from clear.”); *id.* at 721 (“Why these? Is it that similar restrictions existed in the late-18th century? The majority fails to cite any colonial analogues.”); Carlton F.W. Larson, *Four Exceptions in Search of a Theory: District of Columbia v. Heller and Judicial Ipse Dixit*, 60 HASTINGS L.J. 1371, 1386 (2009) (“These exceptions will ultimately have to be justified under some standard of scrutiny . . . possibly under an undue-burden or an intermediate-scrutiny test.”).

²³⁷ *See, e.g.,* *Pena v. Lindley*, 898 F.3d 969, 976–86 (9th Cir. 2018) (upholding the constitutionality of a California law requiring magazine safety features and the “microstamping” of discharged bullets with identifying information).

²³⁸ *See Teixeira v. Cnty. of Alameda*, 873 F.3d 670, 677–90 (9th Cir. 2017) (en banc); *id.* at 682 (“Commerce in firearms is a necessary prerequisite to keeping and possessing arms for self-defense, but the right of gun users to acquire firearms legally is not coextensive with the right of a particular proprietor to sell them.”); Corey A. Ciochetti, *The Business of Guns: The Second Amendment and Firearms Commerce*, 46 PEPP. L. REV. 1, 5, 30, 36–41 (2018); *see also* Lars Noah, *Does the U.S. Constitution Constrain State Products Liability Doctrine?*, 92 TEMP. L. REV. 189, 216–17 & n.150 (2019) (explaining that, in the contraception context, “these represent two sides of the same coin”). The FDA generally does not enjoy authority over end users, which means that any restrictions on the production and sale of guns and ammunition would not impact the continued possession of existing stockpiles.

²³⁹ *See Heller*, 554 U.S. at 627 (“We also recognize another important limitation on the right to keep and carry arms. . . . [T]he sorts of weapons protected were those ‘in common use at the time.’”); *id.* (conceding that this would allow a ban on “M-16 rifles and the like” even though less sophisticated “small arms” in common use may have little value against modern military threats); *id.* at 625 (“[T]he Second Amendment does not protect those weapons not typically possessed by law-abiding citizens for lawful purposes, such as short-barreled shotguns.”). The dissenters expressed puzzlement over this “circular reasoning.” *Id.* at 721 (Breyer, J., dissenting); *see also id.* at 720–21 (“Nor is it at all clear to me how the majority decides *which* loaded ‘arms’ a homeowner may keep. . . . In essence, the majority determines what regulations are permissible by looking to see what existing regulations permit.”); *id.* at 721 (“On the majority’s reasoning, if tomorrow someone invents a particularly useful, highly dangerous self-defense weapon, Congress and the States had better ban it immediately, for once it becomes popular Congress will no longer possess the constitutional authority to do so.”).

thereby mean only firearms used by the Founders,²⁴⁰ but it did suggest that this “limitation is fairly supported by the historical tradition of prohibiting the carrying of ‘dangerous and unusual weapons.’”²⁴¹ Who decides what weapons so qualify and what level of specificity to use in defining such an unprotected class? The broad sweep of the District’s prohibition—namely, all handguns—allowed the majority to use a high level of generality,²⁴² but what about restrictions applicable to narrower subsets thought to carry marginally higher dangers?²⁴³ Finally, what about ammunition? The majority offered no hint of whether the Second Amendment would impact laws limiting access to certain classes of projectiles used in firearms,²⁴⁴

²⁴⁰ See *id.* at 582 (majority opinion) (“[T]he Second Amendment extends, prima facie, to all instruments that constitute bearable arms, even those that were not in existence at the time of the founding.”).

²⁴¹ *Id.* at 627; see also *Hollis v. Lynch*, 827 F.3d 436, 447–51 (5th Cir. 2016) (rejecting a challenge to the federal prohibition on machine guns manufactured after 1986 because these firearms qualify as dangerous and unusual); cf. Joseph Blocher, *Hunting and the Second Amendment*, 91 NOTRE DAME L. REV. 133, 176 (2015) (“If it is true . . . that long guns are useful for hunting but *not* for self-defense, then the Second Amendment protection of those guns should be correspondingly weaker.”).

²⁴² See *Heller*, 554 U.S. at 628 (“The [District’s] handgun ban amounts to a prohibition of an entire class of ‘arms’ that is overwhelmingly chosen by American society for that lawful purpose [i.e., self-defense.]”); *id.* at 629 (“[H]andguns are the most popular weapon chosen by Americans for self-defense in the home, and a complete prohibition of their use is invalid.”); *id.* at 636 (“[T]he enshrinement of constitutional rights necessarily takes certain policy choices off the table. These include the absolute prohibition of handguns held and used for self-defense in the home.”); see also Jordan E. Pratt, *Uncommon Firearms as Obscenity*, 81 TENN. L. REV. 633, 636–37 (2014); Eugene Volokh, *Implementing the Right to Keep and Bear Arms for Self-Defense: An Analytical Framework and a Research Agenda*, 56 UCLA L. REV. 1443, 1457 (2009) (“How can we decide whether, say, a hypothetical ban on revolvers bans ‘an entire class of “arms”’ or only a subclass of the broader class of handguns?”); *id.* at 1479 (“Handguns are in common use, but particular brands of handguns are less common, and some are uncommon, simply because they come from small companies or are of unusual caliber or design.”); *id.* at 1481 (“[W]hether a weapon is in common use depends a lot on how generally one defines the weapon: for instance, as a handgun generally, or as a Glock 17 in particular.”).

²⁴³ In subsequent litigation between these same parties, the question arose with respect to certain semiautomatic rifles such as the AR-15 and large-capacity magazines. Compare *Heller v. District of Columbia*, 670 F.3d 1244, 1260–64 (D.C. Cir. 2011) (holding that, even if they qualified as in common use, the prohibition survived intermediate scrutiny), with *id.* at 1286–90 (Kavanaugh, J., dissenting); see also *supra* note 104 (discussing the popularity of semiautomatic firearms). Other courts have upheld state and local bans on assault weapons and large-capacity magazines. See, e.g., *Worman v. Healey*, 922 F.3d 26, 35–36, 39–41 (1st Cir. 2019); *Kolbe v. Hogan*, 849 F.3d 114, 134–35 (4th Cir. 2017) (en banc) (joining four other federal appellate courts that previously had rejected such challenges); *id.* at 135–37, 141–44 (holding that assault rifles and large-capacity magazines fall entirely outside of the Second Amendment); *id.* at 138–41, 145–46 (explaining in the alternative that, even if covered, the state prohibition would survive intermediate scrutiny); see also *Duncan v. Bonta*, 19 F.4th 1087, 1100–13 (9th Cir. 2021) (en banc) (rejecting Second Amendment and Takings clause objections to California’s prohibition on the possession of large-capacity magazines); *Ass’n N.J. Rifle & Pistol Clubs, Inc. v. Atty. Gen. N.J.*, 910 F.3d 106, 116–23 (3d Cir. 2018) (rejecting a constitutional challenge to New Jersey’s prohibition on the possession of large-capacity magazines); Cody J. Jacobs, *End the Popularity Contest: A Proposal for Second Amendment “Type of Weapon” Analysis*, 83 TENN. L. REV. 231, 251–89 (2015) (endorsing the tendency of the lower federal courts in such cases to focus on dangerousness and utility for self-defense rather than resorting to imprecise measures of popularity). But see David B. Kopel, *The History of Firearms Magazines and of Magazine Prohibition*, 78 ALB. L. REV. 849, 883–84 (2015) (concluding that state bans on large-capacity magazines are unconstitutional).

²⁴⁴ Cf. *Heller*, 554 U.S. at 684–85 (Breyer, J., dissenting) (During the colonial period, “several towns and cities (including Philadelphia, New York, and Boston) regulated, for fire-safety reasons, the storage [in the home] of gunpowder, a necessary component of an operational firearm.”); Obermeier,

though such an end-run obviously could gut the newfound right to bear arms for self-defense in the home.²⁴⁵

McDonald offered rather less guidance about the contours of the right to bear arms, focusing instead on the question of the Second Amendment's application to states and their subdivisions.²⁴⁶ As the FDA plainly exercises federal authority, the debate over incorporation through the Fourteenth Amendment need not detain us. Notably, however, in explaining the fundamental nature of the right recognized in *Heller*, Justice Alito's opinion for the plurality found it inconsequential that "intense disagreement [exists] on the question whether the private possession of guns in the home increases or decreases gun deaths and injuries."²⁴⁷ He also saw no relevance in the fact that "England, Canada, Australia, Japan, Denmark, Finland, Luxembourg, and New Zealand either ban or severely limit handgun ownership."²⁴⁸ The plurality reiterated *Heller*'s dicta about "longstanding regulatory measures" that permissibly limited gun possession,²⁴⁹ prompting the dissenters to again point out the failure to explain why these but not others passed muster.²⁵⁰

The FDA already regulates several other products that enjoy special constitutional protection, including but not limited to contraceptives,²⁵¹ so the fact that the Second Amendment comes into play would hardly exempt firearm manufacturers from that agency's device jurisdiction even if it might constrain the reach of potentially applicable safety regulations. Fundamental rights do not entitle citizens to access any and all means for pursuing a

supra note 107, at 710–12 (discussing *Heller*'s possible application to restrictions on different types of exotic ammunition).

²⁴⁵ See *Jackson v. City & Cnty. of S.F.*, 746 F.3d 953, 967 (9th Cir. 2014) (The Second Amendment "does not explicitly protect ammunition. Nevertheless, without bullets, the right to bear arms would be meaningless. . . . [It] implies a corresponding right to obtain the bullets necessary to use them." (internal quotation marks omitted)); *id.* at 968–70 (affirming the denial of a preliminary injunction against a local prohibition only against the sale of hollow-point ammunition after applying intermediate scrutiny); *Herrington v. United States*, 6 A.3d 1237, 1243 (D.C. 2010) ("[G]iven the obvious connection between handgun ammunition and the right protected by the Second Amendment, we are hard-pressed to see how a flat ban on the possession of such ammunition in the home could survive heightened scrutiny of any kind."); see also *supra* note 243 (referencing court decisions upholding restrictions on large-capacity magazines); cf. Nicholas J. Johnson, *The Power Side of the Second Amendment Question: Limited, Enumerated Powers and the Continuing Battle over the Legitimacy of the Individual Right to Arms*, 70 HASTINGS L.J. 717, 763 n.204 (2019) (noting that the federal government strictly rationed ammunition during World War II).

²⁴⁶ See *McDonald v. City of Chi.*, 561 U.S. 742, 778 (2010) (plurality opinion) ("[I]t is clear that the Framers and ratifiers of the Fourteenth Amendment counted the right to keep and bear arms among those fundamental rights necessary to our system of ordered liberty.").

²⁴⁷ *Id.* at 782–83.

²⁴⁸ *Id.* at 781. Instead, he took comfort in the fact that amicus briefs in support of the petitioners had been filed on behalf of majorities in Congress as well as among the states. See *id.* at 789.

²⁴⁹ See *id.* at 786.

²⁵⁰ See *id.* at 925 (Breyer, J., dissenting) (complaining that this "haphazardly created a few simple rules").

²⁵¹ See Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 16–19, 46–47; see also Noah, *supra* note 82, at 65–95 (discussing commercial speech constraints).

constitutionally protected purpose.²⁵² Perhaps the application of PMN requirements, with 1976 serving as the initial baseline, to bar the introduction of novel and more dangerous firearms would operationalize *Heller*'s "in common use" standard.²⁵³ Similarly, if the FDA can encourage the introduction of marginally safer models, then long-used types of firearms and ammunition that have become unduly dangerous by comparison may lose their protected status under the Second Amendment.²⁵⁴

CONCLUSION

Perhaps this Article represents a gag after all, designed to illustrate rather starkly where an excessive faith in the good sense of bureaucrats might lead us.²⁵⁵ Then again, given the increasing partisanship that infects our three branches of government,²⁵⁶ an administrative approach may offer a second best way of addressing a serious problem that has gone largely unaddressed for far too long. Experts embedded in regulatory agencies enjoy some insulation from the increasingly crass political calculus that impacts their executive, legislative, and even judicial overseers—yes, although not elected like many of their brethren in the state courts, persons anxious to join

²⁵² See Michael R. Ulrich, *A Public Health Law Path for Second Amendment Jurisprudence*, 71 HASTINGS L.J. 1053, 1079–84 (2020); see also Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 664 (2003) ("[C]onstitutional regard for procreative liberties should not stand as an obstacle to the withdrawal of fertility drugs if the FDA decides that they no longer represent safe and effective products, just as it would not prevent the agency from denying a marketing application for a new fertility drug that failed to satisfy normal criteria for approval."); *id.* at 663 ("The well-established right to avoid procreation by choosing from among safe and effective methods of contraception or abortion does not translate automatically into a right to procreate by any means that someone may desire."); *id.* at 664 ("Even in the context of abortion, where the right to privacy and the protection of liberty interests continue to erect a barrier against government intrusion absent compelling justifications unattainable by other means, the Supreme Court has not gone so far as to deregulate the choice of methods.").

²⁵³ See *supra* note 161 and accompanying text; cf. Howell Raines, Opinion, *To Fix Our Gun Laws, We Should Go Back to the 1960s*, WASH. POST, Sept. 3, 2019, at A15 ("No one argued that a six-shot revolver was inadequate for home-protection emergencies. Deer and elk hunters who used larger-caliber rifles felt amply equipped with standard magazines of a half-dozen or so cartridges."). In judging other burdens on fundamental rights, federal decisions about availability may help to define the baseline against which to judge the constitutionality of state restrictions. See Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Tolerate?*, 124 DICK. L. REV. 633, 662 (2020).

²⁵⁴ Cf. Joseph Blocher & Darrell A.H. Miller, *Lethality, Public Carry, and Adequate Alternatives*, 53 HARV. J. LEGIS. 279, 301 (2016) ("[I]f there are new technologies with which people can vindicate their Second Amendment rights, policy-makers should have expanded discretion to regulate the public carrying of deadly weapons."); *id.* at 287 n.54 ("In 1791, a musket could typically fire three rounds in a minute. . . . Today, even some non-military weapons can fire nine hundred rounds in the same amount of time."); Paul H. Robinson, *A Right to Bear Firearms but Not to Use Them? Defensive Force Rules and the Increasing Effectiveness of Non-Lethal Weapons*, 89 B.U. L. REV. 251, 253 (2009) ("[A]s non-lethal weapons become more available, the authority to use firearms in defense diminishes."); *id.* at 254–58 (canvassing the range of options and forecasting continued technological improvements).

²⁵⁵ Cf. Noah, "Go Sue Yourself!," *supra* note 8, at 693 ("Welcome to my waking nightmare.").

²⁵⁶ See Lars Noah, *BDSM in Administrative Procedure: Using Agency Guidance for Bondage and Discipline*, at 3 (Jan. 25, 2020), <https://ssrn.com/abstract=3391569> ("When did legal academics become so terribly trusting of regulatory officials . . . ? Perhaps it reflects a growing loss of faith in the other institutions of government, making it seem like the civil servants occupying the Fourth Branch remain the only adults left to run the country.").

or move up in the ranks of the federal judiciary increasingly must signal their bona fides in playing to the incumbents' base.²⁵⁷

Even if colorable arguments would support an FDA assertion of device jurisdiction over guns and ammunition, I do not imagine for a moment that this will ever happen.²⁵⁸ It would require vision by those put in charge of the agency, tolerance by the White House, courage by just enough members of Congress, and an open mind by the federal judges asked to assess statutory and constitutional objections lodged against such an initiative. Talk about daunting odds! Then again, crazier ideas have gotten traction, and the FDA's experience with tobacco products amply demonstrates that something previously unthinkable and ultimately unsuccessful can still bear fruit.

²⁵⁷ Cf. Jeremy W. Peters, *New Litmus Test for Trump's Court Picks: Taming the Bureaucracy*, N.Y. TIMES, Mar. 28, 2018, at A1 ("Weeding out judicial candidates based on an ideological checklist is something Democratic and Republican presidents have long done. But it is rare for a White House to be so open about what it considers disqualifying."); Rebecca R. Ruiz & Robert Gebeloff, *More Than Others, Trump Judges Show Penchant for Dissent*, N.Y. TIMES, Dec. 17, 2020, at A16 ("The judges who exhibited the pattern included some who had been under consideration for the Supreme Court, and some who had deep political connections on Capitol Hill.").

²⁵⁸ Cf. Noah, *supra* note 13, at 37 ("Although these illustrations [such as handgun control] seem fanciful, FDA action might not be entirely frivolous or implausible under its broad statutory authority to regulate medical devices."); Lars Noah, *When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?*, 85 GEO. WASH. L. REV. 1462, 1482 (2017) ("Perhaps narrow tailoring is best understood as a thought exercise about ideal policy design, largely divorced from practical reality (much like academia itself)."). Call me quixotic!