EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN, INC., NATURAL RESOURCES DEFENSE COUNCIL, and COMMUNICATIONS WORKERS OF AMERICA, AFL-CIO,

Plaintiffs,

v.

DONALD J. TRUMP, et al.

Civil Action No. 17-253 (RDM)

BRIEF OF PUBLIC HEALTH LAW CENTER, AMERICAN ACADEMY OF PEDIATRICS, BIG CITIES HEALTH COALITION, CAMPAIGN FOR TOBACCO-FREE KIDS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CHANGELAB SOLUTIONS, COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS, NATIONAL WOMEN'S HEALTH NETWORK, PUBLIC GOOD LAW CENTER, PUBLIC HEALTH ADVOCACY INSTITUTE, PUBLIC HEALTH AND TOBACCO POLICY CENTER, AND TRUTH INITIATIVE AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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May 22, 2017

CORPORATE DISCLOSURE STATEMENT

No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any party to this filing.

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INTEREST OF AMICI

Amici curiae are preeminent nationwide organizations dedicated to protecting and advancing public health. Amici work on a variety of public health issues related to products regulated by the federal government, particularly the U.S. Food and Drug Administration—including tobacco, pharmaceuticals, medical devices, and food. Given their wealth of experience (*see* addendum describing each amicus), amici know firsthand that FDA regulations have a huge impact on public health, from reducing tobacco use, to ensuring the safety and efficacy of pharmaceuticals and medical devices, to protecting our food supply from contaminants, and more. Following clear dictates from Congress, much of the FDA's work is targeted at protecting America's most vulnerable populations, including children and those suffering from myriad illnesses and medical disorders. Amici are concerned that Executive Order No. 13771, 82 Fed. Reg. 9,339 (Jan. 30, 2017), will deter, weaken, or cause the repeal of important regulations that protect the public and our most vulnerable populations from the hazards posed by FDA-regulated products. Amici have a strong interest in the implementation of statutes that authorize federal agencies to protect public health, and this case strongly implicates that interest.

INTRODUCTION

Executive Order 13771 threatens to halt—and potentially reverse—the progress in public health that the nation has experienced since Congress established the U.S. Food and Drug Administration in the early twentieth century. Due in part to the widespread sale of fraudulent and dangerous patent medicines and the shocking and unsanitary food-production conditions reported in Upton Sinclair's book *The Jungle*, Congress enacted the Federal Food and Drugs Act of 1906 (now the "Federal Food, Drug, and Cosmetic Act"). That Act created the FDA and prohibited the marketing of adulterated or misbranded foods and drugs. In subsequent decades, Congress increased the FDA's power. In the wake of the extensive birth defects caused by

thalidomide, for example, Congress empowered the FDA to ensure that only drugs approved as safe and effective for a specified use are sold in the United States. *See* Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87-781, 76 Stat. 780. Currently, the FDA is charged with "promot[ing] public health" by, among other things, ensuring that "foods are safe [and] sanitary," that "drugs are safe and effective," that medical devices have a "reasonable assurance of [] safety," that the public is "protected from electronic product radiation," and that tobacco products are regulated as is "appropriate for the protection of public health." 21 U.S.C. §§ 393, 387. Today, over a century after the FDA was established, Americans take for granted the many public health protections guaranteed by FDA regulations. The FDA now has processes in place to ensure that the food supply is protected from *e coli* outbreaks; that drugs sold to consumers are not "snake oil" products that promise cures but only cause harm; that medical implants function appropriately after surgery; and that we get basic information about what is in our food. The public health advances furthered by the FDA contributed substantially to the stunning 30-year increase in life expectancy over the course of the twentieth century. Jane E. Henney, Comm'r of Food and Drugs, Remarks at the Institute of Medicine Food Forum: Good Science: Critical to Regulatory Decisionmaking (July 13, 1999), http://bit.ly/2neZqPj; *see also* D. J. Wagstaff, *Public Health and Food Safety: A Historical Association*, 101 Pub. Health. Reports 624 (1986); John P. Bunker, Howard S. Frazier & Frederick Mosteller, *Improving Health: Measuring Effects of Medical Care*, 72 Milbank Q. 225 (1994).

The FDA's work remains crucial for facing current and future health challenges. Congress specifically gave the FDA "broad authority" so it could use its expertise to respond to and update its regulations based on new products coming on the market, emerging threats to public health, and new science and technologies. *See Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981 (1986). And Congress is continually charging the FDA with implementing new legislation—

from the Family Smoking Prevention and Tobacco Control Act of 2009 that delegated the FDA authority to impose "regulatory controls on the tobacco industry," 21 U.S.C.A. § 387, to the Food Safety Modernization Act that charged the agency with updating the protections to our food supply, Pub. L. No. 111-353, 124 Stat. 3885 (Jan. 4, 2011), to the recently enacted 21st Century Cures Act that requires the FDA to create new pathways related to pharmaceutical development and approval, Pub. L. No. 114-255, 130 Stat. 1033 (Dec. 13, 2016).

Executive Order 13771, however, and the Office of Information and Regulatory Affairs Guidance implementing it, M-17-21 (April 5, 2017), jeopardize this vital and congressionally mandated work by deterring and delaying new needed regulations, and threatening the repeal (or weakening) of existing regulations that the FDA has already determined necessary to protect public health. It does so in two interrelated ways:

First, it requires "that for every one new regulation issued" by the Department of Health and Human Services (FDA's parent agency), "at least two prior [HHS] regulations be identified for elimination." Exec. Order No. 13771 § 1; *accord id.* § 2(a); OIRA Guidance, Q1.[1] This "one-in-two-out" requirement applies to any "significant regulatory action" taken after January 20, 2017, as that term was defined in Executive Order 12866 (Oct. 4, 1993)—*i.e.*, any action that has an annual effect on the economy of at least $100 million or otherwise materially impacts a sector of the economy. *See* OIRA Guidance, Q2. Given that the FDA regulates large industries supplying food, drugs, and medical devices to the entire nation, meeting such thresholds is not

[1] The regulations that must be rescinded under the Order can come from anywhere in the department-level agency—here, HHS, the parent agency of the FDA. *See* OIRA Guidance, Q1, Q30. Like the FDA, the other components of HHS are tasked with protecting our health, making any tradeoffs between FDA regulations and other HHS regulations equally arbitrary and capricious. According to OMB, a new regulation from one agency may be traded for rescission of two regulations of another, at OMB's discretion. *Id.* at Q31. Such speculative possibilities do not reduce the harm of the Order to the promulgation of needed FDA regulations. Nor is it less arbitrary to trade public health regulations for environmental, labor, or other agency regulations promulgated under congressionally established standards.

uncommon. The Order not only applies to formally promulgated regulations, but also to "significant guidance document[s]," *id.* at Q3—a critical issue for the FDA given that it often acts through guidance documents (often requested by industry to clarify agency statutes and rules), Seth D. Rothman, *FDA Faces Uncertainty Implementing 21st Century Cures Act*, Law360, Mar. 15, 2017, http://bit.ly/2ocXF60.[2] And the Order applies to significant regulations that are explicitly mandated by Congress. Thus, even when Congress specifically requires the FDA to promulgate regulations on a particular issue, the FDA or HHS must repeal twice as many existing regulations. *See* OIRA Guidance, Q6, Q33.

Second, the Order requires that the two regulations repealed "offset" any "new incremental costs associated with [the] new regulation[]." Exec. Order No. 13711 § 2(c). For fiscal year 2017, the "total incremental costs of all new regulations, including repealed regulations, . . . shall be no greater than zero." *Id.* § 2(b). That is, the net costs of the agency's new regulations must be zero; if the agency promulgates a regulation imposing costs, the two regulations repealed must completely offset those costs. And in future years, the Office of Management and Budget will set agency "budgets" for limiting regulatory action—"budgets" that are neither required nor authorized by Congress. Critically for public health concerns, the "cost" of the regulation is measured only by the costs imposed on the regulated entities, not by the balance of costs and benefits to society as a whole. *See* OIRA Guidance, Q21. Thus, regulations that impose minimal costs on regulated entities—even if they produce great cost savings in medical care, productivity for employers, or other economic benefits to society as a

[2] The FDA's guidance documents are nonbinding; therefore, it is unclear that any guidance document could mandate costs on industry. But the OIRA Guidance (at Q2, Q3) contemplates that nonbinding guidance can still be considered "significant regulatory action" subject to the Order.

whole—cannot be promulgated unless all such costs are "offset" by repealing other regulations. *See id.*

These requirements are not only disastrous for public health but also require arbitrary decision-making, in violation of the standards for promulgating regulations that are imposed upon the agency by Congress. The examples are boundless: To promulgate a food-safety regulation preventing bacterial contamination, the FDA would either have to undermine food safety by eliminating two regulations protecting our food supply or eliminate two regulations in another area of HHS's purview (say, testing requirements for medical devices) to offset the costs. The FDA could be forced to trade tobacco control for safer radiology standards, or regulations securing the dependability of the blood supply for those increasing transparency in clinical trials to foster patient safety and medical research, even though such trade-offs will neither improve public health nor benefit society economically. Any existing FDA regulations—all already deemed necessary via notice-and-comment rulemaking to protect the public health and further Congress's goals—are on the chopping block. No statute imposes or authorizes such limitations.

This amicus brief provides but a few examples of upcoming or proposed FDA actions likely impacted by the Order. These are just non-exhaustive examples, meant to illustrate the scope of arbitrary decision-making required by the Order. Indeed, the magnitude of the peril brought on by this "one-in-two-out" requirement is difficult to pinpoint because rules and guidance that have not yet been proposed will be deterred or weakened, and amici cannot yet know what existing rules may be repealed or reduced to make room for new ones. But given the obesity epidemic, the opioid crisis, the continued threat posed by tobacco use, and the ever-present risks to our food and drug system, we already know that this generation may—for the first time in our nation's history—live shorter lives than the last. S. Jay Olshansky et al., *A Potential*

Decline in Life Expectancy in the United States in the 21st Century, 352 New Eng. J. Med. 1138 (2005). This Order arbitrarily cripples Congress and the FDA's ability to fight back. It cannot stand.

ARGUMENT

Executive Order 13771 will deter, weaken, or force the repeal of FDA actions on multiple fronts. Specifically, amici highlight that the Order (1) hinders the FDA's ability to finalize existing proposed rules deemed necessary to protect the public health; (2) impedes the agency from updated existing regulations based on new science and technology; (3) jeopardizes the agency's implementation of new congressional enactments; and (4) threatens the FDA's efforts to protect youth. As these examples demonstrate, the Executive Order fundamentally impairs the FDA's ability to comply with congressional mandates designed to ensure that drugs and devices are safe and effective, food is not contaminated, and the devastating health effects of tobacco are reduced.

I. The Executive Order threatens the FDA's ability to finalize existing proposed rules deemed necessary to protect the public's health.

Perhaps the most noticeable and immediate impact is that the Order stops regulations in their tracks if they were not finalized before January 20, 2017, by requiring that before any economically significant regulation is finalized, two others must be identified for repeal.[3] A prime example is the FDA's proposed "NNN rule" that would regulate a specific carcinogenic compound in smokeless tobacco products (like snuff and chewing tobacco). *See Tobacco Product*

[3] The corresponding two regulations must be repealed, or have notice-and-comment procedures initiated for their repeal, before September 30, 2017. And an agency must "[f]ully offset the total incremental costs of [a newly promulgated] EO 13771 regulatory action as of September 30, 2017." OIRA Guidance, Q38. To repeal the regulations, the agency must follow the Administrative Procedure Act's substantive and procedural requirements, including notice-and-comment. Additionally, the OIRA Guidance (at Q37) states that "offsetting the costs of regulatory actions to comply with the requirements of EO 13771 should not serve as the basis or rationale, in whole or in part, for issuing an EO 13771 deregulatory action." Yet, under the Order, to promulgate a new significant regulation, the agency must rescind rules that it has already deemed to be necessary and satisfy the congressional standards.

Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8,004 (proposed Jan. 23, 2017). The FDA proposed the NNN rule under the authority Congress conferred in the Tobacco Control Act of 2009. Recognizing that tobacco products contain substances that are both lethal and addictive, and that their use is "the foremost preventable cause of premature death in America," Congress directed the FDA to regulate tobacco products to advance the public health. Pub. L. No. 111-31, 123 Stat. 1776, 1777 (June 22, 2009), codified at 21 U.S.C. § 387 note. To further this goal, Congress specifically authorized the FDA to promulgate "product standards" for tobacco products, including regulating levels "for nicotine yields of the product" or requiring "the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product." 21 U.S.C. §§ 387g(a)(3)(A), (B), (4)(A). In doing so, Congress acknowledged the FDA's unique "scientific expertise to identify harmful substances in products to which consumers are exposed [and] to design standards to limit exposure to those substances." Pub. L. No. 111-31 § 2, 123 Stat. at 1780.

The statute gives the FDA explicit instructions about factors that must be considered in designing a product standard. *See* 21 U.S.C. §§ 387g(a)(3)(A), (B). To promulgate a product standard, the FDA must determine that such a standard is "appropriate for the protection of public health," taking into consideration scientific evidence concerning: (1) "the risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products"; (2) "the increased or decreased likelihood that existing users of tobacco products will stop using such products"; and (3) "the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.* Additionally, the FDA is directed to consider any objection that the proposed standard will not reduce the risk of illness; the technical achievability of complying with the standard; and the potential countervailing effects, such as the creation of significant demand for contraband. 21 U.S.C. §§ 387g(a)(3)(B)(ii), 387g(b)(1), (2).

In developing the NNN rule, the FDA found overwhelming scientific evidence demonstrating that "NNN is a potent carcinogenic agent found in smokeless tobacco" and "is the predominant driver of excess oral cancer risk among smokeless tobacco users." 82 Fed. Reg. at 8,020. After considering the factors above, it proposed reducing the amount of NNN in smokeless tobacco products to a specific measure.

Because the NNN rule is deemed "economically significant" under Executive Order 12866, *id.* at 8,037, it is subject to the new Order's requirement that all the new costs to the tobacco industry attributable to the NNN rule be zeroed-out by rescinding other regulations. But the costs to the industry are only a small part of the story; the primary story focuses on the gains to public health. The NNN rule, according to the FDA's analysis, would be a net benefit to both health and the economy. It would dramatically reduce the morbidity associated with oral cancer, leading to over 12,700 fewer cases of oral cancer and a gain of approximately 15,200 life years over the next twenty years. *Id.* at 8,005. And the economic impact overall—balancing the costs of compliance with the benefits from the reduction in oral cancer—is a net gain: approximately $15 billion over the next twenty years. *See id.* at 8,038. That estimate does not even count the benefits associated with the FDA's expectation that the rule will also reduce the risk of esophageal, pancreatic, laryngeal, prostate, and lung cancers. *Id.*

Despite the proposed rule's importance to public health, and the FDA's measured exercise of its expertise and authority, the Order threatens its future by requiring either that it be tabled or weakened, or that other regulations within HHS that have already been deemed necessary be sacrificed without regard for their continuing merit. As such, the Order creates barriers to the NNN rule that are incompatible with the standards set forth by Congress in the Tobacco Control Act. The FDA can no longer implement a science-backed tobacco product standard when it is "appropriate for the protection of public health." It must contend with extra-

statutory requirements that apply regardless of the benefits of the rule or the fact that that such benefits far outweigh the costs. The Order effectively nullifies the criteria specified in the statute.

Moreover, the Order requires the agency to act in an arbitrary and capricious manner. To promulgate the NNN rule, the FDA has to swap other public health protections (without regard to the statutorily mandated pubic health considerations) or find other duly-promulgated rules to eliminate within HHS more broadly. Yet a rule limiting the level of a cancer-causing constituent in tobacco is entirely unrelated to whether or not other rules involving food, drugs, or medical devices should be abolished. And having to trade rules based on costs to entities regulated by the HHS generally, without any consideration of those rules' benefits, makes no sense. For instance, no matter how many lives would be saved by limiting NNN in smokeless tobacco, a rule yielding such benefits cannot be issued unless two other HHS rules are rescinded; and, indeed, those existing rules will need to be rescinded irrespective of whether they yield benefits far in excess of their costs. The NNN rule is but one example of how the Order severely compromises the FDA's ability to finalize existing proposed rules—and threatens the arbitrary elimination of existing public health protections—in violation of the clear intent of Congress.

II. The Executive Order hinders the FDA's ability to update outdated regulations in response to learned experience, new science, and emerging technologies.

Not only does the Order impact the FDA's ability to regulate in new areas, but it also impedes the FDA's ability to update existing regulations. Unsurprisingly, regulations issued decades ago sometimes need to be updated based on experience, new scientific research, or emerging technologies. Existing regulations regarding medical devices, for instance, may fail to address devices created with 3-D printers; updating regulations to ensure that those devices are safe and effective is precisely what Congress charged the FDA to do. *See* 21 U.S.C. § 360c; *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug*

Admin. Staff 1–2 (May 10, 2016), http://bit.ly/2od9c5j. To take one example, the FDA has proposed an economically significant rule to bring medication-prescribing information in line with modern technology, requiring manufacturers to switch from paper to electronic (and thus updatable) "package inserts" to "ensure that the most current prescribing information for prescription drugs will be available and readily accessible to health care professionals at the time of clinical decisionmaking and dispensing." 79 Fed. Reg. 75,506, 75,511, 75,524 (proposed Dec. 18, 2014). Indeed, Congress delegated the FDA broad discretion related to the regulation of food and drugs in part because "public health authorities may be called upon to respond to 'unanticipated and rapidly emerging needs and threats.'" Micah L. Berman, *Smoking Out the Impact of Tobacco-Related Decisions on Public Health Law*, 75 Brook. L. Rev. 1, 15 (2009) (quoting Sara Rosenbaum et al., *New Models for Prevention Systems: Public Health Emergencies and the Public Health/Managed Care Challenge*, 30 J. L. Med. & Ethics 63, 64 (2002)). But, given the Order, the FDA may only update regulations in one area by eliminating regulations in others.

The agency's efforts to update radiology regulations illustrate this point. A critical initiative included in the FDA's most recent "Unified Agenda" (*i.e.*, list of agency priorities) was updating regulations relating to radiology devices, particularly computed tomography (CT) X-ray systems. *See* FDA Unified Agenda, *Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System*, RIN 0910-AH03 (Fall 2016). A CT X-ray system is "a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles." *Id*. More simply, CT scans work by shooting radiation at a patient to take detailed pictures of the inside the patient's body, helping doctors diagnose medical conditions. Although the FDA regulates CT X-ray systems now, existing statutes and rules "primarily establish[] requirements for labeling and for providing product performance information" rather than set "patient radiation dose

limits" or standards for imaging performance or efficacy. U.S. Food & Drug Admin., *How Does FDA Regulate CT Systems?*, http://bit.ly/2mMJeJ3 (last visited May 19, 2017).

In light of significant increases in the use of CT imaging in the last decade and greater awareness about the dangers of radiation exposure, Center for Devices & Radiological Health, U.S. Food & Drug Admin., *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging* 4 (2010) ("Center for Devices Initiative"), the FDA recognized that regulating in this area was a priority. Specifically, the FDA explained that, because ionizing radiation can cause damage to DNA, the exposure a patient receives during a CT scan can increase a person's lifetime risk of developing cancer. Center for Devices Initiative at 5. And even without the long-term risks, recent experience has demonstrated that "[h]igh doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning." FDA Unified Agenda, RIN 0910-AH03.

Given these risks, and Congress's charge that the FDA establish controls "sufficient to provide reasonable assurance of the safety and effectiveness of [a medical] device," 21 U.S.C. § 360c, the FDA now seeks to reduce "[u]nnecessary radiation exposure [that] may result from the use of a radiation dose above what is optimal to meet the clinical need in a given procedure." Center for Devices Initiative at 5. As the agency recognizes, "[t]o a point, using a higher radiation dose can produce a higher-resolution image," because "[i]f the dose is too low, the quality of the resulting image may be poor, and, as a result, a physician may not be able to make an accurate clinical determination." *Id.* The "optimal radiation dose" is "one that is as low as reasonably achievable while maintaining sufficient image quality to meet the clinical need." *Id.* Thus far, however, the agency has provided no standards for what that dosing is. And as CT X-ray technology has expanded and become more widespread, radiation levels from CT imaging run the gamut. Different CT systems use different amounts of radiation, *id.* at 6, and the amount

of exposure from some types of CT scans can be significant. For example, "the radiation dose associated with a CT abdomen scan is the same as the dose from approximately 400 chest X-rays." Food & Drug Admin. News Release, FDA Unveils Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, Feb. 9, 2010, http://bit.ly/2ovatnA.

To address this problem, the agency initiated collaborations with private industry, held public meetings, and requested the collection of dose-dependent data. Center for Devices Initiative at 9. Then, in its Unified Agenda, it signaled its intent to propose a rule to ensure that CT X-ray systems are designed and used such that the radiation dosing "balance[s] the benefits of the device (*i.e.*, the ability of the device to produce a diagnostic quality image) with the known risks (*e.g.*, exposure to ionizing radiation)." FDA Unified Agenda, RIN 0910-AH03.

But, again, the Order threatens to deter, weaken, or altogether prevent these necessary advances in radiology regulation. The FDA's proposed CT X-ray rule is expected to be "economically significant," and trigger the Order's limitations. *Id.* But such "special controls" for the use of CT X-ray systems, the FDA's research indicates, "are necessary to provide reasonable assurance of the safety and effectiveness" of CT X-ray systems, as required by Congress. 21 U.S.C. § 360c. Quite simply, these radiology rules are required to prevent people from suffering unnecessary burns or sterilization, and to reduce cancer risks. And if a lower dose of radiation can still provide clinicians with sufficient images for diagnosis and treatment, why should patients suffer unnecessary exposure? Yet the Order may thwart this entire rulemaking initiative by requiring the FDA to eliminate two offsetting regulations within HHS just to update its standards for CT X-ray machines. What other public health protections must go? What other areas cannot be updated? What must HHS trade to protect us from unnecessary radiation exposure? The Order may focus on costs to regulated industries, but it wholly ignores the cost to public health of arbitrarily limiting the FDA's authority to keep pace with new science and technology.

III. The Executive Order complicates the FDA's ability to implement new congressional enactments.

The Order also makes it harder for FDA to respond to new congressional enactments. When Congress passes a new law, it often either explicitly directs an agency to promulgate rules or guidance on a particular matter or generally delegates to an agency the responsibility to fill in details necessary for the law's implementation. The Order's limitations on agency action apply in these scenarios, meaning that if an agency is responding to either a direct mandate to promulgate a regulation, or to a new statute that has yet to be implemented, it must find other regulations to repeal. To be clear, though the Executive Order "does not prevent agencies from issuing regulatory actions in order to comply with an imminent statutory or judicial deadline, even if they are not able to satisfy EO 13771's [repeal] requirements by the time of issuance," agencies are still "required to offset any such [statutorily mandated] regulatory actions as soon as practicable thereafter." OIRA Guidance, Q33. Quite simply, the Order attaches strings to congressional directions that Congress neither sanctioned nor anticipated—requiring the agency to arbitrarily eliminate regulations to make room to implement new laws.

Three examples of legislation from the past decade demonstrate this point.

1. *Tobacco Control Act*. As mentioned above, Congress passed the Tobacco Control Act in 2009, giving the FDA authority to regulate tobacco products. As part of that law, Congress directly instructed the FDA to promulgate regulations on a series of matters. Although the agency has already satisfied some of these mandates, others remain outstanding; indeed, the FDA has failed to meet the congressional deadline on some of these. For instance:

- Congress mandated that, within two years after the TCA's enactment, the FDA had to establish guidance or rules for the scientific showing a company had to make before a product qualifies as a "modified risk tobacco product," such that a company can make any health claims (*e.g.*, that a product was "safer" or a "less hazardous" alternative than another tobacco product). Pub. L. No. 111-31, § 911(l)(1), 123 Stat. at 1818, codified at 21 U.S.C. § 387k. The FDA issued draft guidance in 2012, but it has yet to be finalized.

- Congress mandated that, within three years after the TCA's enactment, the FDA had to "promulgate regulations [that] . . . shall require testing and reporting of tobacco product constituents, ingredients, and additives . . . ." *Id.* §§ 915(a), (b)(1), 123 Stat. at 1820, codified at 21 U.S.C. § 387o. The purpose of this section is to ensure that tobacco products are tested so that the agency and the public know what is in them. The FDA has yet to issue regulations satisfying this mandate.

- Congress also mandated that, within two years of the TCA's enactment, the FDA had to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" nine new textual warnings on cigarette packages and advertising. *Id.* § 201(d), 123 Stat. at 1845, codified at 15 U.S.C. § 1333(d). Though the FDA promulgated regulations mandating "graphic warnings" in 2011, those specific images were subject to a successful *as-applied* court challenge, prompting the FDA to withdraw its defense of the regulations, and undertake research to support a new rule mandating graphic warnings that would meet constitutional scrutiny (indeed, the Sixth Circuit held that the mandate did not *facially* violate the First Amendment). *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012). Over four years have passed since the FDA withdrew its rule, prompting a lawsuit by several public health groups (including several amici here) seeking a court order compelling the FDA to issue a new rule mandating graphic warning labels in accordance with the statute. *See American Academy of Pediatrics, et al. v. FDA*, No. 16-cv-11985 (D. Mass., filed Oct. 4, 2016); Melissa Jenco, *AAP, health groups file lawsuit pushing for graphic cigarette warnings*, AAP News, Oct. 4, 2016, http://bit.ly/2nryk8v. Research indicates that graphic warnings would decrease the number of adult smokers by 5.3 to 8.6 million in the first year. *Id.*

Each of these overdue congressionally required rulemakings now face another hurdle—the "one-in-two-out" Order. To follow Congress's orders in the Tobacco Control Act, the FDA (or HHS) will now have to figure out which other regulations to cut—even though Congress mandated no such thing.

2. *Food Safety Modernization Act.* The Food Safety Modernization Act, enacted in 2011, aims to ensure that the U.S. food supply is safe from contaminants by shifting the focus of federal regulators (mainly the FDA) from responding to contamination to preventing it. Given that about 48 million Americans (1 in 6) get a foodborne illness each year, sometimes causing hospitalization and death, Congress sought to update its approach to food safety. Food & Drug Admin., Background on the FDA Food Safety Modernization Act (FSMA),

http://bit.ly/2orxNny (last visited May 19, 2017). Indeed, new challenges made it critical to modernize, including the fact that 15% of the U.S. food supply is imported, and that there are new foods and new hazards not previously seen. Food & Drug Admin., Report to Congress on the FDA Foreign Offices (Feb. 2012), http://bit.ly/2p1cnko. A central part of Congress's law was to mandate comprehensive preventative controls for food and feed facilities. The idea of prevention is, of course, not new. But with the Act, Congress gave the FDA explicit authority to require more preventative efforts and to strengthen accountability for prevention measures.

As a result, the FDA has promulgated numerous new rules to implement the Act. It has, for example, established science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms. 80 Fed. Reg. 74,353 (Nov. 27, 2015). And it has established a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications in foreign facilities, ensuring that imported food meets the same safety standards as domestic food. 80 Fed. Reg. 74,569 (Nov. 27, 2015). The FDA finalized many of the foundational rules implementing the Act by the end of 2016. But had the Order applied, the FDA may have had to find other public health regulations to repeal to offset the costs of keeping our food supply safe. Indeed, as new regulations and guidance documents are needed to further implement the Act, that is exactly the challenge the FDA will face. *See* Food & Drug Admin., FSMA Rules and Guidance for Industry, http://bit.ly/2odCL70 (last visited May 19, 2017) (listing draft guidance yet to be finalized). With the new constraints that the Order places on implementing the Act, the agency's further efforts to prevent contaminants in the food supply may be deterred, delayed, or even stymied altogether.

3. *21st Century Cures Act.* The bipartisan 21st Century Cures Act is hot off the press, having been signed into law on December 13, 2016. And there is a lot the FDA has to do to implement the law that could be hampered by the Order. This new law, as a general matter,

requires the FDA to issue guidance documents and regulations to fulfill the legislative goal of implementing new pathways for the FDA to approve medical devices, biologics, and pharmaceuticals. Although the FDA will still undertake premarket review of these products for safety and efficacy, these new approval pathways and methods require significant regulatory and sub-regulatory actions by the FDA. At this early stage it is unclear which guidance and regulations will constitute "significant regulatory action" subject to the Order. In all, the FDA will have to figure out how to implement more than one hundred sections of the new law, some of which have direct congressional commands (with deadlines) for the agency to issue regulations or guidance documents. A few examples include:

- Congress requires the FDA to issue new guidance to address the use of complex adaptive and other novel trial designs in the development of new drugs or biologics. Pub. L. No. 114-255 § 3021, 130 Stat. at 1095–96. A complex adaptive study design is one that, even once the study has started, may be altered based on analysis of interim data. Among other requirements, the new guidance must address how to use these types of studies to demonstrate the safety and effectiveness of new drugs for approval. *See id.*

- Congress requires the FDA, within two years after enactment, to develop and begin to implement a framework to evaluate the use of "real world evidence" in supporting the approval of a new indication for a previously approved drug, or to support post-approval study requirements. *Id.* §§ 3022(a), (c), 130 Stat. at 1096–97. "Real world evidence" refers to data about the usage, benefits, and risks of a drug that are derived from sources other than randomized clinical trials. *Id.* § 3022(b), 130 Stat. at 1096. In particular, the law requires the FDA to issue guidance describing: (1) the circumstances from which such real world evidence may be derived, including ongoing safety surveillance, observational studies, registries, and patient claims; (2) the standards and methodologies for collecting such data; and (3) the potential priority areas and opportunities to pilot the use of this real world evidence. *Id.* §§ 3022(c), (d), 130 Stat. at 1096–97.

- Congress requires the FDA to update its regulations and guidance on how it will evaluate and approve "regenerative advanced therapies," which are drugs that utilize cell and tissue engineering to treat, modify, reverse, or cure serious and life-threatening diseases. *Id.* §§ 3033, 3034, 3036, 130 Stat. at 1101–05. For instance, within one year of the law's enactment, the FDA must issue guidance delineating how it will evaluate devices used in the "recovery, isolation, or delivery" of these cell- and tissue-based therapies. *Id.* § 3034, 130 Stat. at 1103. And it must update its regulations establishing research standards in this area. *Id.* § 3036, 130 Stat. at 1104–05.

As FDA commentators—including industry attorneys—have observed, the Order "may hinder implementation" of the Act. Rothman, *FDA Faces Uncertainty Implementing 21st Century Cures Act*; *see also* Arent Fox, *Trump's 2-for-1 Executive Order, its Impact on FDA, and the Significance of "Significant"* (Feb. 10, 2017), http://bit.ly/2p0XuhQ ("Requiring the FDA to 'trade in' existing regulations and guidance documents to implement the Cures Act is likely to cause delay in the agency's implementation."). When Congress passed 21st Century Cures, setting the stage for advancements in medical products, it did not contemplate that such progress would be traded for other existing public health protections. Yet, for any economically significant regulatory action the FDA takes—even though it is congressionally mandated—the FDA or HHS will have to sacrifice existing regulations.

IV. The Executive Order impedes the FDA's ability to protect youth.

Lastly, the Order impedes the FDA's ability to protect children from hazardous products. Although the Order makes costs to regulated entities the paramount concern, the goals of Congress, the FDA, and the public health community have often centered on protecting our youngest citizens, or other vulnerable populations, even when doing so imposes some expense on industry. Because of the Order, when the FDA now takes steps to protect children, it has to determine what other regulations to repeal. The result: The FDA may be deterred from or delayed in adopting rules that protect children—even when, in the absence of the Order, it would have done so.

The FDA's proposed rule prohibiting youth use of tanning beds is just one example. Given the heightened cancer risk associated with using ultraviolet sunlamp products (*i.e.*, tanning beds and tanning booths), in December 2015 the FDA proposed limiting their use to individuals age 18 and older, while also requiring other protections and disclosures for adults. The FDA acted well within its authority in proposing this rule based on its scientific expertise. Specifically,

the Food, Drug, and Cosmetic Act gives the FDA authority to regulate medical devices intended for human use, and allows the FDA to impose "restrictions upon the sale, distribution, or use of a device if, because of its potentiality for harmful effects . . . FDA determines that absent such restrictions, there cannot be reasonable assurance of its safety and effectiveness." 21 U.S.C. §§ 360c, 360j(e). Additionally, Congress gave the FDA specific authority over "electronic product radiation control [] to protect the public health and safety." 80 Fed. Reg. 79,493, 79,494 (proposed Dec. 22, 2015). That authority "provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products." *Id.; see* 21 U.S.C. § 360ii. There is no question that Congress gave the FDA authority to regulate potentially dangerous electronic radiation devices, like tanning beds, and even conferred on it the power to prohibit the use of such products when, exercising the agency's scientific expertise, such limits are deemed necessary to protect the public health. Notably, the FDA's statutory authority in this regard—as with the entire FDC Act—is not constrained by the costs to industry for complying with the agency's safety rules.

The FDA's age restriction is necessary to protect our youth. As is well established in the scientific literature, "UV radiation exposure can lead to permanent damage to DNA in the skin, which has been shown to lead to an increased risk of skin cancer." 80 Fed. Reg. at 79,495. Indeed, some doses of UV radiation emitted by high-power sunlamp products "may be up to 10 to 15 times higher than that of the midday sun, resulting in an intense amount of exposure that does not exist in nature." *Id.* Although the increased risk of cancer associated with tanning bed use is "applicable to all persons," *id.* at 79,496, the FDA's proposed rule targets youth under age 18 for two important reasons. First, scientific evidence suggests that "individuals who begin indoor tanning at ages younger than 18 years are particularly vulnerable to the carcinogenic impact of indoor tanning"—in part because they start tanning earlier, leading to a greater

cumulative effect of UV radiation, but also because their bodies are simply more "vulnerable to the damaging effects of UV radiation." *Id.* at 79,495–96. "Published medical evidence demonstrates that there is a direct correlation between sunlamp product use among youths and their developing melanoma skin cancer, as well as other skin cancers." *Id.* at 79,496. Indeed, "[m]elanoma is a leading cause of cancer death in women ages 15 years to 29 years and there is some evidence that suggests use of sunlamp products is an underlying cause." *Id.*

The FDA also concluded that the age restriction is necessary because youth "often fail to appropriately evaluate the significant health risks associated with indoor tanning." *Id.* For example, one study cited in the FDA's proposed rule shows that college-age students often use sunlamp products despite awareness of the long-term risks. *Id.* "[P]ersons under age 18 years appear to be discounting whatever risk information they are receiving or may have difficulty incorporating the information into their decisionmaking." *Id.* As with other risk-taking behaviors, "adolescents use sunlamp products for self-esteem or sensation seeking reasons, irrespective of known health risks." *Id.* As with many risky products or behaviors, we don't let youth make harmful decisions based on impulse and peer pressure. Likewise, given the epidemiological evidence linking UV sunlamp devices and skin cancer, it makes no sense to let youth undertake the risky choice of using tanning beds.

Yet the future of this rule to protect youth from skin cancer is now uncertain in the face of the Order. Because the agency estimates that the rule will impose costs of $104 million to $144 million annually (including the parts of the rule that require disclosures for adult tanning bed users), this proposed rule is a significant regulatory action as defined by Executive Order 12866. *Id.* at 79,498–99. It is therefore now subject to the "one-in-two-out" Order. But the agency also estimates that the rule will have benefits of $70 million to $248 million annually from the reduction in incidence of skin cancer, *id.* at 79,498–99—benefits irrelevant under the Order.

Applying the Order, the FDA will have to decide whether to finalize this rule, and if so, what other health protections must be eliminated to offset its costs. Forcing these arbitrary tradeoffs not only contravenes Congress's mandate to the FDA to ensure the safety of medical devices, but also limits the ability of the FDA to protect children—a core part of our country's public health mission.

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Americans depend upon the FDA to protect the food supply, ensure that drugs are safe and effective, reduce the harmful effects of tobacco use, and otherwise advance the nation's health. Yet, as these examples illustrate, the Executive Order threatens to block, weaken, or delay critical public health protections in contravention of congressional intent, jeopardizing the progress in public health seen since the early 20th Century.

CONCLUSION

For these reasons, amici respectfully request that the Court grant the plaintiffs' motion for summary judgment.

Respectfully submitted,

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May 22, 2017

ADDENDUM

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, tribal, and global leaders promote health by strengthening public policies. For almost twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. The Center has filed more than fifty briefs as amicus curiae in the highest courts in the United States and before international bodies, including many briefs filed by the Center's tobacco program, the Tobacco Control Legal Consortium.

The American Academy of Pediatrics is an organization of 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

The Big Cities Health Coalition (BCHC) is a forum for the leaders of America's largest metropolitan health departments to exchange strategies and jointly address issues to promote and protect the health and safety of the 54 million people they serve. Together, these public health officials directly affect the health and well-being of one in six Americans. BCHC supports the role of regulatory agencies at the local, state, and federal levels to protect the health and safety of all Americans.

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit, and protect everyone from secondhand smoke

Center for Science in the Public Interest (CSPI) is a nonprofit, nonpartisan organization whose mission is to advocate on behalf of the public on issues of nutrition and health. Founded in 1971, CSPI has played a key role in successful campaigns to: ban artificial trans fats from the food supply; obtain a ban on sugar-sweetened beverages in public schools; obtain voluntary agreements to restrict advertising to children from major food and beverage manufacturers; and prescribe the content and legibility of important nutrition information on product labels. CSPI also represents consumers through litigation that targets, mainly, false advertising of foods—making it easier for consumers to live nutritious and healthy lifestyles. As a consumer advocacy organization working to promote public health and nutrition, and by corollary to protect federal regulations that advance these goals, CSPI has an important interest and a valuable perspective on the issues presented in this case.

ChangeLab Solutions is a national nonprofit organization that creates innovative laws and policies to ensure everyday health for all, whether that is providing access to affordable, healthy food and beverages, creating safe opportunities for physical activity, or ensuring the freedom to enjoy smoke-free air and clean water. Our solutions address all aspects of a just, vital, and

thriving community, such as food, housing, childcare, schools, transportation, public safety, jobs, and the environment. ChangeLab Solutions creates and helps implement legal and policy solutions designed to improve health outcomes and advance health equity.

The Collaboration for Research Integrity and Transparency (CRIT) is a multi-disciplinary initiative of Yale Law School, Yale Medical School, and Yale School of Public Health. CRIT's mission is to promote public health by improving the transparency and integrity of biomedical and clinical data. CRIT's scientists have conducted research showing that data transparency and integrity are crucial to the accurate and informed use of drugs, devices, and biologics. Guided by CRIT's doctors and biostatisticians, CRIT's legal team ensures the regulatory frameworks surrounding data transparency and integrity are effective. Through litigation and policy work, CRIT focuses on enforcement of statutes and rules governing the accurate reporting of clinical trial results as well as the effective imposition of safety and efficacy pre- and post-market requirements by the FDA. CRIT has particular experience with regulations and guidance that could be affected by this Order.

The National Association of County and City Health Officials (NACCHO) represents the nation's nearly 3,000 local governmental health departments. These city, county, metropolitan, district, and tribal departments work every day to protect and promote health and well-being for all people in their communities. NACCHO supports the role of regulatory agencies at the local, state, and federal levels to protect the health and safety of all Americans.

National Women's Health Network
The National Women's Health Network (NWHN) is a non-profit advocacy organization that is supported by its members and does not accept financial support from pharmaceutical or medical device companies or the insurance industry. The NWHN works to improve the health of all women by developing and promoting a critical analysis of health issues in order to effect policy change and support informed consumer decision-making. The NWHN has a significant interest in protecting the health of women from injuries due to untested, unsafe, and misbranded drugs and devices.

The Public Good Law Center is a public interest law firm dedicated to defending statutory and constitutional interpretations that vindicate the proposition that everyone is equal before the law. Through amicus participation in cases of particular significance for public health, consumer protection, and civil liberties, Public Good seeks to ensure that the protections of the law remain available to all. Public Good has submitted amicus briefs defending important government protections of public health in state courts and federal Courts of Appeals around the nation.

The Public Health Advocacy Institute ("PHAI") is a legal and policy research and advocacy organization located at Northeastern University School of Law focusing its efforts on tobacco prevention, obesity prevention, and improving the health and safety of workers.

The Public Health and Tobacco Policy Center provides local governments legal and technical policy guidance through research, development, and implementation of tobacco control and other public health initiatives. The Center is contracted by the New York State Department of Health, among others, to develop and support policy initiatives that will reduce

morbidity and mortality. We are housed at the Public Health Advocacy Institute at Northeastern University School of Law.

Truth Initiative envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Truth Initiative's proven-effective and nationally recognized public education programs include **truth**®, the national youth smoking prevention campaign that has been cited as contributing to significant declines in youth smoking; EX®, an innovative smoking cessation program; and research initiatives exploring the causes, consequences, and approaches to reducing tobacco use. Truth Initiative also develops programs to address the health effects of tobacco use, with a focus on priority populations disproportionately affected by the toll of tobacco, through alliances, youth activism, training, and technical assistance. Located in Washington, D.C., Truth Initiative was created as a result of the November 1998 Master Settlement Agreement between 46 states, five U.S. territories, and the tobacco industry.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Local Rule 7(o)(4) because it contains fewer than 25 pages, exclusive of the portions excluded by Fed. R. App. P. 32(f).

/s/ Deepak Gupta
Deepak Gupta

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2017, I electronically filed the foregoing with the Clerk of the Court of the United States District Court for the District of Columbia by using the CM/ECF system. All participants are registered CM/ECF users, and will be served by the CM/ECF system.

/s/ Deepak Gupta
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