# WHAT ABOUT THE KIDS? ADVANCING A CHILD-CENTERED APPROACH TO FOOD & DRUG LAW

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*This Article contends that food and drug law has fallen short in safeguarding and advancing children's health. The Food and Drug Administration's (FDA's) mission is to protect and promote public health, and children's health is an integral part of that. This Article uses the feminist legal method of "asking the woman question" to examine how food and drug law has impacted issues related to children's health. To better address children's health, this Article argues that FDA should create a children's health office to actively identify, assess, monitor, and address issues impacting children in and across all the major FDA-regulated product categories—food, drugs, biologics, devices, cosmetics, and tobacco products.*



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## INTRODUCTION

Recent high-profile issues involving Food and Drug Administration (FDA)-regulated products have highlighted FDA's limitations and shortcomings when it comes to protecting and promoting children's health. Formula shortages,[1] baby foods reported to contain heavy metals,[2] children's cosmetics reported to contain asbestos,[3] drug shortages,[4] and

1. *Infant Formula Information and Ongoing FDA Efforts to Increase Supply*, U.S. FOOD & DRUG ADMIN. (Aug. 5, 2022), https://www.fda.gov/news-events/public-health-focus/infant-formula-information-and-ongoing-fda-efforts-increase-supply [https://perma.cc/D4Z6-936U].

2. SUBCOMM. ON ECON. & CONSUMER POL'Y COMM. ON OVERSIGHT & REFORM, U.S. HOUSE OF REPRESENTATIVES, STAFF REPORT: BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF ARSENIC, LEAD, CADMIUM, AND MERCURY (Feb. 4, 2021) [hereinafter BABY FOODS], https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf [http://perma.cc/HB4D-JUCJ].

3. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition, on Tests Confirming a 2017 Finding of Asbestos Contamination in Certain Cosmetic Products and New Steps that FDA is Pursuing to Improve Cosmetics Safety (Mar. 5, 2019) [hereinafter Statement of Commissioner & CFSAN Director], https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and [https://perma.cc/S4SZ-TR7T].

youth e-cigarette use are only a few examples of recent issues involving FDA-regulated products that may threaten children's health.[5]

Addressing children's needs is essential to FDA's ability to fulfill its mission of "[p]rotecting and [p]romoting [p]ublic [h]ealth."[6] Public health aims to "fulfill[] society's interest in assuring conditions in which people can be healthy."[7] Children comprise about 22% of the United States population, and health during childhood impacts adult health.[8] "[Children's] health is the public's health," and we all have a stake in it.[9]

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4. *FDA Drug Shortages*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm [https://perma.cc/7JVY-V6J7] (choose "Therapeutic Categories" from menu, then choose "Pediatric").

5. *Results from the Annual National Youth Tobacco Survey*, U.S. FOOD & DRUG ADMIN. (Dec. 20, 2022) [hereinafter Tobacco Survey], https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey [https://perma.cc/7HHZ-QZW3].

6. *What We Do*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do [https://perma.cc/TW4K-KAST]; FDCA § 1003(b), 21 U.S.C. § 393(b); United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969) ("[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."); Penka D. Gatseva & Mariana Argirova, *Public Health: The Science of Promoting Health*, 19 J. PUB. HEALTH 205–06 (2011); LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 4 (3rd ed. 2016) ("The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice."); *see also* Ralph S. Tyler, *The Goals of FDA Regulation and the Challenges of Meeting Them*, 22 HEALTH MATRIX 423, 425 (2013); Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, §§ 301, 405.

7. INST. OF MED. COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, *Summary & Recommendations*, *in* THE FUTURE OF PUBLIC HEALTH at 7 (1988).

8. *See POP2 Children as a Percentage of the Population: Persons in Selected Age Groups as a Percentage of the Total U.S. Population, and Children Ages 0–17 as a Percentage of the Dependent Population, 1950–2021 and Projected 2022–2050*, CHILDSTATS, https://www.childstats.gov/americaschildren/tables/pop2.asp [https://perma.cc/A4K4-MCZ7]; *A Child's Health Is the Public's Health*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 24, 2022), https://www.cdc.gov/childrenindisasters/features/children-public-health.html [https://perma.cc/786G-BXZ7]; Alice A. Kuo, Pauline A. Thomas, Lance A. Chilton & Laurene Mascola, *Pediatricians and Public Health: Optimizing the Health and Well-Being of the Nation's Children*, PEDIATRICS, Feb. 2018, at 1, 6, https://publications.aap.org/pediatrics/article/141/2/e20173848/38076/Pediatricians-and-Public-Health-Optimizing-the.

9. *See* Eric J. Dziuban, Georgina Peacock & Michael Frogel, *A Child's Health Is the Public's Health: Progress and Gaps in Addressing Pediatric Needs in Public Health Emergencies*, 107 AM. J. PUB. HEALTH S134, S134–37 (Supp. 2 2017); Barbara Bennett Woodhouse, *Hatching the Egg: A Child-Centered Perspective on Parents' Rights*, 14 CARDOZO L. REV. 1747, 1842 (1992); *see*

Despite the importance of FDA-regulated products to children's—and society's—well-being and FDA's mission,[10] FDA has frequently addressed issues surrounding children's health in a piecemeal fashion by product category.[11] Moreover, where FDA has used a broader, more comprehensive approach, it has frequently focused on drugs, biological products (biologics), and medical devices and excluded food, cosmetics, and tobacco products.[12] This Article argues that there is a need to examine the impact of FDA regulation on children *across all* the product categories, which may help FDA better anticipate, avoid, respond to, and move beyond specific issues to advance children's health.

To do this, this Article examines how federal food and drug law impacts children.[13] Drawing on feminist legal scholarship and methods, it asks a series of questions modeled on the "woman question" to examine how this

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*also* Jacob P. Byl, Note, *Protecting the Innocent with a Premium for Child Safety Regulations*, 8 U. MASS. L. REV. 264, 267, 270 (2013) (arguing that agencies, including FDA, "should shift more focus to regulations that promote child safety" and, specifically, "that agencies should . . . put a premium on saving the lives of children when analyzing the benefits and costs of regulations").

10. *What We Do*, *supra* note 6; *see, e.g.*, *Nutrition*, FOOD & AGRIC. ORG. OF THE U.N., https://www.fao.org/nutrition/en/ [https://perma.cc/22BF-D7UJ] (stating that "[n]o matter how it is defined, nutrition starts with what we eat, the products of the food and agriculture sector" and "[g]ood nutrition is our first defense against disease and our source of energy to live and be active"); *Think It Through: Managing the Benefits and Risks of Medicines*, U.S. FOOD & DRUG ADMIN. (June 18, 2018), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/think-it-through-managing-benefits-and-risks-medicines [https://perma.cc/99CR-BQWA] (stating that "medicines are relied upon to treat disease and improve health").

11. *See infra* Part II; *see also FDA Overview Organization Chart*, U.S. FOOD & DRUG ADMIN. (Apr. 25, 2023), https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart [https://perma.cc/95PG-SVFS].

12. *See FDA Overview Organization Chart*, *supra* note 11; *infra* Parts II.B & III.A; *see, e.g.*, *Office of Pediatric Therapeutics*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2021), https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-pediatric-therapeutics [https://perma.cc/KUT5-6XSA] ("The Office of Pediatric Therapeutics (OPT) helps assure access for children to innovative safe and effective medical products."); *see also* Patricia J. Zettler, *The FDA's Power over Non-Therapeutic Uses of Drugs and Devices*, 78 WASH. & LEE L. REV. 379, 388, 390 (2021) (noting that "the FDA has not formally explained—such as through guidance or a regulation—the agency's thinking about what constitutes a therapeutic or a non-therapeutic use of a drug or device").

13. Despite its name, food and drug law includes biological products (biologics), cosmetics, devices, and tobacco products.

area of law impacts children.[14] It asks if children have been left out of consideration.[15] Using examples from each of the six major FDA-regulated product categories—food, drugs, biologics, devices, cosmetics, and tobacco products, this Article answers that question affirmatively.[16] It then asks how that omission might be corrected and what difference it would make to do so.[17] Ultimately, this Article argues that FDA needs an office of children's health devoted to actively identifying, assessing, monitoring, and addressing issues impacting children in and across *all* product categories.[18]

This Article proceeds as follows: Part I considers how the term "children" has been defined and explains how this Article uses it. Part I then discusses the legal scholarship and methods that provide the framework for this examination of food and drug law. After a brief discussion of children and the development of food and drug law, Part II uses examples from each of the major FDA-regulated product categories to argue that FDA regulation has failed to fully consider children's needs to the detriment of children's health. Part III then asks how that omission might be corrected. It considers how focused attention to food and drug law's impact on children's health matters might advance FDA's mission. Part III also explores potential models for a children's health office, including FDA's Office of Women's Health (OWH) and Office of Minority Health and Health Equity (OMHHE), and the Environmental Protection Agency's (EPA's) Office of Children's Health Protections (OCHP).

## I. BACKGROUND

### *A. "Children"*

#### *1. Terminology*

This Article focuses on the impact of food and drug law on "children." While the lay, legal, and medical definitions of "child" differ somewhat,[19] this

14. *See* Katharine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 837 (1990) (framing the woman question as several questions: "[H]ave women been left out of consideration? If so, in what way; how might that omission be corrected? What difference would it make to do so?"); Woodhouse, *supra* note 9, at 1838 ("asking the 'child question'").

15. Bartlett, *supra* note 14.

16. FDA also regulates radiation emitting electronic products. *See infra* note 71.

17. *See* Bartlett, *supra* note 14.

18. *See infra* Part III. FDA does have an Office of Pediatric Therapeutics, however, that office focuses solely on medical products. *See Office of Pediatric Therapeutics*, *supra* note 12.

19. *See, e.g.*, *Child*, OXFORD ENG. DICTIONARY, https://www.oed.com/view/Entry/

Article focuses on persons from birth up to age eighteen, which, for simplicity, it refers to as "children." Where possible, this Article specifies the children to which it is referring. Accordingly, it sometimes uses other terms, such as babies, infants, toddlers, and teens, to refer to subgroups of children.

Where this Article cites a specific source, it tries to adopt the source's terminology and explain how it is defined. For example, FDA often uses the term "pediatric" when discussing children's health, however, the meaning of "pediatric" varies. While the definition of "pediatric" overlaps with this Article's definition of "children," it is not coterminous as it is used to refer to patients younger than seventeen as well as patients up to twenty-one.[20]

### *2. Children in the United States*

In the United States, there were approximately 72.5 million children aged zero to seventeen in 2022.[21] These children were roughly equally

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31619?rskey (defining child, in part as, "[a] young person of either sex, usually one below the age of puberty"); *Child*, MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/child [https://perma.cc/L2Q3-SUVR] (listing several definitions of "child," including "a young person especially between infancy and puberty" and "a person not yet of the age of majority"); TABER'S CYCLOPEDIC MEDICAL DICTIONARY 452–53 (23d ed. 2017) (defining "child" as "[a]ny human between infancy and puberty"); *id.* at 52 (defining "adolescent" as "pert[aining] to adolescence," which is in turn defined as "[t]he period from the beginning of puberty until maturity" and noting that "[b]ecause the onset of puberty and maturity is a gradual process and varies among individuals, it is not practical to set exact age or chronological limits in defining the adolescent period"); *Child*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "child," in part as "[a]n unemancipated person under the age of majority" and "a young person" and noting that "[a]t common, law a person who has not reached the age of 14").

20. *See* 21 U.S.C. § 360ff(a)(3) (stating that a "rare pediatric disease" means a disease primarily affecting individuals from birth to age eighteen); 21 U.S.C. § 360j(m)(6)(E)(i)-(ii) (defining "pediatric patient[]" as someone who is twenty-one years old or younger); 21 C.F.R. § 201.57(c)(9) (stating that "the pediatric age group" is "from birth to 16 years"); U.S. FOOD & DRUG ADMIN., PEDIATRIC DRUG DEVELOPMENT: REGULATORY CONSIDERATIONS—COMPLYING WITH THE PEDIATRIC RESEARCH EQUITY ACT AND QUALIFYING FOR PEDIATRIC EXCLUSIVITY UNDER THE BEST PHARMACEUTICALS FOR CHILDREN ACT GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE 3 (2023) [hereinafter PEDIATRIC DRUG DEVELOPMENT: REGULATORY CONSIDERATIONS], https://www.fda.gov/media/168201/download [https://perma.cc/5GAQ-QK56] (stating that "FDA generally considers the pediatric population to include those patients from birth to younger than 17 years").

21. *POP1 Child Population: Number of Children (in Millions) Ages 0–17 in the United States by Age, 1950–2022 and Projected 2023–2050*, CHILDSTATS, https://www.childstats.gov/americas

divided among the three age groups: zero to five (approximately 22.4 million children), six to eleven (24.2 million), and twelve to seventeen (25.8 million), with slightly more children in the older groups.[22] There were slightly fewer female (approximately 35 million or 49%) than male children (approximately 37 million or 51%).[23] Children are more ethnically and racially diverse than adults,[24] with 49% of children white, non-Hispanic, 26% Hispanic, 14% Black, non-Hispanic, 6% Asian, non-Hispanic, and 6% non-Hispanic "[a]ll other races" in 2022.[25] In addition, children are more likely to live in poverty than those over age eighteen.[26] More than one in seven (or 15.3% of) children lived in poverty in 2021, with younger children and children of color being more likely to live in poverty than older children and white, non-Hispanic children.[27]

### *B. "Children Are Not Just Small Adults"*[28]

Children are a vulnerable population.[29] Children are still developing

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children/tables/pop1.asp [https://perma.cc/QSX9-6K4X].

22. *See id.*

23. *See* Annie E. Casey Found., *Child Population by Gender in United States*, KIDS COUNT DATA CTR. (July 2023), https://datacenter.aecf.org/data/tables/102-child-population-by-gender#detailed/1/any/false/1095,2048/14,15,65/421,422 [https://perma.cc/MN5E-REB6].

24. Kenneth Johnson, *New Census Reflects Growing U.S. Population Diversity, with Children in the Forefront*, UNIV. OF N.H. CARSEY SCH. OF PUB. POL'Y (Oct. 6, 2021), https://carsey.unh.edu/publication/new-census-reflects-growing-US-population-diversity [https://perma.cc/J95C-CEYT].

25. *Demographic Background*, CHILDSTATS, https://www.childstats.gov/americaschildren/demo.asp [https://perma.cc/7TLR-QSC9].

26. *Child Poverty in America 2019: National Analysis*, CHILD.'S DEF. FUND, https://www.childrensdefense.org/wp-content/uploads/2020/12/Child-Poverty-in-America-2019-National-Factsheet.pdf [https://perma.cc/F8NF-MBS5].

27. *Child Poverty and Income Distribution*, CHILDSTATS, https://www.childstats.gov/americaschildren/eco1.asp [https://perma.cc/9NM6-8PSV]. The monthly poverty estimate for children in August 2023 was 18.3%. *Monthly Poverty Data*, COLUM. UNIV. CTR. ON POVERTY & SOC. POL'Y, https://www.povertycenter.columbia.edu/forecasting-monthly-poverty-data [https://perma.cc/2LTN-G5RF].

28. Jonathan Gillis & Patricia Loughlan, *Not Just Small Adults: The Metaphors of Paediatrics*, 92 ARCHIVES OF DISEASE IN CHILDHOOD 946, 946 (2007) (arguing that despite the differences between children and adults there is a need for "firm recognition of the commonalities of adults and children").

29. *See* 45 C.F.R. § 46.107(a) (2023) (identifying children as "a category of subjects that is vulnerable to coercion or undue influence"). The regulations, which set forth the Department of Health and Human Services' (HHS's) basic policy for the protection of

and differ from adults in important ways relevant to food and drug law.[30] For example, "[c]hildren are at greater risk from environmental hazards than adults because they have different and unique exposures, . . . different responses to risks that are exacerbated by longer life expectancy[, and] . . . critical windows of vulnerability that have no parallels in adult physiology."[31] Pediatric patients "are not just small adults."[32] Diseases may have different clinicopathological features in children compared to adults, and some adult-onset conditions (e.g., type 2 diabetes and hypertension) may be rooted in childhood lifestyles.[33] Children may react differently to medicines than adults, and medicines may alter children's future outcomes.[34]

Congress and FDA have required and sought to incentivize pediatric research.[35] Children are cognitively different from adults.[36] "They lack the

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human research subjects and are limited in their application to research with certain links to the federal government, define children as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 C.F.R. § 46.402(a); 21 C.F.R. § 50.3(o) (2023); *see also* 45 C.F.R. pt. 46; *Additional Protections for Children*, U.S. FOOD & DRUG ADMIN. (Sept. 21, 2015), https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/additional-protections-children [https://perma.cc/ZDZ3-QUW8] (noting that "FDA has historically relied on the HHS regulations to provide appropriate guidance for pediatric studies"). Some subpopulations of children have other vulnerabilities, for example, "[c]hildren who are wards of the State or any other agency, institution, or entity." *See* 21 C.F.R. §§ 50.50–50.56 (2023).

30. Vic Larcher, *Children Are Not Small Adults: Significance of Biological and Cognitive Development in Medical Practice*, *in* HANDBOOK OF THE PHILOSOPHY OF MEDICINE 371, 375 (Thomas Schramme & Steven Edwards eds., 2017).

31. *Id.*

32. Gillis & Loughlan, *supra* note 28, at 946; Larcher, *supra* note 30, at 377–78.

33. Larcher, *supra* note 30, at 378.

34. *Id.*

35. *See* Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936 (requiring pediatric assessments); Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002); Daniel K. Benjamin, Jr., Philip Brian Smith, M. Dianne Murphy, Rosemary Roberts, Lisa Mathis, Debbie Avant, et al., *Peer-Reviewed Publication of Clinical Trials Completed for Pediatric Exclusivity*, 296 JAMA 1266 (2006); Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993, 1039; 59 Fed. Reg. 64,240 (Dec. 13, 1994); 63 Fed. Reg. 66,632 (Dec. 2, 1998) (declared unlawful by Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204 (D.D.C. 2002)); PEDIATRIC DRUG DEVELOPMENT: REGULATORY CONSIDERATIONS, *supra* note 20, at 19 n.90.

36. Larcher, *supra* note 30, at 379.

autonomy and [decisionmaking] capacity to ethically and legally consent to participate in research and to understand and assume" research risks.[37] There are also "inequalities of power between" children and adults.[38] Accordingly, Congress, the Department of Health and Human Services (HHS), and FDA have taken measures to protect children as human subjects.[39] But children are also vulnerable because historically, children's health issues have been understudied, and there would be no appropriately evaluated therapeutic products for them without pediatric research.[40] "Clinical investigations involving children are essential for obtaining data

37. *See* PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, VULNERABLE POPULATIONS IN SAFEGUARDING CHILDREN: PEDIATRIC MEDICAL COUNTERMEASURE RESEARCH 2 (2016) [hereinafter VULNERABLE POPULATIONS], https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/6%20Vulnerable%20Populations%20Safeguarding%20Children%209.30.16.pdf [https://perma.cc/R3XC-SQJE]; PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, SAFEGUARDING CHILDREN: PEDIATRIC MEDICAL COUNTERMEASURE RESEARCH (2013) [hereinafter SAFEGUARDING CHILDREN], https://www.medicalcountermeasures.gov/BARDA/Documents/PCSBI_Pediatric-MCM508.pdf [https://perma.cc/XF8T-HV8F].

38. *See* VULNERABLE POPULATIONS, *supra* note 37; SAFEGUARDING CHILDREN, *supra* note 37.

39. *See* 21 C.F.R. pt. 50, subpt. D (2023); 45 C.F.R. pt. 46, subpt. D (2009); *see also* Children's Health Act of 2000, H.R. 4365, 106th Cong. (enacted); 46 Fed. Reg. 8,975 (Jan. 27, 1981).

40. VULNERABLE POPULATIONS, *supra* note 37; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: E11 CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS IN THE PEDIATRIC POPULATION 1–2 (2000) [hereinafter E11 CLINICAL INVESTIGATION], https://www.fda.gov/media/71355/download [https://perma.cc/D3JN-EEVW] (stating that "[p]ediatric patients should be given medicines that have been appropriately evaluated for their use in those populations" in the context of guidance "encourag[ing] . . . timely pediatric medicinal product development"); Ryan Brewster, Melissa Wong, Christopher J. Magnani, Hailey Gunningham, Madison Hoffer, Samuel Showalter, et al., *Early Discontinuation, Results Reporting, and Publication of Pediatric Clinical Trials*, PEDIATRICS, Apr. 2022, at 1, 2, https://publications.aap.org/pediatrics/article/149/4/e2021052557/185586/Early-Discontinuation-Results-Reporting-and?autologincheck=redirected; *see also* Press Release, U.S. Food & Drug Admin., New FDA Draft Guidance Aims to Protect Children Who Participate in Clinical Trials (Sept. 23, 2022), https://www.fda.gov/news-events/press-announcements/new-fda-draft-guidance-aims-protect-children-who-participate-clinical-trials [https://perma.cc/T7G2-RG9Y]; Press Release, Nat'l Insts. of Health, NIH Policy and Guidelines on the Inclusion of Children As Participants in Research Involving Human Subjects (Mar. 6, 1998), https://grants.nih.gov/grants/guide/notice-files/not98-024.html [https://perma.cc/L7QA-4AQ9] (discussing the need for pediatric research and setting forth NIH's policy with respect to the same).

on the safety and effectiveness of medical products in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective."[41] Children also may be vulnerable due to factors or characteristics beyond their age, such as gender, sex, race, socioeconomic status, and other factors.[42]

### *C. Using the Woman Question to Ask About Children*

This Article uses "the child question" to examine how food and drug law impacts children.[43] Asking the child question is rooted in feminist legal methods, specifically, "asking 'the woman question.'"[44] The exact phrasing of the woman question varies,[45] but at its heart, it highlights the gendered impacts of aspects of the law that may "otherwise appear to be neutral or objective."[46] For example, Katharine T. Bartlett has framed the woman

41. 87 Fed. Reg. 58,357 (Sept. 26, 2022).

42. *See, e.g.*, ORG. FOR ECON. COOP. & DEV., CHANGING THE ODDS FOR VULNERABLE CHILDREN: BUILDING OPPORTUNITIES AND RESILIENCE 15–21 (2019) (discussing "[f]actors contributing to child vulnerability").

43. Woodhouse, *supra* note 9, at 1838; *see also* Katherine Hunt Federle, *On the Road to Reconceiving Rights for Children: A Postfeminist Analysis of the Capacity Principle*, 42 DEPAUL L. REV. 983, 985 (1993); Jonathan Todres, *Women's Rights and Children's Rights: A Partnership with Benefits for Both*, 10 CARDOZO WOMEN'S L.J. 603 (2004); Benjamin Shmueli, *What Has Feminism Got to Do with Children's Rights? A Case Study of a Ban on Corporal Punishment*, 22 WIS. WOMEN'S L.J. 177, 220 (2007) ("These methods, though not directly correlated to methods in the children's rights movements, can be transferred by analogy to asking 'the child's question' and using this perspective to add a broader perspective to guide judicial decisions and legislation.").

44. Woodhouse, *supra* note 9, at 1838 n.401, 1840.

45. *See, e.g.*, Heather Ruth Wishik, *To Question Everything: The Inquiries of Feminist Jurisprudence*, 1 BERKELEY WOMEN'S L.J. 64, 72–76 (1985); Lydia A. Clougherty, *Feminist Legal Methods and the First Amendment Defense to Sexual Harassment Liability*, 75 NEB. L. REV. 1, 8 (1996).

46. Bartlett, *supra* note 14, at 837. Sex and gender "are often (incorrectly) used interchangeably, including in scientific literature, policy, and popular culture." NAT'L INSTS. OF HEALTH, OFF. OF RSCH. ON WOMEN'S HEALTH, INTRODUCTION TO SEX AND GENDER: CORE CONCEPTS FOR STUDYING SEX AND GENDER IN HEALTH RESEARCH 9 (Nov. 2022), https://orwh.od.nih.gov/system/files?file=docs/Introduction_to_Sex_Gender_2022update_508c.pdf (login required). Sex and gender have also been used interchangeably in the law. Mary Anne C. Case, *Disaggregating Gender from Sex and Sexual Orientation: The Effeminate Man in the Law and Feminist Jurisprudence*, 105 YALE L.J. 1, 10 (1995). However, "scholars in women's studies" commonly distinguish "between the concepts of sex and gender" with "'sex' refer[ring] to the anatomical and physiological distinctions between men and women [and]

question as: "[H]ave women been left out of consideration? If so, in what way[?] [H]ow might that omission be corrected? [And w]hat difference would it make to do so?"[47] Scholars and commentators have used the question to examine rules and practices in various legal areas,[48] including health-related ones.[49]

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'gender,' . . . refer[ring] to the cultural overlay on those anatomical and physiological distinctions." *Id.* While FDA has noted the distinct meanings of "sex" and "gender," in practice, the line between these terms has been blurred. For example, FDA in guidance concerning the diversity of clinical trial population uses the term "women" to refer to "biological construct," i.e., "sex," "the classification of living things, generally as male or female according to their reproductive organs and functions assigned by chromosomal complement." FOOD & DRUG ADMIN., ENHANCING THE DIVERSITY OF CLINICAL TRIAL POPULATIONS—ELIGIBILITY CRITERIA, ENROLLMENT PRACTICES, AND TRIAL DESIGNS: GUIDANCE FOR INDUSTRY 6 nn.14–15 (2020) [hereinafter ENHANCING THE DIVERSITY OF CLINICAL TRIAL POPULATIONS]. FDA noted, however, that "the majority of clinical trial participants enroll by self-identified gender," which is a "social construct." *Id.* Nevertheless, FDA assumed for the purposes of the guidance that "sex and gender are concordant" as "for many participants, gender and sex are concordant." *Id.* It recognized, however, that for some participants, it may not be. *Id.*; *see also* FDA OFF. OF WOMEN'S HEALTH, WOMEN'S HEALTH RESEARCH ROADMAP: A STRATEGY FOR SCIENCE AND INNOVATION TO IMPROVE THE HEALTH OF WOMEN 20 (2015), https://www.fda.gov/media/97501/download?attachment (noting under the "Definition of Woman" that "[FDA's Office of Women's Health] intends to include transgender-related research as it relates to FDA regulatory products"). Accordingly, when FDA discusses the "sex" of clinical trial participants, the participants themselves may be reporting gender, which may not be concordant with sex. ENHANCING THE DIVERSITY OF CLINICAL TRIAL POPULATIONS, *supra* note 46.

47. Bartlett, *supra* note 14, at 837.

48. *See id.* at 838; Clougherty, *supra* note 45, at 3 n.7 (citing works "applying the woman question" to various areas of the law).

49. *See, e.g.*, Achalie Kumarage, *Genderizing Life, Choice and Rights: Asking the Woman Question in the Abortion Debate*, 26 VA. J. SOC. POL'Y & L. 137, 138 (2019); Breanne Sergent, Commentary, *To Include or to Exclude? The Policy Question Plaguing Women's Role in Clinical Trials*, 34 J. LEGAL MED. 235 (2013); Claire A. Smearman, *Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 501 (2006); Dolly M. Trompeter, *Sex, Drugs, and the* Restatement (Third) of Torts*, Section 6(c): Why Comment E Is the Answer to the Woman Question*, 48 AM. U. L. REV. 1139, 1145 (1999); John A. Robertson, *Asking the "Woman Question" About Health Care Reform*, 3 TEX. J. WOMEN & L. 1, 1–2 (1994); Mary Anne Bobinski, *Women and HIV: A Gender-Based Analysis of a Disease and Its Legal Regulation*, 3 TEX. J. WOMEN & L. 7, 56 (1994); *see also* Seema Mohapatra & Lindsay F. Wiley, *Feminist Perspectives in Health Law*, 47 J.L. MED. & ETHICS 103, 104 (2019); Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 284 (2018) [hereinafter Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*].

As framed by Barbara Bennett Woodhouse, the child question, like the woman question in which it is rooted,[50] is several questions.[51] Woodhouse reworks the woman question to ask: "How have children's experiences and values been left out of the law? . . . . [And i]n an ideal world, what would the life situation of children look like and how could law play a role in bringing this ideal world about?"[52]

As a feminist legal method, "asking the woman question" draws attention to the laws, policies, and practices that stand in the way of women and "members of other excluded groups" flourishing.[53] By asking about the effect of the law on women and members of other excluded groups, the woman question seeks to examine "other bases of exclusion" and "overlapping forms of oppression."[54] It seeks to account for the fact that, among other things, race, ethnicity, sexual orientation, and class intersect with gender and shape women's experiences.[55]

Asking the child question is consistent with—and inextricably intertwined with—asking the woman question.[56] This Article asks the child question to examine how food and drug law impacts children as a vulnerable and excluded group.[57] For clarity, this Article refers to this as

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50. Bartlett, *supra* note 14, at 837.

51. Woodhouse, *supra* note 9, at 1838 n.401. Whether a child is a result of biology or is a cultural construct has been subject to significant debate. DIANA GITTINS, THE CHILD IN QUESTION 22 (Jo Campling ed., 1998). Children have biological differences from adults. *See supra* Part I.B. But the age at which children become adults varies in different societies. *See, e.g.*, Sultana Norozi & Torill Moen, *Childhood as a Social Construction*, 6 J. EDUC. & SOC. RSCH. 75 (2016).

52. Woodhouse, *supra* note 9, at 1838 n.401 (Woodhouse also asks "[h]ow does the mismatch between children's experiences and law's assumptions and imposed structures serve the interests of those who hold power over children?"); *see also* Barbara Bennett Woodhouse, *A World Fit for Children Is a World Fit for Everyone: Ecogenerism, Feminism, and Vulnerability*, 46 HOUS. L. REV. 817, 821 (2009) [hereinafter Woodhouse, *A World Fit for Children*].

53. *See* Bartlett, *supra* note 14, at 831, 836.

54. *Id.* at 848.

55. *See, e.g.*, Kimberlé Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, U. CHI. LEGAL F. 139, 140 (1989) ("Because the intersectional experience is greater than the sum of racism and sexism, any analysis that does not take intersectionality into account cannot sufficiently address the particular manner in which Black women are subordinated."); Angela P. Harris, *Race and Essentialism in Feminist Legal Theory*, 42 STAN. L. REV. 581, 586 (1990) (arguing for "[t]he need for multiple consciousness in feminist movement").

56. Woodhouse, *supra* note 9, at 1838.

57. *See, e.g.*, VULNERABLE POPULATIONS, *supra* note 37, at 2 ("Children are a vulnerable

asking the child question, although, asking about vulnerable groups *is* asking the woman question. Ultimately, asking the woman question should not solely be viewed as a means of promoting women's flourishing but also as a tool for expanding human flourishing more broadly,[58] including for children. As Woodhouse has written, "building a world in which children flourish is integral to the project of building a world in which women flourish, and vice versa."[59] Accordingly, improving food and drug law for children may improve it for women and other adults.[60]

On its face, the woman question does not ask about girls, i.e., children. The focus on women, i.e., adults, excludes them. Nevertheless, to comprehensively analyze gender, one must account for how gender and age intersect and shape girls' and women's experiences.[61] "Full equality"[62] of

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population because they lack the autonomy and decision making capacity to ethically and legally consent to participate in research and to understand and assume the risks of research, and because of inequalities of power between adults and children"); *see also* Joaquín González Ibánez, *Legal Pedagogy, The Rule of Law, and Human Rights: The Professor, The Magistrate's Robe, and Miguel de Unamuno*, 7 INTERDISC. J. HUM. RTS. L. 147 (2012); Barbara Bennett Woodhouse, *The Courage of Innocence: Children as Heroes in the Struggle for Justice*, 2009 U. ILL. L. REV. 1567 (2009); Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCIENCES 4, 15 (2017) (noting that clinical trials often exclude children); Federle, *supra* note 43, at 1025; Tom D. Campbell, *The Rights of the Minor: As Person, As Child, As Juvenile, As Future Adult*, 6 INT'L J.L., POL'Y & FAM. 1, 4 (1992). Individual children may also be members of other excluded groups because, for example, of their gender, sex, race, ethnicity, and socio-economic status. *See supra* Part I.A.2. As noted earlier, there are slightly fewer female children than male, and as a group, children are more ethnically and racially diverse than adults and more likely to live in poverty. *See* Annie E. Casey Foundation, *supra* note 23; Johnson, *supra* note 24.

58. *See, e.g.*, Bartlett, *supra* note 14, at 888; Stephanie L. Phillips, *Claiming Our Foremothers: The Legend of Sally Hemings and the Tasks of Black Feminist Theory*, 8 HASTINGS WOMEN'S L.J. 401, 463 (1997); Woodhouse, *A World Fit for Children*, *supra* note 52, at 819; Martha Chamallas, Introduction to Feminist Legal Theory 9–21 (1999) (discussing feminism and human flourishing).

59. Woodhouse, *A World Fit for Children*, *supra* note 52, at 819.

60. *See* Gillis & Loughlan, *supra* note 28, at 946–47 (discussing the "essential commonality of children and adults" in the medical context and stating that: "[p]rogress in medicine more often than not can be applied to and be of benefit to all"); *see also* Woodhouse, *A World Fit for Children*, *supra* note 52, at 819 ("Caregivers of vulnerable persons are vulnerable because of their role as caregivers.").

61. *See* Deborah L. Rhode, *Feminist Critical Theories*, 42 STAN. L. REV. 617, 619 (1990); Todres, *supra* note 43, at 608 (noting that "[w]omen's rights apply equally to girls"); J.C. Westman, *Juvenile Ageism: Unrecognized Prejudice and Discrimination Against the Young*, 21 CHILD PSYCHIATRY HUM. DEV. 237 (1991); Toni Calasanti, Kathleen F. Slevin & Neal King,

women cannot be achieved without considering girls' experiences.

Women's and children's fortunes are often closely intertwined. Almost half of all children are female, and children become adults, including women.[63] Girls' use of and exposure to FDA-regulated products may impact their health as adults. For example, exposure to lead through FDA-regulated products can lead to long-term adverse health effects.[64] In addition, food and drug law's limitations for children may negatively impact women who disproportionately do the work of caring for them.[65]

Asking the child question is not without limitations.[66] Using "children" as a category, like using "women," is too general and risks essentialism.[67]

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*Ageism and Feminism: From "Et Cetera" to Center*, 18 NWSA J. 13, 13 (2006); Nicole Buonocore Porter, *Sex Plus Age Discrimination: Protecting Older Women Workers*, 81 DENV. U.L. REV. 79 (2003); Linda S. Whitton, *Ageism: Paternalism and Prejudice*, 46 DEPAUL L. REV. 453 (1997).

62. Rhode, *supra* note 61.

63. *See* Annie E. Casey Foundation, *supra* note 23.

64. *See infra* Parts b & III.

65. *See generally* SARAH JANE GLYNN, CTR. FOR AM. PROGRESS, AN UNEQUAL DIVISION OF LABOR: HOW EQUITABLE WORKPLACE POLICIES WOULD BENEFIT WORKING MOTHERS 1 (2018), https://www.americanprogress.org/wp-content/uploads/sites/2/2018/05/Parent-Time-Use.pdf [https://perma.cc/6WFY-ME6E] (discussing the hardships of working women "due to a lack of national public policies to support" working families); Beth Jarosz & Paola Scommegna, *U.S. Women, Work, and the COVID Pandemic: Myths and Realities*, POPULATION REFERENCE BUREAU (Nov. 5, 2021), https://www.prb.org/articles/blog-u-s-women-work-and-the-covid-pandemic-myths-and-realities/ [https://perma.cc/A3DQ-HTAR] (analyzing how women took on a disproportionate share of the childcare when faced with the childcare gap created during the COVID-19 pandemic); Gena Zanarri & María J. Prados, *Gender Differences in Couples' Division of Childcare, Work and Mental Health During COVID-19*, 19 REV. ECON. HOUSEHOLD 11 (2021) (stating that women faced a heavier burden of childcare during the COVID-19 pandemic); *see also* Neena Modi, Diogo Ayres-de-Campos, Eduardo Bancalari, Manon Benders, Despina Briana & Gian Carlo Di Renzo, *Equity in Coronavirus Disease 2019 Vaccine Development and Deployment*, 224 AM. J. OBSTETRICS & GYNECOLOGY 423, 424 (2021) ("[Women] are more likely to contract the [COVID-19] infection from children, a group that will not receive the vaccine until much further down the line, because women still carry the major share of childcare responsibilities."); Laura Ungar, *The Gender Vaccine Gap: More Women Than Men Are Getting Covid Shots,* KFF HEALTH NEWS (Apr. 12, 2021), https://kffhealthnews.org/news/article/gender-vaccine-gap-more-women-than-men-vaccinated-against-covid/ [https://perma.cc/CVV7-Y2HX].

66. *See* Bartlett, *supra* note 14, at 847–48 (discussing limitations of asking the woman question).

67. *Id.*; Harris, *supra* note 55. Asking how food and drug law impacts "women" suggests a binary world of women and men, female or male, feminine or masculine, for example, and does not account for sex and gender's complexities. *See, e.g.*, Sara R. Benson, *Hacking the*

Asking how food and drug law impacts children fails to account for differences between neonates and adolescents, for example.

Many intersecting factors shape food and drug law's impact on children.[68] Accordingly, when this Article discusses children, it tries to indicate to which children it refers, though even referring to specific categories may still be too general.[69] At the same time, focusing on the impact of food and drug law on children is also too specific, as the products regulated by FDA may pose dangers and risks or offer benefits to all who use and consume them, not just children.[70] Nevertheless, this Article asks the child question about food and drug law to advance this area for children and everyone who was once a child.

## II. FDA REGULATION & ITS IMPACT ON CHILDREN

This Part provides examples of how tragedies and other issues impacting children have shaped food and drug law's development. It then asks the child question about food and drug law to show that this area has fallen short in protecting and promoting children's health.[71]

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*Gender Binary Myth: Recognizing Fundamental Rights for the Intersexed*, 12 CARDOZO J.L. & GENDER 31 (2005) (discussing legal issues faced by children born intersexed and forced into a gender binary); Katie Reineck, Note, *Running from the Gender Police: Reconceptualizing Gender to Ensure Protection for Non-Binary People*, 24 MICH. J. GENDER & L. 265 (2017) (stating that current antidiscrimination laws do not recognize and protect non-binary plaintiffs); Meredith Rolfs Severtson, Note, *Let's Talk About Gender: Nonbinary Title VII Plaintiffs Post-Bostock*, 74 VANDERBILT L. REV. 1507, 1509–14 (2021) (analyzing the distinction between gender and sex).

68. *See* Crenshaw, *supra* note 55, at 141–50 (examining the intersection of race and gender).

69. *See* Bartlett, *supra* note 14, at 848 (stating "[a]ny category, no matter how narrowly defined, makes assumptions about the remaining characteristics of the group that fail to take account of members of the group who do not have those characteristics.").

70. *C.f.* Martha Minow, *Introduction: Finding Our Paradoxes, Affirming Our Beyond*, 24 HARV. C.R.-C.L. L. REV. 1 (1989) (noting the existence of "large social and economic patterns that cannot be addressed by focusing solely on women" and stating that "the category 'women' is both too general and too specific to permit analysis and renovation of institutions and practices that oppress or harm people who are females").

71. *See* Bartlett, *supra* note 14; Woodhouse, *supra* note 9, at 1838. FDA also regulates radiation-emitting products (e.g., laser toys, laser light shows, microwave ovens, television receivers, baggage x-rays, and suntan beds) under the Radiation Control provisions of the FDCA. *See* Federal Food, Drug, & Cosmetic Act §§ 531–542, 21 U.S.C. §§ 360hh–360ss; 21 C.F.R. subch. J (Radiological Health); *Examples of Radiation-Emitting Electronic Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/77753/download [https://perma.cc/UT9F-JMNS]. Radiation emitting electronic products may impact

FDA's power to regulate drugs, biologics, devices, food, cosmetics, and tobacco products primarily derives from the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA), as amended.[72] FDA's authority varies significantly by product category. While drugs and biologics require premarket approval/licensure, only some devices and tobacco products and one subcategory of food (food additives) do, and approval is not required for cosmetics.[73]

### *A. Children & the Development of Food & Drug Law*

Historically, tragedies involving children and FDA-regulated products have shaped the development of food and drug law.[74] For example, Congress passed the 1902 Biologics Control Act after nearly two dozen

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children's health. For example, in 2015, FDA proposed restricting the use of sunlamp products and UV lamps (products which are categorized as both medical devices and electronic products) by those under the age of eighteen due to these products' hazards. *See* 80 Fed. Reg. 79,493, 79,503 (Dec. 22, 2015) (proposing that "[a] tanning facility operator must not permit the use of a sunlamp product unless the prospective user is at least 18 years of age . . . ."); *see also* 80 Fed. Reg. 79,505 (Dec. 22, 2015) (discussing proposed amendments to performance standards for sunlamp products); *Sunlamps and Sunlamp Products (Tanning Beds/Booths)*, U.S. FOOD & DRUG ADMIN. (Sept. 28, 2020), https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/sunlamps-and-sunlamp-products-tanning-bedsbooths [http://perma.cc/ZG9Q-MDT9] (noting that "because people under age 18 are especially at risk, the FDA has proposed to restrict tanning facility operators from allowing use of the device by consumers under 18 years old"). FDA had not finalized this restriction when this Article was written, almost eight years after FDA proposed the restriction. *See* 21 C.F.R. § 878.4635; 80 Fed. Reg. 79,493, 79,494, 79,503 (Dec. 22, 2015) (proposed 21 C.F.R. § 878.4635). As another example, FDA has noted that children can be injured by toys with lasers and that lasers for other purposes "can be dangerous," a fact that "may not be evident, particularly to the children who inappropriately use them as toys . . . ." *Laser Toys: How to Keep Kids Safe*, U.S. FOOD & DRUG ADMIN. (May 3, 2021), https://www.fda.gov/consumers/consumer-updates/laser-toys-how-keep-kids-safe [https://perma.cc/LG8D-6PXB].

72. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682 (1944).

73. 21 U.S.C. ch. 9; 42 U.S.C. ch. 6A. However, color additives do require premarket approval and listing. 21 U.S.C. 379e; *see also infra* note 357.

74. For a discussion of the passage of the Food Quality Protection Act of 1996 and the role of the government in adopting standards to protect children, see James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENV'T L.J. 273, 275 (1998) (discussing the children's vulnerabilities and the Food Quality Protection Act of 1996).

children died of tetanus after receiving a contaminated antitoxin or vaccine.[75] Public outrage following "the death of nearly [100] children" who had taken "an antibiotic sulfanilamide . . . containing a highly toxic diethylene glycol," helped prompt the enactment of the 1938 FDCA.[76] Moreover, the 1962 Drug Amendments were passed "partly in response to the reported teratogenic effects of Thalidomide,"[77] a drug that caused severe congenital abnormalities in children whose mothers took it during pregnancy.[78] FDA did not allow thalidomide's pending new drug application to become effective in the United States.[79] However, it was marketed elsewhere, and "approximately 10,000 children were born with phocomelia,"[80] which "causes the upper or lower limbs of [a] child to be underdeveloped or missing."[81]

More recently, when Congress enacted the Tobacco Control Act in 2009, it found that "[r]educing the use of tobacco by minors by [50%] would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature

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75. Linda Bren, *The Road to the Biotech Revolution - Highlights of 100 Years of Biologics Regulation*, FDA CONSUMER MAG., Jan.–Feb. 2006, https://www.fda.gov/files/about%20fda/published/The-Road-to-the-Biotech-Revolution--Highlights-of-100-Years-of-Biologics-Regulation.pdf [https://perma.cc/W9FT-E86P] (stating that "[a]fter 13 children died of tetanus because of contaminated antitoxin" used to treat diphtheria patients and "[n]ine children died from tetanus after receiving contaminated smallpox vaccine," Congress passed the 1902 Biologics Control Act).

76. Elaine M. Cochran, *The Unguarded Gate: The Jurisdictional Gap Within FDA "Device" Regulation*, 5 J.L. & FAM. STUD. 189, 190 (2003).

77. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1764 (1996).

78. *See* James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and Effective Treatment of Disease*, 122 TOXICOLOGICAL SCI. 1 (2011).

79. PETER BARTON HUTT, RICHARD A. MERRILL, LEWIS A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, FOOD AND DRUG LAW 833 (5th ed. 2022); *see also* U.S. Food & Drug Admin., *Frances Oldham Kelsey: Medical Reviewer Famous for Averting a Public Health Tragedy* (Feb. 1, 2018), https://www.fda.gov/about-fda/fda-history-exhibits/frances-oldham-kelsey-medical-reviewer-famous-averting-public-health-tragedy [https://perma.cc/BQ8A-4ULP] (discussing FDA Medical Officer Dr. Kelsey's refusal to approve thalidomide in the United States, for which she received the President's Award for Distinguished Federal Civilian Service, the highest recognition for a U.S. civil servant).

80. Kim & Scialli, *supra* note 78.

81. WebMD Editorial Contributors, *What is Phocomelia?*, WEBMD (May 20, 2023), https://www.webmd.com/children/what-is-phocomelia [https://perma.cc/Z5N4-PB2A].

death due to tobacco-induced disease."[82]

In addition, outbreaks of foodborne illnesses, including a 2008–2009 multistate salmonella outbreak linked to peanuts, led Congress to enact the Food Safety Modernization Act (FMSA) in 2011.[83] Foodborne illnesses may disproportionately impact children.[84] For example, CDC indicated that the median age of the 714 people reported to be infected in the salmonella outbreak was sixteen, "mean[ing] that half of [the] ill persons [were] younger than 16."[85] Accounts of child victims of foodborne illnesses were used to garner support for the FSMA.[86] The testimony drew on images of "very young" victims of foodborne illness, "[t]he archetype of a nurturing mother preparing food for her children," and "promising li[ves] felled before [their] time."[87]

More recently, concerns about cosmetic safety for children may have helped advance cosmetic reform and enactment of the Modernization of

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82. Family Smoking Prevention & Tobacco Control & Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1777 (2009).

83. *Multistate Outbreak of* Salmonella *Typhimurium Infections Linked to Peanut Butter, 2008–2009 (Final Update)*, CTRS. FOR DISEASE CONTROL & PREVENTION [hereinafter Salmonella *Outbreak*], https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html [https://perma.cc/NS7R-XTV9] (noting that "[m]ore than 2833 peanut-containing products produced by a variety of companies may have been made with ingredients recalled by PCA"); FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); Sandra Eskin, PEW, *Families Affected by Contaminated Peanut Butter Pivotal to Enactement and Implementation of Food Safety Law* (Sept. 1, 2015), https://www.pewtrusts.org/en/research-and-analysis/articles/2015/09/01/families-affected-by-contaminated-peanut-butter-pivotal-to-enactment-and-implementation.

84. *See, e.g.*, PEW HEALTH GRP., CHILDREN AND FOODBORNE ILLNESS (Nov. 12, 2009), https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/26485.pdf [https://perma.cc/6RWQ-3S29] (stating that "[c]hildren are disproportionately affected by foodborne illness"); CONG. RSCH. SERV., P.L. 111-353, THE FDA FOOD SAFETY MODERNIZATION ACT 2 (2011) [hereinafter THE FDA FOOD SAFETY MODERNIZATION ACT] (noting that "[i]n 2008, melamine contamination of infant formula in China sickened thousands of children and raised concerns about the safety of infant formula in the United States").

85. Salmonella *Outbreak*, *supra* note 83; *see also* THE FDA FOOD SAFETY MODERNIZATION ACT, *supra* note 84, at 2.

86. Clare Keefe Coleman, *Dangerous Tongues: Storytelling in Congressional Testimony and an Evidence-Based Solution*, 19 N.Y.U. J. LEGIS. & PUB. POL'Y 291, 310–11 (2016).

87. *See id.* at 291, 310–11; 156 CONG. REC. 16,319 (2010) (statement of Senator Harkin); Melody Finnemore, *Looking Out for the Little Guy: Consumer Law Attorneys Say Federal, State Protections Becoming Increasingly Stronger*, OR. STATE B. BULL., Apr. 2011, at 19–20.

Cosmetics Regulation Act of 2022 (MoCRA).[88] Following "reports of contamination, like the 2017 reports of asbestos contamination in certain cosmetic products sold by Claire's and Justice retailers," retailers which specifically cater to children,[89] FDA's Commissioner and Center for Food Safety and Applied Nutrition (CFSAN) Director highlighted the limits of FDA's authority,[90] noting that "[t]o significantly shift the safety paradigm of

88. *See* Modernization of Cosmetics Regulation Act of 2022, Pub. L. No. 117-328 (2022); Letter from Congressman Frank Pallone, Jr. to FDA Commissioner Scott Gottlieg (Feb. 2, 2018), https://dig.abclocal.go.com/wtvd/docs/FDA.2018.02.02.%20Letter%20re%20childrens%20cosmetics%20and%20contaminants.pdf [https://perma.cc/WG6C-F7Y2] (noting that the Congressman was writing "to urge the U.S. Food and Drug Administration (FDA) to examine the alarming issue of dangerous contamination of imported cosmetic products, in particular those marketed to children"); *see also* H.R. 4296, 116th Cong. (introduced Sept. 12, 2019) (including provisions for the protection of vulnerable populations, which is defined to include "infants" and "children"); Letter from Jan Schakowsky, Member of Cong., to Mr. Alex Gorsky, Chairman & Chief Exec. Officer, Johnson & Johnson (Dec. 10, 2019), https://schakowsky.house.gov/sites/evo-subsites/schakowsky.house.gov/files/wysiwyg_uploaded/Schakowsky%20Pressley_Ltr%20to%20Johnson%20and%20Johnson_FINAL.pdf; Congresswoman Jan Schakowsky, *Hearing On My Cosmetics Legislation*, YouTube (Dec. 4, 2019), https://schakowsky.house.gov/media/videos/hearing-my-cosmetics-legislation; Sen. Dianne Feinstein, *80-Year-Old Law Authorizing FDA To Regulate Personal Care Products Must Be Updated*, THE HILL (Sept. 21, 2022, 5:17 PM), https://thehill.com/opinion/congress-blog/3654643-80-year-old-law-authorizing-fda-to-regulate-personal-care-products-must-be-updated/; S. 2100, 117th Cong. (2021); *Murray Discusses How Key Reforms She Delivered Will Help Protect Consumers From Unsafe Cosmetics*, U.S. SENATOR PATTY MURRAY (Feb. 16, 2023) [hereinafter *Key Reforms*], https://www.murray.senate.gov/murray-discusses-how-key-reforms-she-delivered-will-help-protect-consumers-from-unsafe-cosmetics/.

89. Statement of Commissioner & CFSAN Director, *supra* note 3; *see Brands*, CLAIRE'S, https://corporate.claires.com/brands/ [https://perma.cc/Z3NZ-NDBY] ("Since 1974, Claire's has been the fun fashion destination for . . . cosmetics . . . for tweens, teens, and young girls between 3 and 18 years of age."); JUSTICE, https://www.shopjustice.com/?osp=toplogo [https://perma.cc/B37T-9NJQ] ("Tween girls clothes . . . and more"); *Girls Accessories*, JUSTICE, https://www.shopjustice.com/collections/girls-accessories?Style[]=style%3ABeauty [https://perma.cc/N8EV-4F34] (including "Beauty Products" under "Girls Accessories").

90. Statement of Commissioner & CFSAN Director, *supra* note 3 ("Because of the health risks posed by asbestos, which are well-documented by other government agencies, we want to reassure all parents and consumers that the FDA is dedicated to exploring new ways to better protect Americans from this and other public health risks and preventing consumers from being exposed to similar risks from cosmetics. These findings serve as an important reminder that under our current authority, the FDA has only limited tools to ensure the safety of cosmetics products."); *see also FDA Advises Consumers to Stop Using Certain*

cosmetics in the U.S., [they] would need to work with stakeholders, including Congress, to modernize the outdated regulatory framework [for cosmetics] that the FDA ha[d] been operating under for more than 80 years."[91] Senator Murray, who originally introduced the Modernization of Cosmetics Regulation Act of 2022 as part of the Senate version of the Food and Drug Administration Safety and Landmark Advancements Act of 2022,[92] noted concerns about the safety of children's cosmetics.[93]

However, food and drug law still falls short in protecting and advancing children's health.

### *B. Asking the Child Question About Food & Drug Law*

#### *1. Asking the Child Question About Drug, Biologic, and Device Regulation*

This Section employs the child question to show how drug, biologics, and device law has fallen short in protecting and advancing children's health.

FDA's mission is to "protect[] the public health by ensuring the safety, efficacy, and security of human . . . drugs, biological products, and medical devices" and to "advanc[e] the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products . . . to maintain and

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*Cosmetic Products*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022) [hereinafter *FDA Advises*], https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products [https://perma.cc/7MYH-YJM5]. CFSAN oversees the regulation of cosmetics. FDA, *What We Do at CFSAN* (Sept. 16, 2019) [hereinafter FDA, *CFSAN*], https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm [https://perma.cc/5YWD-73RE].

91. Statement of Commissioner & CFSAN Director, *supra* note 3; *Key Reforms*, *supra* note 88.

92. *See* Food and Drug Administration Safety and Landmark Advancements Act of 2022 S. 4348, 117th Cong. (2022). A continuing resolution was eventually enacted without the cosmetics provisions. Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, Pub. L. No. 117-180, 136 Stat. 2114 (2022).

93. *See, e.g.*, *Key Reforms*, *supra* note 88 ("We've found asbestos in children's make up kits. I mean, my goodness, we've even found asbestos in baby powder."); Rachel Grabenhofer, *U.S. Senate Bill to Strengthen Cosmetic Oversight Advances*, Cosmetics & Toiletries (June 15, 2022), https://www.cosmeticsandtoiletries.com/regulations/regional/news/22275869/us-senate-bill-to-strengthen-cosmetic-oversight-advances.

improve their health."[94] Protecting and advancing children's health is undoubtedly part of that mission.

How a product is categorized is important because what a product is determines how, if at all, FDA will regulate it.[95] While the drug, biologic, and device definitions encompass medical uses of these products, they are not limited to these uses (e.g., tanning beds (devices) used for non-medical uses).[96] The drug, device, and biologic categories include the most highly regulated FDA-regulated products. Drugs and biologics are subject to premarket approval requirements.[97] Some devices—i.e., most Class III ("high risk") devices—also require premarket approval.[98] Generally, approval requires the product's sponsor to show FDA that the product is "safe" and "effective"[99] with well-controlled clinical trial results.[100]

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94. *What We Do*, *supra* note 6.

95. *See* 21 U.S.C. § 321(g), 321(h); 42 U.S.C. § 262(i).

96. *See Tanning Products*, U.S. FOOD & DRUG ADMIN. (Apr. 26, 2019), https://www.fda.gov/radiation-emitting-products/tanning/tanning-products [https://perma.cc/H8BZ-RZQW].

97. *See* 21 U.S.C. § 355; 42 U.S.C. § 262. Or in the case of biologics, licensure. *Id.*

98. 21 U.S.C. § 360e. Other devices (most Class II ("moderate risk") devices) must be "cleared" by FDA before marketing. Federal Food, Drug, and Cosmetic Act § 513(a)(1)(**B**), 21 U.S.C. § 360c(a)(1)(**B**).

99. 21 U.S.C. § 355; 21 U.S.C. § 360e; 42 U.S.C. § 262. The Public Health Service Act (PHSA) requires that the sponsor of the biologic show that the product is "safe, pure, and potent." 42 U.S.C. § 262. FDA has interpreted the potency requirement to include effectiveness. *See* 42 U.S.C. § 262(j) (providing that the FDCA "applies to a biological product subject to regulation under [21 U.S.C. § 351], except that a product for which a license has been approved under [21 U.S.C. § 351(a)] shall not be required to have an approved application under section 505 of [the FDCA]"); U.S. DEP'T OF HEALTH & HUM. SERVS., U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGIES EVALUATION & RSCH. & CTR. FOR DRUG EVALUATION & RSCH., DEMONSTRATING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS: GUIDANCE FOR INDUSTRY (Draft Guidance) (2019), https://www.fda.gov/media/133660/download [https://perma.cc/2CFK-N3G7]. FDA has also generally considered "substantial evidence" of effectiveness necessary for licensure. U.S. DEP'T OF HEALTH & HUM. SERVS., U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGIES EVALUATION & RSCH. & CTR. FOR DRUG EVALUATION & RSCH., GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS (1998), https://www.fda.gov/media/71655/download [https://perma.cc/YC7J-3JT3]; 21 C.F.R. § 600.3(s); *see also* Removal of Review and Reclassification Procedures for Biological Products Licensed Prior to July 1, 1972, 81 Fed. Reg. 7445-01 (discussing FDA's "Methods for Ensuring the Safety and Effectiveness of Biological Products"); *Frequently Asked Questions About Therapeutic Biological Products*, U.S. FOOD & DRUG ADMIN. (July 7, 2015), https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products [https://perma.cc/

*a. Off-Label Use*

Asking the child question about the off-label use of drugs reveals the limitations of food and drug law in this space. Off-label use is the use of an approved product for an unapproved use,[101] for example, in pediatric patients.

Conducting clinical research involving children can be more challenging than research involving adults because, among other things, it involves different ethical and regulatory considerations.[102] Children are a vulnerable group, and Congress, HHS, and FDA have sought to protect them in the research context.[103] However, children are also vulnerable because if

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GU3P-NL7Q] ("[P]otency is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests, to yield a given result."); Food and Drug Administration Modernization Act, Pub. L. No. 105-115, § 123(f), 111 Stat. 2324; Terry S. Coleman, *Early Developments in the Regulation of Biologics,* 71 FOOD & DRUG L.J. 544, 598 (2016) ("[T]he legal basis for requiring proof of effectiveness as a prerequisite for licensing is arguably as unclear now as it was a century ago . . . .[t]oday, however, FDA unequivocally requires license applicants to show that their biologics are effective . . . .").

100. *See* FDCA § 515, 21 U.S.C. § 360e; 21 C.F.R. § 860.7.

101. *See Understanding Unapproved Use of Approved Drugs 'Off Label'*, U.S. Food & Drug Admin (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label [https://perma.cc/B7XR-3G78]. For cleared medical devices, off-label use also refers to a use that has not been cleared. *See* Kathy J. Jenkins, Robert H. Beekman, Michael G. Vitale & William L. Hennrikus, *Off-Label Use of Medical Devices in Children*, PEDIATRICS, Jan. 2017, at 1, 2, https://publications.aap.org/pediatrics/article/139/1/e20163439/52002/Off-Label-Use-of-Medical-Devices-in-Children; Kathy J. Jenkins, *AAP Policy Clarifies Acceptable Off-Label Use of Medical Devices in Children*, AAP NEWS (Dec. 26, 2016), https://publications.aap.org/aapnews/news/6950 [https://perma.cc/DU23-ETHQ] (noting that "studies of device use in children are less common, so use of devices 'off-label,' or in circumstances different than FDA-cleared or -labeled use, is widespread in pediatric practice").

102. *See* MARILYN J. FIELD & RICHARD E. BEHRMAN, INST. OF MED. OF THE NAT'L ACADS., ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN 58–92 (2004) ("[T]hese challenges include the relatively small numbers of children with serious medical problems, the need for developmentally appropriate outcome measures for children of different ages, the complexities of parental involvement and family decision making, and the adaptations required in research procedures and settings to accommodate children's physical, cognitive, and emotional development"); *see also* Sharon Conroy, John McIntyre, Imti Choonara & Terence Stephenson, *Drug Trials In Children: Problems and the Way Forward*, 49 BRIT. J. CLINICAL PHARMACOLOGY 93 (2000).

103. 21 C.F.R. pt. 50, subpt. D (2023); 45 C.F.R. pt. 46, subpt. D (2024); *see also* Protection of Human Objects; Standards for Institutional Review Board for Clinical Investigations, 46 Fed. Reg. 8958, 8975 (Jan. 27, 1981) (codified in scattered sections of 21

products are not studied for and with children, there will not be appropriately evaluated therapeutic products for them.[104] Congress and FDA have tried to address issues posed by these vulnerabilities.[105] The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act of 2003 (PREA) seek to foster pediatric studies.[106] Under the BPCA, FDA can issue a written request for submission of a pediatric study or studies that "may produce health benefits," but completion of the studies is *voluntary*.[107] In contrast, the PREA *requires* pediatric assessments and molecularly targeted pediatric cancer investigations for covered drug and biologics applications.[108]

Despite Congress and FDA's efforts to increase the availability of appropriately studied—and labeled—products for children,[109] "there is still a significant lack of both pediatric-specific drug information and governmental

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C.F.R.). *See generally* Children's Health Act of 2000 § 1003, Pub. L. No. 106-310, 114 Stat. 1101, 1129 (requiring the Secretary of Health and Human Services to review and consider modifying regulations protecting children participating in research).

104. VULNERABLE POPULATIONS, *supra* note 37, at 2; E11 CLINICAL INVESTIGATION, *supra* note 40, at 1–2.

105. *See, e.g.*, Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936; Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat 1408 (2002); 21 U.S.C. §§ 355a, 355c; U.S. FOOD & DRUG ADMIN., PEDIATRIC DRUG DEVELOPMENT UNDER THE PEDIATRIC RESEARCH EQUITY ACT AND THE BEST PHARMACEUTICALS FOR CHILDREN ACT: SCIENTIFIC CONSIDERATIONS: GUIDANCE FOR INDUSTRY (DRAFT GUIDANCE) (2023); E11 CLINICAL INVESTIGATION, *supra* note 40, at 1–2 (stating that "[p]ediatric patients should be given medicines that have been appropriately evaluated for their use in those populations" in the context of guidance "encourag[ing] . . . timely pediatric medicinal product development").

106. Best Pharmaceuticals for Children Act; Pediatric Research Equity Act; *see also* 21 U.S.C. §§ 355a, 355c.

107. § 355a(b)(1).

108. § 355c.

109. *See, e.g.*, Holly Fernandez Lynch, *Give Them What They Want? The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act*, 16 ANNALS HEALTH L. 79, 93–97, 100 (2007); Samuel J. Lee, Lauren Cho, Eyal Klang, James Wall, Stefano Rensi & Benjamin S. Glicksberg, *Quantification of US Food and Drug Administration Premarket Approval Statements for High-Risk Medical Devices With Pediatric Age Indications*, JAMA NETWORK OPEN, June 22, 2021, at 1, 2; Florence T. Bourgeois & Juan C. Espinoza, *Advancing Equity in Medical Device Development for Children*, 177 JAMA PEDIATRICS 561 (2023); *FDA's Efforts to Optimize Medical Device Innovation for Pediatrics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/115027/download [https://perma.cc/R32U-BN7T]; Esther W.B. Bleicher, *Encouraging Research and Development of Pediatric Medical Devices Through Legislative and Regulatory Action: The Pediatric Medical Device Safety and Improvement Act of 2007 in Context*, 64 FOOD & DRUG L.J. 531 (2009).

approvals for on-label pediatric prescribing."[110] Many drugs, biologics, and devices are used off-label in children.[111] Just because a product is used off-label does not mean that its use is "improper, illegal, contraindicated, or investigational."[112] Nevertheless, off-label use may expose children to risks and adverse outcomes; at times, the results have been tragic.[113]

As a result of the lack of pediatric approvals, drugs are often used off-label in children.[114] Many drugs and biologics lack "adequate pediatric prescribing information."[115] One review noted that the high use of off-label medications in children is a worldwide phenomenon and that "the incidence of off-label use is higher among younger populations, especially neonates."[116] Studies have also found "a high incidence of off-label

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110. Christine H. Allen, M. Connor Garbe, Julie Lees, Naila Aziz, Hala Chaaban, Jamie L. Miller, et al., *Off-Label Medication Use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J. OKLA. STATE MED. ASS'N 776, 776 (2018).

111. Kathleen A. Neville, Bridgette Jones, Jennifer Foster, Constance S. Houck, Matthew M. Laughon, J. Routt Reigart, et al.,*Off-Label Use of Drugs in Children*, 133 PEDIATRICS 563 (2014); Katelyn Yackey, Kristin Stukus, Daniel Cohen, David Kline, Sonia Zhao & Rachel Stanley, *Off-Label Medication Prescribing Patterns in Pediatrics: An Update*, 9 HOSP. PEDIATRICS 186, 187–90 (2019); Allen et al., *supra* note 110.

112. *See* Neville et al., *supra* note 111.

113. *See* Katelyn Yackey & Rachel Stanley, Commentary, *Off-Label Prescribing in Children Remains High: A Call for Prioritized Research*, PEDIATRICS, Oct. 2019, at 1, 1, https://publications.aap.org/pediatrics/article/144/4/e20191571/38452/Off-Label-Prescribing-in-Children-Remains-High-A; *Drug Research and Children*, U.S. FOOD & DRUG ADMIN. (May 4, 2016), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/drug-research-and-children [https://perma.cc/3AXZ-AHDZ].

114. Allen et al., *supra* note 110; *see also* Bourgeois & Espinoza, *supra* note 109; *Understanding Unapproved Use of Approved Drugs "Off Label,"* U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label [https://perma.cc/5PV2-Y6X2] (stating that "[u]napproved use of an approved drug is often called 'off-label' use" and that if an approved drug is used for an unapproved use, "FDA has not determined that the drug is safe and effective for the unapproved use"); Neville et al., *supra* note 111 (stating that "[t]he term 'off-label' use refers to use of a drug that is not included in the package insert (approved labeling) for that drug" and that the purpose of such "use is to benefit an individual patient" and that "the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use").

115. Mary Carmack, Thomas Hwang & Florence T. Bourgeois, *Pediatric Drug Policies Supporting Safe and Effective Use of Therapeutics in Children: A Systematic Analysis*, 39 HEALTH AFFS. 1799, 1804 (2020).

116. Allen et al., *supra* note 110; *see also* Divya Hoon, Matthew T. Taylor, Pooja Kapadia, Tobias Gerhard, Brian L. Strom & Daniel B. Horton, *Trends in Off-Label Drug Use in Ambulatory Settings: 2006–2015*, PEDIATRICS, Oct. 2019, at 1, 2, 5–6,

medication prescriptions" and use in children in the United States.[117]

The lack of labeling for children may mean that a drug is used "with limited information about . . . dosing, effectiveness, and side effects."[118] Extrapolation of dosing from adult studies may "result in under or overdosing of a medication and the associated risk of therapeutic failures or adverse events."[119] The use of drugs that "have not been appropriately studied in pediatric populations" may lead to "inappropriate doses," "unforeseen adverse events," or a lack of therapeutic benefit.[120] Medical devices are also often used off-label in children due to the lack of devices approved or cleared for pediatric indications, which may similarly lead to suboptimal performance.[121]

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https://publications.aap.org/pediatrics/article/144/4/e20190896/76978/Trends-in-Off-Label-Drug-Use-in-Ambulatory.

117. Allen et al., *supra* note 110; *see also* Hoon, *supra* note 116, at 3 (finding that U.S. office-based physicians ordered at least one "off-label systemic drug at 18.5% . . . of visits" and that "[o]ff-label ordering was most common proportionally in neonates (83%) and in absolute terms among adolescents" and that "[o]ff-label ordering was associated with female sex, subspecialists, polypharmacy, and chronic conditions"); Albert Fung, Xiaomeng Yue, Patricia R. Wigle & Jeff J. Guo, *Off-Label Medication Use in Rare Pediatric Diseases in the United States*, 10 INTRACTABLE & RARE DISEASES RSCH. 238, 240 (2021) (discussing off-label use of biologics); Neville et al., *supra* note 111; Carmack, *supra* note 115.

118. Angela S. Czaja, Pamela D. Reiter, M. Lynn Schulz & Robert J. Valuck, *Patterns of Off-Label Prescribing in the Pediatric Intensive Care Unit and Prioritizing Future Research*, 20 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 186, 192 (2015); *see also* Kazeem A. Oshikoya, Gerold T. Wharton, Debbie Avant, Sara L. Van Driest, Norman E. Fenn III, Allison Lardieri, et al., *Serious Adverse Events Associated with Off-Label Use of Azithromycin or Fentanyl in Children in Intensive Care Units: A Retrospective Chart Review*, 21 PEDIATRIC DRUGS 47 (2019); Sara K. Pasquali, Matthew Hall, Anthony D. Slonim, Kathy J. Jenkins, Bradley S. Marino, Meryl S. Cohen, et al., *Off-Label Use of Cardiovascular Medications in Children Hospitalized With Congenital and Acquired Heart Disease*, 1 CARDIOVASCULAR QUALITY AND OUTCOMES 74 (2008).

119. Czaja et al., *supra* note 118, at 192.

120. Carmack et al., *supra* note 115, at 1799.

121. *See* Jenkins et al., *supra* note 101; Lee, *supra* note 109; Juan C. Espinoza, Commentary, *The Scarcity of Approved Pediatric High-Risk Medical Devices*, JAMA NETWORK OPEN, June 22, 2021, at 1, 1 (discussing study finding a scarcity of approved pediatric high-risk medical devices); *see also* U.S. FOOD & DRUG ADMIN. & NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIS., UNMET MEDICAL DEVICE NEEDS FOR PATIENTS WITH RARE DISEASES, https://www.fda.gov/media/111309/download [https://perma.cc/8CMZ-KTZ8] (discussing the unmet medical device needs of children with rare diseases); Sujatha Vathyam, Note, *No More "Hand-Me-Downs" Please!: Children Deserve Medical Devices Specifically Designed for and Tested on Children*, 58 RUTGERS L. REV. 719, 720, 733 (2006) (discussing "the need for

*b. Pediatric Drug Shortages*

Asking the child question about drug shortages also reveals limitations of the current law and policy.[122] A "drug shortage" is a period "when the demand or projected demand for the drug within the United States exceeds the supply of the drug."[123] While "drug shortages can pose a significant public health threat" that can impact adults and children,[124] shortages of pediatric products "are especially concerning because children constitute a uniquely vulnerable and . . . underserved population."[125] The causes of

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appropriately designed and adequately tested pediatric medical devices"); Michael Barbella, *Pediatric Medical Devices: Little World Lost*, MED. PROD. OUTSOURCING MAG. (Apr. 8, 2014), https://www.mpo-mag.com/issues/2014-04-01/view_features/pediatric-medical-devices-little-world-lost/ [https://perma.cc/5AXX-CS4X]; Jamie S. Sutherell, Russel Hirsch & Robert H. Beekman, III, *Pediatric Interventional Cardiology in the United States is Dependent on the Off-label Use of Medical Devices*, 5 CONGENITAL HEART DISEASE 2 (2010); Joy H. Samuels-Reid & Judith U. Cope, *Medical Devices and Adolescents: Points to Consider*, 170 JAMA PEDIATRICS 1035 (2016) (discussing data on "pediatric medical device adverse events for US pediatric emergency department visits" and noting "that almost one-third of the total pediatric medical device adverse events involved ophthalmic devices").

122. Although this Article focuses on drug shortages, there have been other pediatric product shortages. *See, e.g.*, Claudia Boyd-Barrett, *For Medically Fragile Children, Pandemic-Induced Supply Shortages Continue*, CAL. HEALTH REP. (Oct. 20, 2020), https://www.calhealthreport.org/2020/10/20/for-medically-fragile-children-pandemic-induced-supply-shortages-continue/ [https://perma.cc/7T2N-RZKN] (noting that suppliers and parents have reported shortages of medical supply products); *CBER-Regulated Products: Resolved Shortages*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-resolved-shortages [https://perma.cc/379M-NVBY].

123. 21 U.S.C. § 356c(h)(2).

124. U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: REPORT TO CONGRESS (2022), https://www.fda.gov/media/169302/download [https://perma.cc/V8EB-LXDV]. *See generally FDA Drug Shortages*, *supra* note 4 (listing "Current and Resolved Drug Shortages and Discontinuations Reported to FDA"). *See also id.* (choose "Therapeutic Categories" from menu, then choose "Pediatric").

125. Carmel Shachar, Philip A. Gruppuso & Eli Y. Adashi, Viewpoint, *Pediatric Drug and Other Shortages in the Age of Supply Chain Disruption*, 329 JAMA 2127, 2127 (2023); Lindsay Butterfield, Jared Cash & Kathy Pham, *Drug Shortages and Implications for Pediatric Patients*, 20 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 149, 149 (2015) ("National drug shortages in the United States disproportionately and negatively impact care of pediatric patients."); *see also* Gottfried Huss, Shimon Barak, Laura Reali, Christine Magendie, Angel Carrasco-Sanz, Eli Somekh, et al., *Drug Shortages in Pediatrics in Europe: The Position of the European Pediatric Societies*, 261 J. PEDIATRICS 1 (2023) (discussing pediatric drug shortages in Europe and

pediatric drug shortages are complex, but "the decreased amount of quality pediatric data (or FDA-approved indications for pediatric use)" discussed in the prior Section may put pediatric patients "at particular risk of harm due to drug shortages."[126] Studies have documented negative impacts of drug shortages on pediatric patients, including cancer patients.[127]

While the COVID-19 pandemic has contributed to drug shortages, drug shortages and their challenges pre-date the pandemic.[128] As of July 10, 2023, FDA's Drug Shortage Database listed thirty-two pediatric drugs in shortage,[129] including a form of an antibiotic that is widely used to treat

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stating that "[c]hildren are a particularly vulnerable patient group with very limited pharmaceutical treatment options" and that "[t]his limitation exposed them to adverse outcomes caused by shortages of essential medications").

126. Butterfield et al., *supra* note 125, at 149–50 (stating that "[d]rug shortages harm patients by adversely impacting drug therapy, causing delays in medical procedures or therapy, and contributing to medication errors. Therapeutic alternatives, when available, are frequently associated with increased cost, decreased efficacy, increased side effects, and medication errors resulting from inexperience and lack of knowledge"); *see also* Shachar et al., *supra* note 125, at 2127 ("Shortages of pediatric pharmaceuticals and related products are especially concerning because children constitute a uniquely vulnerable and . . . underserved population."); *see also* Lori O'Keefe, *Update on Pediatric Drug Shortages a Mixed Picture*, AAP NEWS, Apr. 2013, at 25 (discussing reports of the negative repercussions of drug shortages on pediatric patients). FDA has included biological products, except for plasma and biologics that also meet the definition of a "device," in its drug shortage definition. *See* 21 U.S.C. § 356c(h)(1), 356c(i)(3); 80 Fed. Reg. 38,915 (July 8, 2015) (codified at 21 C.F.R. pts. 20, 310, 314, 600). Device shortages may also negatively impact children. *See, e.g.*, L. Dupree Hatch, Brian C. Bridges, Rachel L. Chapman, Melissa E. Danko, Robert E. Schumacher & Stephen W. Patrick, *Trends in Neonatal Extracorporeal Membrane Oxygenation During a Venovenous Cannula Shortage*, 24 PEDIATRIC CRITICAL CARE MED. 245, 248–49 (2023) (reporting a significant decrease in "[v]enovenous [Extracorporeal Membrane Oxygenation] ECMO for neonatal respiratory failure . . . coincident with withdrawal of one venovenous cannulas from the market"); *see also* FDCA § 506J, 21 U.S.C. § 356j; *Medical Device Supply Chain and Shortages*, U.S. FOOD & DRUG ADMIN. (May 12, 2023), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages [https://perma.cc/P927-UAE5].

127. *See, e.g.*, Butterfield et al., *supra* note 125, at 149–50; Monika L. Metzger, Amy Billett & Michael P. Link, Perspective, *The Impact of Drug Shortages on Children with Cancer—The Example of Mechlorethamine*, 367 NEW ENG. J. MED. 2461 (Dec. 27, 2012); Corrine Hanson, Melissa Thoene, Julie Wagner, Dean Collier, Kassandra Lecci & Ann Anderson-Berry, *Parenteral Nutrition Additive Shortages: The Short-Term, Long-Term and Potential Epigenetic Implications in Premature and Hospitalized Infants*, 4 NUTRIENTS 1977, 1985 (2012).

128. DRUG SHORTAGES: REPORT TO CONGRESS, *supra* note 124, at 2.

129. *FDA Drug Shortages*, *supra* note 4.

bacterial respiratory infections in children (amoxicillin oral powder for suspension), several "essential chemotherapy drugs critical to the care of children with cancer," and parenteral nutrition products.[130] One analysis found that "[o]f the 19 essential pediatric oncology drugs, 14 (74%) have experienced one or more shortages since 2016," and "[t]he average duration of the shortage is . . . over 40 months."[131]

The President, Congress, and FDA have taken steps to prevent and mitigate drug shortages. The FDA Safety and Innovation Act (FDASIA) requires drug manufacturers to report the discontinuance or interruption of the production of lifesaving drugs to FDA.[132] It also requires FDA to report

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130. *See, e.g.*, *id.* (search "amoxicillin," "cisplatin injection," "cytarabine injection," "fludarabine," and "methotrexate injection" in search bar labeled "Search by Generic Name or Active Ingredient"); *id.* (choose "Therapeutic Categories" then choose "Total Parenteral Nutrition") (listing pediatric total parenteral nutrition products); *id.* (choose "Therapeutic Categories" then choose "Pediatric"); Lauren Pommert & Sarah K. Taisan, *Chemotherapy Drug Shortages in Pediatric Oncology: A Global Public Health Crisis Threatening Our Children*, HEMATOLOGIST, June 14, 2021, at 4; U.S. FOOD & DRUG ADMIN., COMPOUNDING CERTAIN BETA-LACTAM PRODUCTS IN SHORTAGE UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: IMMEDIATELY IN EFFECT GUIDANCE FOR INDUSTRY (2022) [hereinafter BETA-LACTAM PRODUCTS], https://www.fda.gov/media/163367/download [https://perma.cc/S2N7-K986]; Jennifer Henderson, *Shortages Persist for Parenteral Nutrition*, MEDPAGE TODAY (Feb. 13, 2023), https://www.medpagetoday.com/special-reports/features/103085 [https://perma.cc/4GV4-MJKA] (discussing shortages). FDA regulates total parenteral nutrition products as drugs. *See* Edward Tabor, *Tutorial on How the US Food and Drug Administration Regulates Parenteral Nutrition Products*, 44 J. PARENTERAL & ENTERAL NUTRITION 174, 174 (2020).

131. CHILD. HOSP. ASS'N & VIZIENT, PEDIATRIC DRUG SHORTAGE TRENDS AND BEST PRACTICES FOR MITIGATION STRATEGIES (2020), https://www.childrenshospitals.org/-/media/files/migration/scs_pediatric_drug_shortages_report.pdf [https://perma.cc/A9QA-VBJ2]; *see also Research Confirms Drug Shortages Disproportionately Affect Children's Hospitals*, CHILD. HOSP. ASS'N (May 4, 2020), https://www.childrenshospitals.org/news/childrens-hospitals-today/2020/05/research-confirms-drug-shortages-disproportionately-affect-childrens-hospitals [https://perma.cc/T3R3-R2D9]; U.S. PHARMACOPEIA, VIZIENT & ANGELS FOR CHANGE, QUANTIFYING DRIVERS OF SUPPLY CHAIN RESILIENCE IN PEDIATRIC ONCOLOGY MEDICATIONS (2021), https://www.usp.org/sites/default/files/usp/document/supply-chain/pediatric-oncology-drugs-and-supply-chain.pdf [https://perma.cc/6FNZ-BCSN] ("Drug shortages can result in significant harm, including increased medication errors, delayed administration of lifesaving therapies, inferior outcomes, and patient deaths.").

132. Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, 126 Stat. 993, 1099 (2012); FDCA § 506C, 21 U.S.C. § 356c; 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, 1153 (2016); Exec. Order No. 13,588, 76 Fed. Reg. 68,295 (Nov. 3, 2011); 80 Fed. Reg. 38,915 (July 8, 2015) (codified at 21 C.F.R. §§ 20, 310, 314, 600); U.S. FOOD & DRUG ADMIN., RISK MANAGEMENT PLANS TO

annually to Congress on drug shortages and to "establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages."[133] The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) expanded the requirements for manufacturers to report permanent manufacturing discontinuances and interruptions to FDA and required them to create and implement redundancy risk management plans to mitigate the potential for drug shortages.[134] It also required drug registrants to report the amount of listed drugs and biologics they manufactured.[135]

Many efforts to prevent and mitigate drug shortages are not pediatric-specific,[136] although there have been efforts to address *specific* shortages impacting pediatric patients.[137] For example, the only specific mention of

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MITIGATE THE POTENTIAL FOR DRUG SHORTAGES: GUIDANCE FOR INDUSTRY (DRAFT GUIDANCE) 3 (2022) [hereinafter RISK MANAGEMENT PLANS], https://www.fda.gov/media/158487/download [https://perma.cc/JJL5-6XP6]; U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES: ROOT CAUSES AND POTENTIAL SOLUTIONS (2019) [hereinafter ROOT CAUSES], https://www.fda.gov/media/131130/download [https://perma.cc/PS8R-L4UK]; Butterfield et al., *supra* note 125.

133. FDASIA § 1003, FDCA § 506D(a)(1)(A); FDCA § 506C, 21 U.S.C. §§ 356c-1, 356d; 21st Century Cures Act § 3101(a)(2); Exec. Order No. 13,588, 76 Fed. Reg. at 68,295; 80 Fed. Reg. at 38,915; RISK MANAGEMENT PLANS, *supra* note 132, at 3–4; ROOT CAUSES, *supra* note 132; Butterfield et al., *supra* note 125, at 150 (noting that "FDA has established a strategic plan to prevent and mitigate drug shortages").

134. Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136, 134 Stat. 281 (2020); FDCA § 506C(a), (j); 21 U.S.C. § 356c(a), (j); *see also* FDCA § 506J, 21 U.S.C. § 356j (medical devices); *Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts*, U.S. FOOD & DRUG ADMIN. (Apr. 5, 2023), https://www.fda.gov/drugs/drug-shortages/coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts [https://perma.cc/D3BN-XAK3].

135. CARES Act § 3112(e) (amending FDCA 510(j)(3), 21 U.S.C. 360(j)(3)).

136. *See* Exec. Order No. 13,588, 76 Fed. Reg. 68,295 (Nov. 3, 2011); RISK MANAGEMENT PLANS, *supra* note 132; ROOT CAUSES, *supra* note 132; Butterfield et al., *supra* note 125, at 149–52 (noting that "issues specific to drug shortages impacting pediatric patients are not specifically addressed in [FDA's 2013 strategic plan to prevent and mitigate drug shortages]" and arguing that FDA should develop a strategy that incorporates pediatric specific considerations); CTR. FOR DRUG EVALUATION & RSCH., MAPP 4190.1 REV. 3, POLICY AND PROCEDURES, DRUG SHORTAGE MANAGEMENT 1, 20 (2018), https://www.fda.gov/media/72447/download [https://perma.cc/ALV3-ECUC] (including the Drug Shortage Staff's assessment of population-specific concerns such as pediatric strengths).

137. *See, e.g.*, BETA-LACTAM PRODUCTS, *supra* note 130. In November 2022, FDA issued a guidance on compounding certain beta-lactam products in shortage under § 503A of the Federal Food, Drug, and Cosmetic Act, noting that "[t]here is currently an acute

children that FDA made in its 2022 report to Congress was that the agency "noticed an increase in demand for certain drugs used to treat COVID-19 and other infectious diseases, especially in children."[138]

Pediatric drug shortages may present different issues than other shortages because children are a vulnerable population and "often have more limited options for medications than adults."[139] Moreover, drug shortages may impact the most vulnerable children and families more intensely.[140]

### *c. Benefit-Risk Assessment in Regulatory Decisionmaking*

Asking the child question about benefit-risk assessments in the context of FDA regulatory decisionmaking highlights the limits of the current regulatory frameworks in assessing the impacts of products on children's health. To gain approval, sponsors must demonstrate that their drug or biologic is safe and effective.[141] Safety and effectiveness have been defined and assessed in relatively narrow ways:[142] "[T]he standard for

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shortage of amoxicillin oral antibiotic powder for suspension" and the shortage "could lead to potentially serious or life-threatening situations in particular in the pediatric population." *Id.* at 1, 3.

138. DRUG SHORTAGES: REPORT TO CONGRESS, *supra* note 124, at 17. The report does, however, discuss efforts to address shortages impacting pediatric patients. *Id.* at 18 (citing BETA-LACTAM PRODUCTS, *supra* note 130); *see also* ROOT CAUSES, *supra* note 133.

139. Shachar et al., *supra* note 125; *see also* Allison Gilchrist, *Pediatric Pharmacy Group Calls for Better Drug Shortage Strategy*, PHARMACY TIMES (May 27, 2015), https://www.pharmacytimes.com/view/pediatric-pharmacy-group-calls-for-better-drug-shortage-strategy [https://perma.cc/6G3V-J93E]; *see also* Huss et al., *supra* note 125 (noting that children are a vulnerable population because of limited treatment options); Neville et al., *supra* note 111 (stating that "off-label uses of drugs should be considered when addressing various drug-related concerns, such as drug shortages").

140. *See* Chabeli Carrazana, *From Formula To Medications and Child Care, Parents Are Being Crushed Under A Wave of Shortages*, 19TH NEWS (Feb. 22, 2023, 1:00 PM), https://19thnews.org/2023/02/tylenol-adderall-formula-child-care-shortages-impact-families/ [https://perma.cc/WPS8-C29B].

141. *See* FDCA § 505(d), 21 U.S.C. § 355(d); PHSA § 351, 42 U.S.C. § 262; *see also* sources cited *supra* note 99.

142. *See supra* note 141 and accompanying text; Edward L. Korwek, *Human Biological Drug Regulation: Past, Present, and Beyond the Year 2000*, 50 FOOD & DRUG L.J. 123, 129 (1995); Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221, 223, 230 (2018); U.S. FOOD & DRUG ADMIN., BENEFIT-RISK ASSESSMENT FOR DRUG AND BIOLOGICAL PRODUCTS: GUIDANCE FOR INDUSTRY 3–6 (2023) [hereinafter BENEFIT-RISK ASSESSMENT], https://www.fda.gov/media/152544/download [https://perma.cc/55F7-T5UX].

approval in the [FDCA] . . . describes drug safety and effectiveness in terms of 'the conditions prescribed, recommended, or suggested in the proposed labeling.'"[143]

Asking the child question about opioid and COVID-19 vaccine regulation (drug and biologic regulation, respectively) helps highlight a broader set of considerations related to the benefits and risks of these products for children. First, asking about FDA's opioid regulation shows how focusing on clinical trials' relatively narrowly defined set of risks and benefits in the context of applications for regulatory authorization overlooks potential adverse effects.[144] For example, parent and caregiver opioid abuse can have negative impacts on children's health and welfare.[145] Second, asking about FDA's COVID-19 vaccine regulation shows how the risk-benefit assessment overlooks many of the ways vaccine access may have benefited school-aged children's health and welfare in the context of school closures and quarantines.[146] Together, these two examples reflect the limits of food and drug law when it comes to assessing products' benefits and risks, protecting and promoting children's health, and advancing FDA's public health mission.

This discussion is not intended to suggest that weighing the broader potential impacts of opioid or COVID-19 vaccine regulation on children *would*—or even *should*—have changed the outcome of any specific FDA regulatory decision. Those assessments are beyond the scope of this Article. In addition, this discussion is not intended to suggest that the broader matters that it considers should supplant the review of the safety and effectiveness of a product as shown through preapproval clinical trials and

143. Zettler et al., *supra* note 142, at 223 (quoting FDCA § 505(d), 21 U.S.C. § 355(d)).

144. *See id.* at 247–48.

145. *See infra* sources notes 159–62 and accompanying text. This is not to discount the important benefits prescription opioids offer for the treatment of pain. *See, e.g.*, Frederick T. O'Donnell & Kathleen R. Rosen, *Pediatric Pain Management: A Review*, 111 MO. MED. 231, 231, 234–35 (2014). Untreated pain is a serious public health problem. *See also* Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 2, 4, 6 (2017) (discussing untreated pain as a serious public health concern as well as disparities in pain treatment); Jacqueline Fox, *The Epidemic of Children's Dental Diseases: Putting Teeth into the Law*, 11 YALE J. HEALTH POL'Y, L. & ETHICS 223, 237–38 (2011) (discussing the impact of "[u]ntreated [d]ental [p]ain on [v]ulnerable [c]hildren").

146. There is some indication that FDA did consider the benefits of COVID-19 vaccines for children on possible herd immunity. *See, e.g.*, *Vaccines and Related Biological Products Advisory Committee Dec. 10, 2020 Meeting Transcript*, 387–88 (2020), U.S., FOOD & DRUG ADMIN., https://www.fda.gov/media/144859/download.

described in the products' approved labeling. Instead, this discussion seeks to demonstrate how asking the child question can help to focus attention on how existing regulatory frameworks and processes fail to consider products' potential impacts on children's health consistently and fully. Using a child-centered lens to examine regulatory decisionmaking in this context suggests additional factors that might be considered to better protect and promote children's health. Finally, while FDA plays an important role in reducing the harms associated with prescription opioids and approving pediatric vaccines, the issues raised are complex and multifaceted, and FDA cannot solve them alone.

This analysis builds on Patricia J. Zettler, Margaret Foster Riley, and Aaron S. Kesselheim's article, which argues that FDA should more "consistently" use a "'public health' basis for decision-making"[147] and "incorporate[] population health information . . . . .into its approval and withdrawal decisions in a systematic way" to better regulate drugs with a high potential for externalities.[148] They argue that this "would effectively serve [the agency's] mission."[149] In guidance, FDA has noted that

> [i]n certain circumstances, FDA's benefit-risk assessment incorporates broader public health considerations for both the intended target patient population and others. For example, in the review of drugs, including vaccines, to diagnose, prevent, or treat communicable diseases, risks related to disease transmission are important considerations. Similarly, for drugs identified as controlled substances, FDA's benefit-risk assessment incorporates considerations such as risks related to misuse or accidental exposure in the intended population and in other populations who may have access to the drug.[150]

The current analysis considers how asking the child question about FDA's benefit-risk assessments highlights how the regulatory system fails to fully account for children's health.

### *i. Opioids*

FDA is an important regulator of prescription opioids and plays a vital role in assessing and regulating their benefits and harms.[151] In 2017,

147. Zettler et al., *supra* note 142, at 224.

148. *Id.* at 224, 235; Scott Gottlieb & Janet Woodcock, *Marshaling FDA Benefit-Risk Expertise to Address the Current Opioid Abuse Epidemic,* 318 JAMA 421 (2017).

149. Zettler et al., *supra* note 142, at 224.

150. BENEFIT-RISK ASSESSMENT, *supra* note 142, at 5.

151. *See Opioid Medications,* U.S. FOOD & DRUG ADMIN. (Mar. 29, 2021), https://www.fda.gov/drugs/information-drug-class/opioid-medications [https://perma.cc/7XNP-K7FU]; Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS

Commissioner Scott Gottlieb noted that among FDA's "new actions" to address the opioid addiction epidemic was FDA's "work to ensure drug approval and removal decisions are made within a benefit-risk framework that evaluates not only the outcomes of opioids when used as prescribed, but also the public health effects of the inappropriate use of these drugs."[152] Commissioner Gottlieb and then-Center for Drug Evaluation and Research Director Janet Woodcock stated that "[g]oing forward, FDA is working to incorporate the effects of decisions on public health into its benefit-risk framework in a more quantitative manner that will supplement and enhance the strong qualitative work that the agency already performs" and that "[b]y ensuring that FDA's decision-making tools are properly matched to the reality of how opioids are used—and misused or abused—[FDA] can do more to confront the crisis."[153]

In addition, in 2019, FDA released for comment draft guidance on how it proposes to assess the broader public health effects related to opioids.[154] FDA noted that the risks considered will include those to the patient's household members, including children and teenagers.[155] Asking the child question about FDA's regulation of opioids is consistent with these efforts as it may help illuminate the risks opioids pose to children's health. A fuller consideration of these risks may improve FDA's regulatory decisionmaking.

For example, while opioids have not spared children from their direct effects,[156] the impact that these drugs have had on children extend far

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743 (2020); Bruce M. Psaty & Joseph O. Merrill, *Addressing the Opioid Epidemic—Opportunities in the Postmarketing Setting*, 376 NEW ENGL. J. MED. 1502 (2017).

152. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on National Academies of Sciences, Engineering, and Medicine Report on Pain Management and Prescription Opioid Abuse (July 13, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-national-academies-sciences-engineering-and-medicine [https://perma.cc/V9DD-64VH].

153. Gottlieb & Woodcock, *supra* note 148.

154. U.S. FOOD & DRUG ADMIN., OPIOID ANALGESIC DRUGS: CONSIDERATIONS FOR BENEFIT-RISK ASSESSMENT FRAMEWORK: GUIDANCE FOR INDUSTRY (2019), https://www.fda.gov/media/128150/download [https://perma.cc/TWT5-KHBD]. The guidance was still in draft form at the time this Article was written. *Id.* Even if finalized, guidance is not binding. *Id.*

155. *Id.* at 5.

156. *See* UNITED HOSP. FUND, THE RIPPLE EFFECT: NATIONAL AND STATE ESTIMATES OF THE U.S. OPIOID EPIDEMIC'S IMPACT ON CHILDREN (2019), https://media.uhfnyc.org/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf; *Data and Statistics About Opioid Use During Pregnancy*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 21, 2023), https://www.cdc.gov/

beyond children who have taken them. In 2017, the number of children "who have [opioid use disorder] themselves or have accidentally ingested opioids" was estimated to be 170 thousand.[157] Additionally "[a]pproximately 2 million young people were affected primarily by parental use" of opioids (i.e., "they were either living with a parent with opioid use disorder, had lost a parent to an opioid-related death . . . , had a parent in prison or jail because of opioids, or had been removed from their home due to an opioid-related issue").[158]

These adverse childhood experiences may negatively impact child health.[159] For example, "[C]hildren of incarcerated parents, compared

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pregnancy/opioids/data.html [https://perma.cc/VP5G-8RDP]; Lauren J. Tanz, Amanda T. Dinwiddie, Christine L. Mattson, Julie O'Donnell & Nicole L. Davis, *Drug Overdose Deaths Among Persons Aged 10–19 Years—United States, July 2019–December 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1576–78 (2022) (noting that "[d]uring July 2019-December 2021, among 2,231 adolescent overdose decedents in 47 jurisdictions with available data . . . . 2,037 (91.3%) deaths involved at least one opioid . . . . [and a]pproximately 10% of deaths involved prescription opioids," with adolescents defined as ten to nineteen years old); Julie R. Gaither, Veronika Shabanova & John M. Leventhal, *US National Trends in Pediatric Deaths From Prescription and Illicit Opioids, 1999–2016*, JAMA NETWORK OPEN, Dec. 28, 2018, at 1, 4, 9; *Opioids*, YOUTH.GOV, https://youth.gov/youth-topics/substance-abuse/opioids [https://perma.cc/PH3H-MTCM]; Andrew Terranella, Gery P. Guy, Jr. & Christina Mikosz, *Buprenorphine Dispensing Among Youth Aged ≤19 Years in the United States: 2015–2020,* PEDIATRICS, Feb. 2023, at 40; *see also* NAT. ACAD. OF SCIS., ENG'G, MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE (2017).

157. UNITED HOSP. FUND, *supra* note 156, at fig. 1.

158. *Id.*; *see also* Ruthanne Palumbo, Brandy M. Mechling & Nancy R. Ahern, *Parental Opioid Use Disorder: Examining Their Children's Experiences, Needs, and Road to Resilience*, 35 J. CHILD & ADOLESCENT PSYCHIATRIC NURSING 24 (2022).

159. *See, e.g.*, Kenneth A. Feder, Elizabeth J. Letourneau & Jody Brook, *Children in the Opioid Epidemic: Addressing the Next Generation's Public Health Crisis*, PEDIATRICS PERSPECTIVES, Jan. 2019, at 1; SUZANNE C. BRUNDAGE & CAROL LEVINE, UNITED HOSP. FUND, THE RIPPLE EFFECT: THE IMPACT OF THE OPIOID EPIDEMIC ON CHILDREN AND FAMILIES (2019), https://uhfnyc.org/media/filer_public/17/2c/172ca968-43aa-45f9-a290-50018e85a9d8/uhf-opioids-20190315.pdf [https://perma.cc/7QUF-RBSQ]; UNITED HOSP. FUND, *supra* note 156; Rebecca Rivera, Malitta Engstrom, Jo Rees, Lisa Saldana, Rinad Beidas & Steven Marcus, *Child Health Consequences of Parental Opioid Use: A Scoping Review,* 21 J. SOC. WORK PRAC. ADDICTIONS 333 (2021); Magdalena Romanowicz Jennifer L. Vande Voort, Julia Shekunov, Tyler S. Oesterle, Nuria J. Thusius, Teresa A. Rummans, et al., *The Effects of Parental Opioid Use on the Parent-Child Relationship and Children's Developmental and Behavioral Outcomes: A Systematic Review of Published Reports*, CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH, Jan. 12, 2019, at 1, 9; *see also* Robert F. Anda Vincent J. Felitti, J. Douglas

with their counterparts, are a vulnerable population who are disadvantaged across an array of health outcomes . . . . [They] are more likely to experience fair or poor overall health, a range of physical and mental health conditions, activity limitations, and chronic school absence."[160] In addition, "research on adult children . . . show[s] that parental incarceration is, indeed, associated with measures of physical health including fair or poor health, asthma, and obesity . . . ."[161] Thus, asking the child question in the context of the opioid epidemic highlights some broader harms to children's health that FDA might consider in its assessment of the risks of prescription opioids.

*ii. COVID-19 Vaccines*

Asking the child question about COVID-19 vaccine regulation highlights the potential benefits of vaccines beyond those studied in trials, which focused on immune response and vaccine efficacy and served as the basis for authorization.[162] The regulatory system is not currently structured to systematically account for the broader public health impacts of regulatory decisions, including on children.[163] Examining the benefits and

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Bremner, John D. Walker, Charles Whitfield, Bruce D. Perry, et al., *The Enduring Effects of Abuse and Related Adverse Experiences in Childhood, A Convergence of Evidence From Neurobiology and Epidemiology*, 256 EUR. ARCHIVES PSYCHIATRY & CLINICAL NEUROSCIENCE 174 (2006).

160. Kristin Turney, *Stress Proliferation Across Generations? Examining the Relationship Between Parental Incarceration and Childhood Health,* 55 J. HEALTH & SOC. BEHAV. 312, 314 (2014); *Incarceration*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION: HEALTHY PEOPLE 2030, https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/incarceration# [https://perma.cc/GSV9-CWJ2]; *see also* Romanowicz et al., *supra* note 159; Erin L. Winstanley & Amanda N. Stover, *The Impact of the Opioid Epidemic on Children and Adolescents*, 41 CLINICAL THERAPEUTICS 1655 (2019).

161. Turney, *supra* note 160, at 315 (internal citations omitted).

162. *See, e.g.*, Press Release, Pfizer, Pfizer-BioNTech COVID-19 Vaccine Receives FDA Emergency Use Authorization for Children 6 Months Through 4 Years of Age (June 17, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-receives-fda-emergency-use [https://perma.cc/37AT-GFFN]; Press Release, Pfizer, Pfizer and BioNTech Announce Updated COVID-19 Vaccine Data Supporting Efficacy in Children 6 Months through 4 Years of Age (Aug. 23, 2022), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-updated-covid-19-vaccine-data [https://perma.cc/3EHB-DH7C]; *see also* 21 U.S.C. § 360bbb-3(c).

163. *See* Ross C. Brownson, Jamie F. Chriqui & Katherine A. Stamatakis, *Understanding Evidence-Based Public Health Policy*, 99 AM. J. PUB. HEALTH 1576, 1576 (2009) ("It has long been known that public health policy, in the form of laws, regulations, and guidelines has a

risks of vaccines through a child-focused lens suggests how a broader understanding of public health coupled with a fuller assessment of a product's benefits and risks might better account for children's health needs. By failing to weigh those potential benefits in assessing a vaccine's risk-benefit profile, the current regulatory process fails to consider children's needs fully.

This analysis is not intended to be a comprehensive analysis of pediatric COVID-19 vaccine development. It focuses on the Pfizer-BioNTech COVID-19 vaccine (Pfizer vaccine) because it was the first COVID-19 vaccine FDA authorized for emergency use.[164] FDA issued the authorization for emergency use (EUA) on December 11, 2020, including for children ages sixteen and older.[165] In addition, FDA also granted the Pfizer vaccine emergency use authorization for use in younger ages—ages twelve through fifteen years old (May 10, 2021),[166] and five through eleven

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profound effect on health status . . . . There is a considerable gap between what research shows is effective and the policies that are enacted and enforced.").

164. Press Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Authorization for First COVID-19 Vaccine (Dec. 11, 2020) [hereinafter Press Release, Emergency Authorization], https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 [https://perma.cc/H9U2-2H7D]. The Moderna COVID-19 vaccine was not authorized for use in children six months through seventeen years until June 17, 2022. *See* Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer BioNTech Covid-19 Vaccines for Children Down to 6 Months of Age (June 17, 2022) [hereinafter Press Release, Moderna and Pfizer], https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children [https://perma.cc/3H9C-4NMW] (noting that previously "[t]he [Moderna] vaccine had been authorized for use in adults 18 years of age and older"). The Novavax COVID-19 vaccine was not authorized for use in children twelve through seventeen years of age until August 19, 2022. *See* U.S. Food & Drug Admin., Letter from Peter Marks, Ctr. For Biologics Evaluation & Rsch., to Kathleen Callahan, Novavax, Inc. 2 n.4 (Oct. 3, 2023), https://www.fda.gov/media/159902/download [https://perma.cc/5XM9-3GVM] (noting that "FDA authorized the use of Novavax COVID-19 Vaccine . . . for individuals 12 through 17 years of age" on August 19, 2022).

165. *See* Press Release, Emergency Authorization, *supra* note 164.

166. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic (May 10, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use [https://perma.cc/EJM3-7J7H].

years old (October 29, 2021)[167]—before other COVID-19 vaccines.[168]

In early 2020, the Secretary of HHS made the determination and declaration necessary to permit FDA to issue an EUA for a COVID-19 vaccine under FDCA § 564.[169] Under Section 564, a medical product, like a vaccine, can be authorized for use in an emergency if, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that . . . the product may be effective in . . . preventing" the serious or life-threatening disease referred to in the declaration justifying emergency use authorization—here COVID-19.[170] In addition, the Secretary must conclude that "the known and potential benefits of the product, when used to . . . prevent . . . such disease or condition, outweigh the known and potential risks of the product . . . ."[171] And, there also must not be any "adequate, approved, and available alternative to the product for . . . treating such disease or condition."[172]

In the summer and fall of 2020, FDA issued guidance on developing and licensing COVID-19 vaccines.[173] In *Guidance, Development and Licensure of*

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167. Press Release, U.S. Food & Drug Admin., FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 Through 11 Years of Age (Oct. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age [https://perma.cc/Q9AG-2MWB].

168. The Pfizer and Moderna vaccines were both authorized for use in children six months through four years old on June 17, 2022. Press Release, Moderna and Pfizer, *supra* note 164. At that time, FDA also expanded the authorization of the Moderna vaccine to include children ages five through seventeen as previously, the Moderna "vaccine had only been authorized for use in adults 18 years of age and older." *Id.*

169. *See* Food, Drug, & Cosmetic Act § 564 (21 U.S.C. § 360bbb-3). In February 2020, the Secretary determined that "a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad" existed due to COVID-19. Determination of Public Health Emergency, 85 Fed. Reg. 7,316, 7,317 (Feb. 7, 2020). Then, based on that determination, the Secretary declared "that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the [FDCA] . . . ." 85 Fed. Reg. 18,250, 18,251 (Apr. 1, 2020).

170. 21 U.S.C. § 360bbb-3(c).

171. *Id.*

172. *Id.*

173. U.S. FOOD & DRUG ADMIN., DEVELOPMENT AND LICENSURE OF VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY at 1 (2020) [hereinafter DEVELOPMENT AND LICENSURE], https://web.archive.org/web/20200701070333/https://www.fda.gov/

*Vaccines to Prevent COVID-19*, FDA stated that the "goal of development programs should be to pursue traditional approval via direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease."[174] The endpoints that FDA discussed in the guidance, including "laboratory-confirmed COVID-19 or laboratory-confirmed SARS-CoV-2 infection," were consistent with this.[175] In a later guidance, *Emergency Use Authorization for Vaccines to Prevent COVID-19*, FDA provided additional information about safety and effectiveness information that sponsors should include in an EUA request.[176] The guidance noted: "Issuance of an EUA requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks."[177] This would include "meeting the prespecified success criteria for the study's primary efficacy endpoint . . . ."[178] In sum, the analysis of benefits is focused on the endpoints of the clinical studies of the vaccine, as is traditionally the case.

FDA also addressed pediatric assessments in its guidance on COVID-19 vaccine development and licensure, stating that it was "important for developers of COVID-19 vaccines to plan for pediatric assessments of safety and effectiveness, given the nature of the COVID-19 public health emergency, and to help ensure compliance with the Pediatric Research Equity Act (PREA) (section 505B of the FD&C Act (21 U.S.C. 355c))."[179] It noted that developers should discuss "the prospect of direct benefit and acceptable risk to support initiation of pediatric studies" and "the appropriate design and endpoints for pediatric studies" in the context of specific development programs to ensure compliance with the regulations setting forth safeguards for children in clinical trials.[180]

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media/139638/download; U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY (2020) [hereinafter EMERGENCY USE], https://web.archive.org/web/20201006215432/https://www.fda.gov/media/142749/download.

174. DEVELOPMENT AND LICENSURE, *supra* note 173, at 2.

175. *Id.* at 13–14, 18 (discussing the potential use of a surrogate endpoint (e.g., immune response) to demonstrate vaccine effectiveness).

176. EMERGENCY USE, *supra* note, 173, at 9–11.

177. *Id.* at 9.

178. *Id.*

179. DEVELOPMENT AND LICENSURE, *supra* note 173, at 11.

180. *Id.*; *see also* 21 C.F.R. pt. 50, subpt. D (2022). The FDA guidance also encouraged developers to consider what data might support the inclusion of pregnant women and women of childbearing potential who were not actively avoiding pregnancy in prelicensure

On March 11, 2020, the World Health Organization declared the novel coronavirus a pandemic.[181] The first COVID-19 vaccine was authorized for emergency use eight months later on December 11, 2020.[182] Based on publicly available data on COVID-19 cases in children in the United States as of December 10, 2020, children represented 12.2% of all reported cases (1,639,728 out of 13,462,337), 1.8% of hospitalizations (7,913 out of 445,394), and 0.06% of deaths (162 out of 249,442).[183]

This discussion focuses on FDA's Vaccines and Related Biological Products Advisory Committee's deliberation because it provides a window into a review process in which public disclosure of certain information is limited.[184] Advisory committees provide FDA independent expert advice and can "help the public understand the FDA's expectations for the data needed to support the agency's determinations about the safety and effectiveness of a product."[185]

On December 10, 2020, the advisory committee met to consider the safety and efficacy of the Pfizer/BioNTech vaccine and found that "based

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trials. DEVELOPMENT AND LICENSURE, *supra* note 173, at 11.

181. Jamey Keaten, Marian Cheng & John Leicester, *WHO Declares Coronavirus a Pandemic, Urges Aggressive Action*, ASSOCIATED PRESS (Mar. 12, 2020), https://apnews.com/article/united-nations-michael-pence-religion-travel-virus-outbreak-52e12ca90c55b6e0c398d134a2cc286e [https://perma.cc/D223-KHG8].

182. Press Release, Emergency Authorization, *supra* note 164; Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Elisa Harkins, Pfizer Inc., (Dec. 11, 2020), https://www.fda.gov/media/144412/download [https://web.archive.org/web/20201212022704/https://www.fda.gov/media/144412/download].

183. E-mail from William Cull, Am. Acad. Pediatrics, to Marie Boyd, Assoc. Professor, Univ. S.C. Joseph F. Rice Sch. of L., (Aug. 9, 2022, 18:15 ET) (on file with Author) (providing a copy of a Dec. 10, 2020, Children and COVID-19: State Data Report from the American Academy of Pediatrics and the Children's Hospital Association); *cf. This Week in Coronavirus: December 4 to December 10,* KFF (Dec. 11, 2020), https://www.kff.org/policy-watch/this-week-in-coronavirus-december-4-to-december-10/ [https://perma.cc/EP55-36ZJ] (estimating that by December 11, 2020, the United States had surpassed approximately 15.6 million cases of COVID-19 and 292,100 deaths). Note that the definition of children varied by state; reported age ranges went from zero to fourteen, seventeen, eighteen, nineteen, and twenty. *Id.*

184. *See, e.g.*, 21 C.F.R. § 601.51 (2022); *see also* 21 C.F.R. § 314.430 (2022); 21 C.F.R. § 20.61 (2022).

185. *Advisory Committees Give FDA Critical Advice and the Public a Voice, Consumer Updates,* U.S. FOOD & DRUG ADMIN. (Sept. 21, 2022), https://www.fda.gov/consumers/consumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice [https://perma.cc/9LG5-AW5N].

on the totality of scientific evidence available, the benefits of the . . . [v]accine outweigh its risks for use in individuals 16 years of age and older[.]"[186] The advisory meeting discussion and the review panel documents reflect a process for evaluating benefits that is closely focused on efficacy as defined by the clinical trial endpoints.

FDA's approach to evaluating COVID-19 vaccines for children is an example of how the regulatory system is not structured to fully account for the ways in which children's health, welfare, and flourishing may be impacted by regulatory decisions.[187] Briefing materials from the December meeting note that at the time there was not enough data to make conclusions about the safety and efficacy of the vaccine for children under sixteen years of age,[188] and "[s]ome committee members expressed concerns about including adolescents 16 and 17 years of age in the indication for the vaccine because of the limited amount of safety and efficacy data available in this population."[189] For example, one member stated that they would have preferred an indication for eighteen years of age and older, noting that "16- and 17-year-old children . . . do not get very sick, seldom get hospitalized, and I'll bet it's a very small number of deaths."[190] Nevertheless, it was noted at another point during the meeting

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186. *Summary Minutes for 162nd Vaccines and Related Biological Products Advisory Committee*, U.S. FOOD & DRUG ADMIN. at 47 (Dec. 10, 2020) [hereinafter *Summary Minutes*], https://www.fda.gov/media/144958/download [https://perma.cc/8L6W-CU56]. Advisory panels provide advice and recommendations to the Secretary. *See* FDCA § 505(n), 21 U.S.C. § 355(n).

187. *See* Evan J. Anderson, James D. Campbell, C. Buddy Creech, Robert Frenck, Satoshi Kamidani, Flor M. Munoz, et al., *Warp Speed for Coronavirus Disease 2019 (COVID-19) Vaccines: Why Are Children Stuck in Neutral?*, 73 CLINICAL INFECTIOUS DISEASES 337 (2021) ("[A]n approved COVID-19 vaccine for children could have far-reaching positive ramifications on health and educational equity.").

188. PFIZER & BIONTECH, VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING: FDA BRIEFING DOCUMENT at 47 (2020), https://www.fda.gov/media/144245/download [https://perma.cc/5HSA-N7RS] ("The representation of pediatric participants in the study population is too limited to adequately evaluate efficacy in pediatric age groups younger than 16 years. No efficacy data are available from participants ages 15 years and younger."); *id.* at 49 ("There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 16 years of age . . . .").

189. *Summary Minutes*, *supra* note 186.

190. *Vaccines and Related Biological Products Advisory Committee Dec. 10, 2020 Meeting Transcript*, U.S. FOOD & DRUG ADMIN. CTR. BIOLOGICS EVALUATION & RSCH. (Dec. 10, 2020), https://www.fda.gov/media/144859/download (quoting H. Cody Meissner, MD,

that "the broader impacts in children perhaps are not entirely clear until the full resumption of normal activities ensues . . . including in person education across all schools . . . ."[191]

Indeed, early in the pandemic, many children were not attending school in person because of COVID-19. At one point, school closures impacted "at least 55.1 million students in 124,000 U.S. public and private schools."[192] One survey found that 89% of adults reported that in September 2020, "classes for their children [under age 18] had moved to a distance learning format using online resources . . . ."[193] In December 2020, "approximately half of students in kindergarten through 12th grade attended school fully remotely . . . . with low-income, Black, and Hispanic groups the most likely to attend fully remote school."[194] While the full impact of COVID-19 school closures remains to be seen, research suggests that remote learning was not without significant costs for children and parents.[195] Such costs may diminish

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Tufts University School of Medicine).

191. *Id.* (quoting Aron Hall, DVM, MSPH, Dipl ACVPM, Centers for Disease Control and Prevention).

192. Map: Coronavirus and School Closures in 2019-2020, Educ. Week (Oct. 13, 2021), https://www.edweek.org/leadership/map-coronavirus-and-school-closures-in-2019-2020/2020/03 [https://perma.cc/2J7K-NPQ2].

193. *Impact of the Coronavirus Pandemic on the Elementary and Secondary Education System*, NAT'L CTR. FOR EDUC. STATS. (May 2021), https://nces.ed.gov/programs/coe/indicator/tcb?tid=3002020 [https://perma.cc/7YPB-3BFW].

194. *E.g.*, Matt Hawrilenko, Emily Kroshus, Pooja Tandon & Dimitri Christakis, *The Association Between School Closures and Child Mental Health During COVID-19*, 4 JAMA NETWORK OPEN, Sept. 3, 2021; *see also* Nicole Bateman & Martha Ross, *Why Has COVID-19 Been Especially Harmful for Working Women?*, BROOKINGS INST. (Oct. 2020), https://www.brookings.edu/articles/why-has-covid-19-been-especially-harmful-for-working-women/ [https://perma.cc/5RH8-8C6E] (explaining the disparate impact "COVID-19's massive disruption to . . . childcare[] and school routines" has had on women).

195. *E.g.*, Jill V. Klosky, Julie A. Gazmararian, Olivia Casimir & Sarah C. Blake, *Effects of Remote Education During the COVID-19 Pandemic on Young Children's Learning and Academic Behavior in Georgia: Perceptions of Parents and School Administrators,* 92 J. SCH. HEALTH 656 (2022) ("The ongoing and immense challenges of providing children's education in a pandemic have the potential to further amplify existing inequities and widen the persistent educational gap."); *see also* Naomi R. Cahn & Linda C. McClain, *Gendered Complications of Covid-19: Towards A Feminist Recovery Plan*, 22 GEO. J. GENDER & L. 1, 21 (2020) (stating that "dynamics around work, family, caretaking, and virtual schooling contribute to a record number of women exiting the workforce, with possible 'long-term ramifications' on their 'careers and earning potential'" and that "[w]ith respect to the effects of the pandemic on children, low-income, Black, and Latinx families experienced the greatest impact from school closures");

children's health and the impact may disproportionately fall upon children who are members of excluded groups.[196]

CDC's guidance regarding quarantine following COVID-19 exposure differed based on the exposed person's vaccination status. In September 2021, an Overview of COVID-19 Quarantine for K-12 Schools from CDC indicated that "[p]eople who are not fully vaccinated and are determined to be a close contact of someone with COVID-19" should "quarantine (stay at home and away from other people) immediately for a period of 14 days from the date of their last exposure, unless they receive different instructions from their school official or a public health official."[197] In contrast, CDC stated that "[p]eople who are fully vaccinated . . . *do not* need to quarantine . . . ."[198] The COVID-19 vaccine had only been authorized for emergency use in those twelve years and older at that time and the CDC's vaccine provider agreement provided that "administering vaccines to individuals younger than the ages for whom the FDA has approved or authorized use is prohibited and risks repercussions to providers, including legal liability, loss of payment, and removal from the Covid-19 vaccine program."[199] This effectively meant that children under twelve were subject to two-week quarantines. News reports from around

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Zachary Parolin, Comment, *Unemployment and Child Health During COVID-19 in the USA,* 5 LANCET PUB. HEALTH E521 (2020) (discussing the rise in hardship due to unemployment "coupled with an inadequate welfare state and little support for domestic caregivers" and "the associated long-term costs for children"); Amanda Barroso & Juliana Menasce Horowitz, *The Pandemic Has Highlighted Many Challenges for Mothers, But They Aren't Necessarily New*, PEW RSCH. CTR. (Mar. 17, 2021), https://www.pewresearch.org/short-reads/2021/03/17/the-pandemic-has-highlighted-many-challenges-for-mothers-but-they-arent-necessarily-new/ [https://perma.cc/2P6G-5NS5] (discussing "challenges facing moms during the pandemic" and noting that "disruptions caused by the pandemic might have long-lasting consequences for gender equality in the workplace").

196. *E.g.,* Klosky, *supra* note 195; Cahn, *supra* note 195; *see also Education & Learning Online,* PEW RSCH. CTR., https://www.pewresearch.org/topic/other-topics/education/education-learning-online-2/ [https://perma.cc/5WSU-LHFS] (listing articles discussing online education and learning during the pandemic).

197. *Overview of COVID-19 Quarantine for K-12 Schools*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 13, 2021), https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjV_8b886mEAxXhEVkFHWZyBYsQFnoECBoQAQ&url=https%3A%2F%2Fstacks.cdc.gov%2Fview%2Fcdc%2F109767%2Fcdc_109767_DS1.pdf&usg=AOvVaw1lTSKhN77edFWXI2SHIl9t&opi=89978449.

198. *Id.*

199. Elizabeth Lanphier & Shannon Fyfe, *Pediatric Off-Label Use of COVID-19 Vaccines: Ethical and Legal Considerations,* 51 HASTINGS CTR. REP., Nov. 8, 2021, at 27.

this time suggest that many students were quarantined following close contact with someone with COVID-19. For example, approximately 17,000 students in Maryland public schools had been quarantined between the start of the school year and the end of September,[200] 20,000 students in Mississippi were quarantined as of mid-August,[201] and 87,000 students in South Carolina had been placed in quarantine by mid-September.[202] One review found that studies of quarantine among children and adolescents, both pre-dating and during the COVID-19 pandemic, showed that quarantine had "considerable psychological impact" and "negative impact on [children and adolescents'] physical health, academics, and social network."[203] As Ami Harbin and colleagues wrote, a narrow conception of risk focused on the risks of infection and adverse vaccine effects in the

200. Elizabeth Shwe, *More than 17,000 Students Across the State Have Quarantined This School Year*, MD. MATTERS (Sept. 29, 2021), https://www.marylandmatters.org/2021/09/29/more-than-17000-students-across-the-state-have-quarantined-this-school-year/ [https://perma.cc/TN9F-P8DZ].

201. Leah Willingham, *About 20,000 Mississippi Students in Quarantine for COVID-19 Exposure, Health Official Says,* USA TODAY (Aug. 17, 2021, 5:17 PM), https://www.usatoday.com/story/news/local/2021/08/17/covid-mississippi-children-20-000-students-quarantine/8171250002/ [https://perma.cc/TK96-H9CE]; *see also* Jeanine Santucci, *'This Will Be a Tough Year': Thousands of Kids are in COVID-19 Quarantine Across the US, and School Has Just Begun*, USA TODAY (Aug. 18, 2021, 4:45 PM), https://www.usatoday.com/story/news/2021/08/17/back-school-thousands-students-quarantine-schools-shutting-down/8174088002/ [https://perma.cc/7W6G-YXVX] (affirming Mississippi figure and noting other student and school staff quarantines in other places during the same time period).

202. Emily Bohatch, *100,000-Plus SC Students Missed School Due to COVID this Semester, DHEC Data Show*, THE STATE (Sept. 20, 2021, 7:18 AM), https://www.thestate.com/article254288428.html.

203. Nazish Imran, Irum Aamer, Muhammad Imran Sharif, Zubair Hassan Bodla & Sadiq Naveed, *Psychological Burden of Quarantine in Children and Adolescents: A Rapid Systematic Review and Proposed Solutions*, 36 PAK. J. MED. SCI. 1106, 1113 (2020); *see also* Samantha Artiga, Latoya Hill & Nambi Ndugga, *Racial Disparities in COVID-19 Impacts and Vaccinations for Children,* KFF (Sept. 16, 2021), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-covid-19-impacts-and-vaccinations-for-children/ [https://perma.cc/86A6-2UCW] ("While data remain limited, available research and data to date suggest that children of color have been disproportionately affected by COVID-19 and may be less likely to have been vaccinated. . . ."); Jessica L. Hawks, *Editorial: The Impact of the COVID-19 Pandemic on Racial Disparities in Pediatric Mental Health,* 62 J. AM. ACAD. CHILD & ADOLESCENT PSYCHOLOGY 398, 398 (2023) (stating that "[t]he COVID-19 pandemic has resulted in a devastating impact on youth mental health concerns" and "racial minority youth have been disproportionately negatively impacted").

context of pediatric vaccine development is problematic because "access to education is a fundamental component of child health" and "[c]hildren are harmed not only when they lack access to disease protection, but also by social and educational disruption, in addition to emotional, financial, social, and professional harms to their family units."[204]

On December 11, 2020, the day after the advisory committee meeting, FDA issued "the first emergency use authorization (EUA) for a vaccine for the prevention of . . . COVID-19 . . . in individuals 16 years of age and older."[205] The FDA review team, in assessing efficacy, similarly focused on whether the vaccine "may be effective in preventing . . . such serious or life-threatening disease or condition that can be caused by SARS-CoV-2" and found that it was reasonable to believe that it would be.[206] It found that "the known and potential benefits of the vaccine outweigh the known and potential risks of the vaccine when used for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older." [207] It listed "[r]eduction in the risk of confirmed COVID-19 occurring at least [seven] days after Dose 2 . . . [r]eduction in the risk of confirmed COVID-19 after Dose 1 and before Dose 2," and "[r]eduction in the risk of confirmed severe COVID-19 any time after Dose 1" as "relative to placebo" as benefits.[208] It also listed "potential benefits that could be further evaluated but are not necessary to support an EUA include prevention of COVID-19 in individuals with previous SARS-CoV-2 infection, prevention of mortality and long-term complications of COVID-19, reduction in asymptomatic SARS-CoV-2 infection and reduction of SARS-CoV-2 transmission."[209] The review team accordingly recommended an EUA be issued. [210]

FDA did not authorize a COVID-19 vaccine for children under five

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204. Ami Harbin, Naomi Laventhal & Mark Navin, *Ethics of Age De-Escalation in Pediatric Vaccine Trials: Attending to the Case of COVID-19*, 41 VACCINE 1584, 1586 (2023); *see also* Artiga, *supra* note 203 (discussing "disproportionate impacts of the pandemic" on Hispanic and Black children).

205. Press Release, Emergency Authorization, *supra* note 164; *see also* Letter from Denise M. Hinton, *supra* note 182.

206. U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM 9 (2020), https://www.fda.gov/media/144416/download [https://perma.cc/SR2E-ZQNA].

207. *Id.* at 8.

208. *Id.* at 49.

209. *Id.* at 55.

210. *Id.*

until roughly a year and a half later.[211] By that time (June 16, 2022), the number of reported child cases had climbed to a total of 13,624,605, representing 18.8% of all reported cases.[212] Earlier that month, a total of 43,316 child hospitalizations and 1,055 child deaths had been reported.[213]

As noted earlier, this discussion of FDA's authorization of the vaccine is not intended to suggest that the broader impacts FDA's regulatory decisions may have on children's health should supplant the review of the safety and effectiveness a product as shown through clinical trials.[214] But rather, it suggests that using a child-centered lens to examine regulatory decisionmaking in this context highlights matters that arguably ought to be considered to more fully account for children's health, broadly understood, in product evaluations.

### *2. Asking the Child Question About Tobacco Products Regulation*

FDA's tobacco product regulation has failed to account for children's needs fully. Using FDA's regulation of e-cigarettes as an example, this Section highlights how regulatory delays have hampered FDA's ability to regulate e-cigarettes and protect youth from their risks.[215] FDA's regulation of e-cigarettes has been marked by significant delays during which youth e-cigarette use has increased substantially.[216]

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211. *See FDA News Release: Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age*, U.S. FOOD AND DRUG ADMIN. (June 17, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children [https://perma.cc/7FXW-ENR4].

212. E-mail from William Cull, Am. Acad. Pediatrics, to Marie Boyd, Assoc. Professor, Univ. S.C. Sch. of L., (Aug. 9, 2022, 18:15 ET) (on file with Author) (providing a copy of a June 16, 2022, Children and COVID-19: State Data Report from the American Academy of Pediatrics and the Children's Hospital Association).

213. *Id.*

214. It also important to note that FDA's decisionmaking in this context was subject to significant constraints beyond the agency's control including the statutory requirements for authorization; the availability and strength of data from clinical trials; and the timing of requests for emergency use authorization. *See, e.g.*, U.S. FOOD AND DRUG ADMIN., EMERGENCY USE AUTHORIZATION (EUA) FOR AN UNAPPROVED PRODUCT REVIEW MEMORANDUM, *supra* note 206, at 9–10, 15–16, 54.

215. The following discussion is not intended to be a comprehensive analysis of FDA's regulation of e-cigarettes and its shortcomings. In addition, it does not attempt to discern reasons for the delays.

216. *Tobacco Survey*, *supra* note 5; *see also* Roseann B. Termini, *A Look Back at the Evolution*

Youth e-cigarette use is concerning because e-cigarettes often contain nicotine, which is addictive.[217] In addition, e-cigarettes pose potential dangers to young users, and youth that use e-cigarettes may have a higher risk of starting to smoke cigarettes.[218] Youth smoking "can cause serious and potentially deadly health issues immediately and into adulthood."[219]

Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009.[220] The TCA gave FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.[221] The TCA established FDA's Center for Tobacco Products (CTP).[222] CTP's mission, unlike those of FDA's other product centers, focuses explicitly on "youth":[223] CTP's mission includes "[t]o protect the public health of the

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*of the Family Smoking Prevention and Tobacco Control Act and the Present-Day Impact on "Overlooked and Belated Issues" — Electronic Nicotine Delivery Systems (Ends) and the Youth Epidemic, Menthol, Corrective Statements and Cigarette Labeling Graphic Health Warnings*, 17 IND. HEALTH L. REV. 107, 108–09 (2020).

217. *Quick Facts on the Risks of E-Cigarettes for Kids, Teens, and Young Adults*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 10, 2022) [hereinafter *Quick Facts*], https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html [https://perma.cc/VQD4-7BZH].

218. *Quick Facts*, *supra* note 217; Lauren M. Dutra & Stanton A. Glantz, *E-Cigarettes and National Adolescent Cigarette Use: 2004–2014*, PEDIATRICS, Feb. 2017, at 1, 2, 5–6; *see also* NICOLE A. TASHAKKORI, BRIAN L. ROSTRON, CAROL H. CHRISTENSEN & KAREN A. CULLEN, NOTES FROM THE FIELD: E-CIGARETTE-ASSOCIATED CASES REPORTED TO POISON CENTERS—U.S., APRIL 1, 2022–MARCH 31, 2023 72, MORBIDITY & MORTALITY WKLY. REP. 694 (June 23, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7225a5.htm?s_cid=mm7225a5_w [https://perma.cc/8MM4-ZLLD].

219. *Smoking & Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/sgr/50th-anniversary/pdfs/fs_smoking_youth_508.pdf (last visited Feb. 1, 2024).

220. Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

221. *See id.* § 3, 123 Stat. at 1781–82.

222. *See id.* § 101, 123 Stat. at 1787.

223. *Compare About the Center for Tobacco Products (CTP)*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2023), https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp# [https://perma.cc/9H9L-X7FW], *with Center for Drug Evaluation and Research | CDER*, U.S. FOOD & DRUG ADMIN. (Aug. 14, 2023), https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder [https://perma.cc/MPY3-3QSH], *CBER Vision & Mission*, U.S. FOOD & DRUG ADMIN. (Sept. 25, 2019), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-vision-mission [https://perma.cc/MX5X-5U66]; *Center for Devices and Radiological Health*, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2024), https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health; *What We Do at CFSAN*, U.S. FOOD &

U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products . . . "[224] The products that CTP regulates, which include cigarettes, smokeless tobacco products, vapes, e-cigarettes, and other electronic nicotine delivery systems (ENDS),[225] have a tremendous impact on children's health.[226]

In enacting the TCA, Congress sought to ensure FDA had the authority to address youth smoking.[227] Congress found that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults"[228] and that reducing tobacco use in minors would decrease premature deaths due to tobacco-induced disease and result in substantial health care savings.[229]

The TCA did not specifically mention e-cigarettes.[230] When Congress

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DRUG ADMIN. (Sept. 16, 2019), https://www.fda.gov/about-fda/center-food-safety-and-applied-nutrition-cfsan/what-we-do-cfsan [https://perma.cc/C329-GB3A]; *Center for Veterinary Medicine*, U.S. FOOD & DRUG ADMIN. (Nov. 15, 2023), https://www.fda.gov/about-fda/fda-organization/center-veterinary-medicine [https://perma.cc/FJ28-KA9S].

224. *About the Center for Tobacco Products (CTP)*, U.S. FOOD & DRUG ADMIN., *supra* note 223 (emphasis added).

225. FDCA § 901, 21 U.S.C. § 387a; Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016).

226. *See, e.g.*, *Surgeon General's Advisory on E-Cigarette Usage Among Youth, Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2018) [hereinafter *E-Cigarette Usage*], https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html [https://perma.cc/KW4H-6Q4B]; U.S. DEP'T OF HEALTH & HUM. SERVS., *The Health Consequences of Tobacco Use Among Young People*, *in* PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 13–128 (2012).

227. Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776, 1781–82 (2009) (stating that the purposes of the Act are "to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people" and "to ensure that [tobacco products] are not sold or accessible to underage purchasers").

228. § 2, 123 Stat. at 1777.

229. *Id.*

230. *See id.* The TCA specified that it applied to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter." § 101, 123 Stat. at 1786 (2009). It defined "tobacco product," in part as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco

enacted the TCA, e-cigarettes were relatively new to the U.S. market, having "entered the U.S. marketplace around 2007."[231] They were also not as widely used as they would later be.[232] Since 2009, e-cigarette use in the United States, including by youth, has increased substantially.[233]

While the TCA did not explicitly mention e-cigarettes, it gave FDA authority to "deem[]" e-cigarettes subject to the TCA by regulation.[234] Despite this, and despite a 2010 decision by the United States Court of Appeals for the District of Columbia holding that "FDA has authority to regulate customarily marketed tobacco products—including e-cigarettes—under the [TCA],"[235] FDA did not propose regulations deeming e-cigarettes subject to the TCA until February 2014.[236] It published final regulations in May 2016. [237]

In the rule's preamble, FDA announced a compliance policy for premarket review of newly deemed products (e.g., ENDS) that are "new

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product." *Id.*; FDCA § 201(rr)(1), 21 U.S.C. 321(rr)(1). Congress later gave FDA the authority to regulate products containing synthetic nicotine. *See* Pub. L. No. 117-103, § 111 (2022).

231. *E-Cigarette Usage*, *supra* note 226.

232. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 4 (2016), https://www.cdc.gov/tobacco/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf [https://perma.cc/8R59-XPJC] (noting that the 2012 Surgeon General's report on the health consequences of smoking "was prepared before e-cigarettes were as widely promoted and used in the United States . . . .").

233. Tushar Singh, René A. Arrazola, Catherine G. Corey, Corinne G. Husten, Linda J. Neff, David M. Homa, et al., *Tobacco Use Among Middle and High School Students—United States, 2011–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 361 (2016) ("During 2011-2015, among all high school students, significant nonlinear increases were observed for current use of e-cigarettes (1.5% to 16.0%) . . . .").

234. TCA § 101, 123 Stat. at 1786; FDCA § 901(b), 21 U.S.C. § 387a(b).

235. Sottera, Inc. v. FDA, 627 F.3d 891, 898 (D.C. Cir. 2010); *see also* Smoking Everywhere, Inc. v. FDA, 680 F. Supp. 2d 62 (D.D.C. 2010), *aff'd sub nom.*

236. Proposed Deeming Rule, 79 Fed. Reg. 23,142 (Apr. 25, 2014).

237. Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143). The deeming rule also provided that "[n]o retailer may sell covered tobacco products to any person younger than 18 years of age." *Id.* at 29,103; *see also* Press Release, U.S. Food & Drug Admin., FDA Takes New Steps to Address Epidemic of Youth E-Cigarette Use, Including a Historic Action Against More Than 1,300 Retailers and 5 Manufacturers for Their Roles Perpetuating Youth Access (Sept. 11, 2018), https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more [https://perma.cc/YY5T-EQYD].

tobacco products."[238] Such products are "required to obtain premarket authorization . . . through one of three pathways" (substantial equivalence, exemption from substantial equivalence, or premarket tobacco product application).[239] FDA indicated it did not intend to enforce the premarket review requirements for twenty-four to thirty-six months.[240] In announcing that decision, FDA discussed the products' impact on children. FDA indicated it "received comments and new data regarding the effect of flavored tobacco products on youth and young adult use" and that it "understands that the appeal of flavors and use of flavored tobacco products have an important role in the initiation and continued use of tobacco products."[241] Nevertheless, while FDA had "determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease," it stated that extending the compliance dates would balance that with "emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use."[242]

FDA later extended the compliance deadlines via guidance, resulting in an August 2022 date for non-combustible products.[243] FDA also noted that, for new tobacco products not on the market on the effective date of the deeming regulations, it did not intend to enforce the premarket authorization requirement for applications pending review.[244]

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238. 81 Fed. Reg. 28,974, 28,976–88 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143). The FDCA defines "new tobacco product" as "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007; or . . . any . . . modification of a tobacco product where the modified product was commercially marketed in the United States after [that date]." FDCA § 910(a), 21 U.S.C. § 387j(a).

239. 81 Fed. Reg. at 28,990; FDCA §§ 905, 910(a)(2), 21 U.S.C. §§ 387e, 387j(a)(2).

240. 81 Fed. Reg. 28,977–78.

241. *Id.* at 28,977.

242. *Id.*

243. *See* Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2021), https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline [https://perma.cc/JJ8Q-WJ8D]; Notice of Availability, 82 Fed. Reg. 37,459 (Aug. 10, 2017); U.S. FOOD & DRUG ADMIN., THREE-MONTH EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR INDUSTRY (2017), https://www.regulations.gov/document/FDA-2017-D-2834-0004 [https://perma.cc/9XKF-UKGC].

244. *See* U.S. FOOD & DRUG ADMIN., EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR

The American Association of Pediatrics, and others, sought to vacate the later guidance.[245] The court hearing the action noted that the guidance did "not require manufacturers to submit their applications . . . for five or more years and announce[d] that the FDA will defer enforcement during that period."[246] The court ordered a deadline for submitting new applications for premarket authorization for new tobacco products on the market when FDA's deeming rule took effect.[247] The final court-ordered deadline was September 9, 2020,[248] more than a decade after the TCA was enacted.[249] The court also provided a one-year period (until September 9, 2021) during which products with timely-filed applications could stay on the market pending FDA's review.[250] In November 2021, the plaintiffs requested the court reopen the case and require that FDA provide regular status reports. They alleged that "FDA has not issued a single [Premarket Tobacco Product Application (PMTA)] decision on any of the products with the largest market share in the market as a whole or in the youth market" and that "FDA does not appear to have enforced the premarket review requirements against any product still awaiting a PMTA decision, including products with the greatest market share and those most used by youth."[251] The court issued a remedial order requiring FDA to submit regular status reports regarding the review of

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INDUSTRY (REVISED) (Aug. 2017) [hereinafter EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES] (withdrawn).

245. Am. Acad. of Pediatrics v. FDA, 379 F. Supp. 3d 461, 469 (D. Md. 2019).

246. *Id.* at 477; *see also* EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES, *supra* note 244.

247. Zeller, *supra* note 243.

248. *Id.* Earlier that year, FDA announced that it had finalized its "enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children" and that companies that did not stop manufacturing, distributing, and selling such cartridges risked enforcement actions. Press Release, U.S. Food & Drug Admin., FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children [https://perma.cc/DE43-T8KG].

249. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

250. Zeller, *supra* note 243.

251. Petition to Reopen and Intent to File Motion to Amend, Am. Acad. of Pediatrics et al., v. FDA, No. 8:18-cv-00883 (D. Md. 2018). *See generally* Elizabeth K. Do, *Youth E-Cigarette Initiation After the Food and Drug Administration's Missed Deadline*, 65 AM. J. OF PREVENTIVE MED. 886 (2023) (estimating the number of youth who initiated e-cigarette use following FDA's court-ordered September 9, 2021 deadline).

certain pending applications.[252] As of December 31, 2022, FDA had taken action on 51% of those applications.[253]

Since 2009, when Congress enacted the TCA, youth e-cigarette use in the US has increased substantially.[254] From 2011 to 2015, which falls between the DC Circuit's 2010 decision that FDA had the authority to regulate e-cigarettes and FDA's 2016 deeming rule, e-cigarette use increased 900% among middle and high school students.[255] In 2016 e-cigarettes were "the most commonly used form of tobacco among youth in the United States."[256] In 2019, 27.5% of high school students and 10.5% of middle school students indicated current e-cigarette use.[257]

While recent data suggests that youth e-cigarette use has declined from 5.4 million in 2019 to 3.6 million in 2020, many children still use e-cigarettes.[258] And most (8 out of 10) report using flavored e-cigarettes.[259] Although prefilled pods or cartridges were the most commonly used e-cigarettes during the same period, disposable e-cigarette use increased 1,000% among high school students and 400% among middle school students.[260] Of note, when

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252. Revised Remedial Order, Am. Acad. of Pediatrics et al., v. FDA, No. 8:818-cv-00883 (D. Md. 2018).

253. Status Rep., Am. Acad. of Pediatrics, v. FDA, No. 8:818-cv-00883 (D. Md. 2018).

254. Singh et al., *supra* note 233 ("During 2011-2015, among all high school students, significant nonlinear increases were observed for current use of e-cigarettes (1.5% to 16.0%) . . . .").

255. *E-Cigarette Usage*, *supra* note 226.

256. U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 232.

257. Press Release, Ctrs. for Disease Control & Prevention, Youth E-Cigarette Use is Down, But 3.6 Million Still Use E-Cigarettes, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2020/p0909-youth-e-cigarette-use-down.html [https://perma.cc/5JA3-3K3D] [hereinafter Youth E-Cigarette Use].

258. *Id.*

259. *Id.*; *Get the Facts,* KNOW THE RISKS, https://e-cigarettes.surgeongeneral.gov/getthefacts.html [https://perma.cc/WUH9-SBZQ]. Significant differences in use patterns across racial and ethnic groups have been reported. *See* Hongying Dai, Athena K. Ramos, Babalola Faseru, Jennie L. Hill & Steven Y. Sussman, *Racial Disparities of E-Cigarette Use Among U.S. Youths: 2014–2019,* 111 AM. J. PUB. HEALTH 2050 (2021). Use may also differ by gender. *See also* Grace Kong, Karissa E. Kuguru & Suchitra Krishnan-Sarin, *Gender Differences in U.S. Adolescent E-Cigarette Use*, 4 CURRENT ADDICTION REP. 422 (2017).

260. *See* Youth E-Cigarette Use, *supra* note 257; Teresa W. Wang, Linda J. Neff, Eunice Park-Lee, Chunfeng Ren, Karen A. Cullen & Brian A. King, *E-Cigarette Use Among Middle and High School Students—United States, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1310 (2020); Fatma Romeh M. Ali, Megan C. Diaz, Donna Vallone, Michael A. Tynan, Jamie Cordova, Elizabeth L. Seaman, et al., *E-Cigarette Unit Sales, by Product and Flavor Type—United*

FDA announced that it intended to prioritize enforcement against "any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDs product)" in early 2020, it excluded "completely self-contained disposable products."[261] Disposable products saw significant increases in use in 2020 and became the most commonly used device type by middle and high school students in 2022.[262] More recently, FDA has taken action regarding unauthorized disposable e-cigarettes.[263]

Despite progress, much work remains: 3.08 million middle and high school students reported current use of any tobacco product, more than 2.5 million reported current use of e-cigarettes, and almost 85% of the e-cigarette users used flavored e-cigarettes.[264]

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*States, 2014–2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1313 (2020).

261. U.S. DEP'T OF HEALTH & HUM. SERVS., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION: GUIDANCE FOR INDUSTRY 9, 18–19 (2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market [https://perma.cc/9T3J-6ZJH]; Fatma Romeh M. Ali, Andrew B. Seidenberg, Elisha Crane, Elizabeth Seaman, Michael A. Tynan & Kristy Marynak, *E-Cigarette Unit Sales, by Product and Flavor Type, Top-Selling Brands—United States, 2020–2022*, 72 MORBIDITY & MORTALITY WKLY. REP. 672 (2023) ("Citing the appeal of flavored e-cigarettes to children, FDA announced during January 2020 that it would prioritize enforcement against prefilled e-cigarettes in flavors other than tobacco and menthol based on the prevalence of use of these products among youth at the time. The present study's findings indicate that after this announcement, retail sales of mint- and other- flavored prefilled cartridges halted while notable increases in sales of fruit- and mint-flavored disposable products occurred. Although disposable e-cigarettes constituted approximately less than one quarter of total unit sales during January 2020, disposable sales surpassed refillable sales in March 2022."). For a discussion of the exclusion on menthol and racial health disparities, see Michael R. Ulrich, *E-Racing Tobacco & Nicotine-Related Health Disparities*, 77 FOOD & DRUG L.J. 219 (2022).

262. *Tobacco Survey*, *supra* note 5. Because of changes in methodology due to COVID-19 pandemic, the 2021 and 2022 National Youth Tobacco Survey estimates aren't comparable with those from earlier surveys. *National Youth Tobacco Survey*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 14, 2022), https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm [https://perma.cc/B3X4-6TYN].

263. *See, e.g.*, Press Release, U.S. Food & Drug Admin., FDA Inspection Blitz Leads to More Than 180 Warning Letters to Retailers for the Illegal Sale of Youth-Appealing Elf Bar and Esco Bars E-Cigarettes (June 22, 2023), https://www.fda.gov/news-events/press-announcements/fda-inspection-blitz-leads-more-180-warning-letters-retailers-illegal-sale-youth-appealing-elf-bar [https://perma.cc/YX9D-E529].

264. *Tobacco Survey*, *supra* note 5.

### *3. Asking the Child Question About Food Regulation*

This Section uses examples from FDA's regulation of food to show how FDA food law has failed to account for the needs of children fully and, in so doing, has jeopardized their health.[265] As with earlier sections, this Section is not intended to be a comprehensive analysis of the impact of FDA food law and policy on children but rather serves to highlight some limitations of FDA's regulation of food by asking the child question.

Food is essential for children to live, grow, and flourish. Food is so important to the well-being of children that the government provides food assistance to low-income children through programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the Supplemental Nutrition Assistance Program (SNAP), and the National School Lunch and Breakfast Programs.

FDA's food mission is to "protect[] the public health . . . by ensuring the safety of our nation's food supply."[266] The FDCA defines food broadly as "articles used for food or drink for man," including chewing gum and "articles used for components of any such article."[267] This includes articles used in the way that people commonly use food, for taste, aroma, and nutrition,[268] as well as subcategories of food, such as "food additives" and "dietary supplements."[269] There is no general premarket approval requirement for foods. Instead, FDA largely relies on its post-market authority—including its authority under the adulteration and misbranding provisions—to regulate food.[270]

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265. Other scholars and commentators have explored how aspects of FDA's regulation of food has impacted children. *See, e.g.*, Mathilde Cohen, *Should Human Milk Be Regulated*, 9 U.C. IRVINE L. REV. 557 (2019); Jennifer L. Pomeranz & Jennifer L. Harris, *Federal Regulation of Infant and Toddler Food and Drink and Labeling*, AM. J.L. & MED. 32 (2019); Jennifer L. Pomeranz, *Extending the Fantasy in the Supermarket: Where Unhealthy Promotions Meet Children and How the Government Can Intervene*, IND. HEALTH L. REV. 117 (2012); Yi Seul Kim, *Reconfiguring Children in Food Law as an Essential Subset: Review of Food Nutrition Facts Labels*, 24 DRAKE J. AGRIC. L. 399 (2019); Gail H. Javitt, *Supersizing the Pint-Sized: The Need for FDA-Mandated Child-Food Labeling*, 39 LOY. L.A. L. REV. 311 (2006); Toby Milgrom Levin, *The Infant Formula Act of 1980: A Case Study of Congressional Delegation to the Food and Drug Administration*, 42 FOOD, DRUG, COSM. L.J. 101 (1987).

266. *What We Do*, *supra* note 6.

267. FDCA § 201(f), 21 U.S.C. § 321(f).

268. *See* Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983).

269. FDCA § 201(f), (s), (ff), 21 U.S.C. § 321(f), (s), (ff).

270. *See* FDCA §§ 402, 403, 21 U.S.C. §§ 342, 343. FDA is required to approve food additives before they can be used in food unless they are generally recognized, among

While food is essential for children to live, grow, and flourish, it may also present risks.[271] For example, children may be harmed by the consumption of a food with microbial or inorganic contamination, they may suffer from obesity and diet-related diseases, and the negative environmental impacts of food production may harm them.[272] Indeed, children may disproportionately bear the burden of many food-related risks. For example, foodborne illnesses disproportionately impact children.[273] Children are "especially vulnerable to the[] carcinogenic and non-carcinogenic effects [of inorganic contaminates in foods]."[274] Furthermore, food allergies are more common in children than adults.[275]

*a. Infant Formula Shortage*

Asking the child question about FDA and the 2022 infant formula shortage highlights how FDA law and policy fell short. Under the FDCA, infant

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qualified experts, as having been adequately shown to be safe under the conditions of the intended use (i.e., Generally Recognized as Safe (GRAS)). FDCA §§ 201, 409, 21 U.S.C. §§ 321(s), 348. There is a notification requirement for new dietary ingredients for dietary supplements. FDCA § 413, 21 U.S.C. § 350b. In addition, some claims used on food and dietary supplements must be approved by FDA before use.

271. *See* Emily M. Broad Leib & Margot J. Pollans, *The New Food Safety*, 107 CAL. L. REV. 1173, 1180 (2019) (arguing that while food safety has traditionally been interpreted narrowly, a more comprehensive definition should be used, which includes "acute ingestion-related harm" as well as "cumulative, whole-diet consumption" risks, and broad "cradle-to-grave" risks); *see also* James G. Hodge, Jr., Megan Scanlon, Alicia Corbett & Andrew Sorensen, *The Consumable Vice: Caffeine, Public Health, and the Law*, 27 J. CONTEMP. HEALTH L. & POL'Y 76, 77–78 (2010) (examining the regulation of caffeine and the potential negative impacts of caffeine on children and adolescents); Jennifer L. Pomeranz & Jennifer L. Harris, *Federal Regulation of Infant and Toddler Food and Drink Marketing and Labeling*, 45 AM. J.L. & MED. 32, 37 (2019) (arguing for regulatory action to address the marketing and labeling of foods marketed for infants and toddlers); Javitt, *supra* note 265, at 313–14 (arguing "that FDA can and should do more to implement the NLEA in a manner more meaningful and useful to children and the adults making nutritional choices for them").

272. *See* Leib & Pollans, *supra* note 271.

273. PEW HEALTH GRP., *supra* note 84.

274. Emily C. Bair, *A Narrative Review of Toxic Heavy Metal Content of Infant and Toddler Foods and Evaluation of United States Policy*, FRONTIERS NUTRITION, June 2022, at 1, 1.

275. Ahmed Elghoudi & Hassib Narchi, *Food Allergy in Children—the Current Status and the Way Forward*, 11 WORLD J. CLINICAL PEDIATRICS 253 (2022); AMY M. BRANUM & SUSAN L. LUKACS, CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF NO. 10, FOOD ALLERGY AMONG U.S. CHILDREN: TRENDS IN PREVALENCE AND HOSPITALIZATIONS (2008) https://www.cdc.gov/nchs/data/databriefs/db10.pdf [https://perma.cc/NWG8-LWGZ].

formulas are "food."[276] Accordingly, the food laws apply to infant formulas, although there are also legal requirements specific to infant formula.[277]

Infant feeding has important life-long health implications,[278] and infant formula is the "sole source of nutrition" for many infants,[279] a vulnerable population, "during a critical period of growth and development."[280] For example, most infants (54%) born in 2018 received formula by the time they were three months old.[281] Accordingly, the infant formula shortage threatened children's health.[282] In addition, the shortage may have disproportionally impacted the most vulnerable infants as "[i]nfants in low-income families, infants of color, and infants living in rural communities are more likely to use formula . . . ."[283] Infants in WIC are estimated to consume 56% of the infant formula in the United States.[284] In addition, the recall that precipitated the

276. FDCA § 201(z), 21 U.S.C. § 321(z).

277. *See Questions & Answers for Consumers Concerning Infant Formula, People at Risk of Foodborne Illness*, U.S. FOOD & DRUG ADMIN. (Jan. 9, 2023) [hereinafter *Questions & Answers*], https://www.fda.gov/food/people-risk-foodborne-illness/questions-answers-consumers-concerning-infant-formula#2 [https://perma.cc/8ABW-UX6A]; FDCA § 412, 21 U.S.C. § 350a; 21 C.F.R. §§ 106–107.

278. *The Changing Face of Malnutrition*, UNICEF (2019), https://features.unicef.org/state-of-the-worlds-children-2019-nutrition/ [https://perma.cc/XA4N-EGQC]; Wendy H. Oddy, *Infant Feeding and Obesity Risk in the Child*, 20 BREASTFEEDING REV. 7 (2012).

279. *Formula Safety and Supply: Protecting the Health of America's Babies: Hearing Before the H. Subcomm. On Oversight & Investigations Comm. on Energy & Commerce*, 117th Cong. 3 (2022) (Testimony of Robert M. Califf, Comm'r of Food & Drugs; Frank Yiannas, Deputy Comm'r, Food Pol'y & Response; Susan T. Mayne, Dir., Ctr. for Food Safety & Applied Nutrition) [hereinafter *Hearing Testimony*].

280. *Questions & Answers*, *supra* note 277.

281. Elizabeth Williams & Samantha Artiga, *Key Characteristics of Infants and Implications of the Recent Formula Shortage*, KFF (June 9, 2022), https://www.kff.org/medicaid/issue-brief/key-characteristics-of-infants-and-implications-of-the-recent-formula-shortage/ [https://perma.cc/5BNH-82DF]; *see also* Mathilde Cohen, *Should Human Milk Be Regulated?*, 9 U.C. IRVINE L. REV. 557 (2019) (discussing economic costs of breastfeeding).

282. Amanda Morris, *2 Children Have Been Hospitalized Because of Formula Shortage*, N.Y. TIMES (May 17, 2022), https://www.nytimes.com/2022/05/17/us/baby-formula-shortage-tennessee-hospitalized.html [https://perma.cc/G6FG-2URD]; Press Release, Am. Acad. Pediatrics, *American Academy of Pediatrics Urges White House, Congress to Take Comprehensive, Urgent Action to Address Infant Formula Shortage* (May 19, 2022), https://www.aap.org/en/news-room/news-releases/aap/2022/american-academy-of-pediatrics-urges-white-house-congress-to-take-comprehensive-urgent-action-to-address-infant-formula-shortage/ [https://perma.cc/S824-66HB].

283. *See* Williams & Artiga, *supra* note 281.

284. *Infants in USDA's WIC Program Consumed an Estimated 56 Percent of U.S. Infant Formula*

shortage included lots of two hypoallergenic formulas.[285]

In 2022, concerns about the safety of powdered infant formula led to an investigation following reports of *Cronobacter* illness in infants who had reportedly consumed formula manufactured at an Abbott Nutrition facility in Sturgis, Michigan, between September 2021 and February 2022.[286] There were four reports of *Cronobacter* infections, which may have contributed to two infant deaths.[287] On February 17, 2022, FDA warned consumers not to use certain infant formula products, and the manufacturer voluntarily recalled specific lots of formula manufactured at that facility.[288] The company also temporarily stopped production at the facility.[289] It later expanded the recall to other products. [290] FDA alleged that the formula was adulterated because it was made under insanitary conditions at the facility.[291] The company ultimately entered a consent

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*in 2018*, U.S. DEP'T AGRIC.: ECON. RSCH. SERV. (May 23, 2022), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=103970 [https://perma.cc/Q85Y-SMSY].

285. *FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022)*, U.S. FOOD & DRUG ADMIN. (Aug. 1, 2022), https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022 [https://perma.cc/C48K-A5KB].

286. Press Release, U.S. Food & Drug Admin., FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan (Feb. 17, 2022) [hereinafter Infant Formula], https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility [https://perma.cc/8LBT-6HKX]; U.S. FOOD & DRUG ADMIN., IMMEDIATE NATIONAL STRATEGY TO INCREASE THE RESILIENCY OF THE U.S. INFANT FORMULA MARKET (2023) [hereinafter NATIONAL STRATEGY].

287. Infant Formula, *supra* note 286.

288. *Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant*, U.S. FOOD & DRUG ADMIN. (Feb. 17, 2022), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant [https://perma.cc/F33F-38RH].

289. NATIONAL STRATEGY, *supra* note 286, at 2.

290. *Id.*; Press Release, Abbott, Abbott is Restarting Similac Production at Sturgis (Aug. 26, 2022) [hereinafter Press Release, Abbott], https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html [https://perma.cc/LLT3-B8EM].

291. Complaint for Permanent Injunction, United States v. Abbott Lab'ys, No. 1:22-cv-00441 (W.D. Mich. Filed May 16, 2022), https://www.justice.gov/d9/press-releases/attachments/2022/05/16/abbott_complaint_0.pdf [https://perma.cc/982C-TE87]; Consent Decree of Permanent Injunction, United States v. Abbott Lab'ys, No. 1:22-cv-00441 (W.D. Mich. Filed May 16, 2022); Press Release, U.S. Food & Drug Admin., FDA Provides New

decree, which allowed it to resume manufacturing powdered infant formula at the facility at issue, which it did in the summer of 2022.[292]

The recall and temporary cessation of production set off an infant formula shortage, which COVID-19-related supply chain issues exacerbated.[293] The formula industry "is highly concentrated" with just four companies accounting for almost the entire U.S. market, and Abbott constituting an estimated 58% of the market.[294] FDA described the factors contributing to the shortage as "a 'perfect' storm resulting in the supply chain disruption in 2022 that affected the entire U.S. market."[295] The estimated out-of-stock rate reached 74% nationally at the end of May 2022.[296]

While the factors contributing to the shortage were complex and would require an analysis beyond the scope of this Article, delays and structural challenges at FDA likely contributed.[297] A former Deputy Commissioner in FDA's Office of Food Policy and Response testified before a House Oversight Committee subcommittee, "With siloed groups in the FDA's decentralized Foods Program, it is impossible for leaders . . . to have clear line of sight on what was happening or to set processes in place to help

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Updates on Activities to Mitigate Infant Formula Supply Challenges, Abbott Nutrition Agrees to Take Corrective Actions at Facility to Produce Safe Infant Formula (May 16, 2022), https://www.fda.gov/news-events/press-announcements/fda-provides-new-updates-activities-mitigate-infant-formula-supply-challenges-abbott-nutrition/ [https://perma.cc/X2PB-EWTV].

292. Press Release, U.S. Dep't of Just.: Off. of Pub. Affs., Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula (May 16, 2022), https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott [https://perma.cc/GE22-L6ZY]; Press Release, Abbott, *supra* note 290.

293. NATIONAL STRATEGY, *supra* note 286, at 2.

294. DONNELL VILLARUEL, IBISWORLD, INDUS. REP. OD4287, INFANT FORMULA MANUFACTURING IN THE US (2023).

295. NATIONAL STRATEGY, *supra* note 286, at 4.

296. Martine Paris, *One in Five U.S. States is 90% Out of Baby Formula,* BLOOMBERG (June 2, 2022, 1:03 PM), https://www.bloomberg.com/news/articles/2022-06-02/us-baby-formula-shortages-hit-74-despite-biden-action [https://perma.cc/KUW9-S5KY].

297. *See generally* U.S. FOOD & DRUG ADMIN., FDA EVALUATION OF INFANT FORMULA RESPONSE (2022), https://www.fda.gov/media/161689/download [https://perma.cc/V6WE-9DH2] (reporting on an internal FDA review of the agency's infant formula response); REAGAN-UDALL FOUND., OPERATIONAL EVALUATION OF THE FDA HUMAN FOODS PROGRAM (2022), https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf [https://perma.cc/YF2L-H986] (reporting on an independent evaluation of FDA's Human Foods Program, including the agency's response to the "infant formula crisis").

catch these critical public health concerns."[298] Following hearings on the shortage,[299] Congress enacted provisions for "critical food[s]," including infant formula.[300] It directed FDA to develop a national strategy on infant formula and the Secretary to establish an Office of Critical Foods within FDA's CFSAN.[301] In March 2023, FDA released an Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market.[302]

*b. "Heavy Metals"*

Asking the child question about the regulation of lead, arsenic, cadmium, and mercury, often referred to as "heavy metals," in food also highlights FDA's limits in protecting and promoting children's health. These metals and metalloid have been found in foods, including foods marketed for babies and young children and other foods they commonly eat (baby foods).[303]

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298. *FDA Oversight Part 1: The Infant Formula Shortage: Hearing Before the H. Subcomm. on Health Care & Fin. Servs. of the H. Comm. on Oversight & Accountability*, 118th Cong. at 6 (2023), https://www.congress.gov/118/meeting/house/115566/witnesses/HHRG-118-GO27-Wstate-YiannasF-20230328.pdf [https://perma.cc/7P4G-L9PN] (testimony of Frank Yiannas, Prior FDA Deputy Comm'r, Food Policy & Response); *see also* REAGAN-UDALL FOUND., *supra* note 297, at 12 ("In the absence of a clear vision, mission or definition, or broader identification and engagement with the Human Foods Program, FDA staff often operate in silos within the organizations or subcultures . . . . For example, during the aforementioned infant formula foodborne-illness outbreak and subsequent product shortage, a review of events indicates that lack of communication and engagement across the Agency accounted, in part, for missteps.").

299. *FDA Oversight Part 1: The Infant Formula Shortage: Hearing Before the H. Subcomm. on Health Care & Fin. Servs. of the H. Comm. on Oversight & Accountability*, 118th Cong. (2023); *FDA Oversight Part II: Responsibility for the Infant Formula Shortage*: *Hearing Before the H. Subcomm. on Health Care & Fin. Servs. of the H. Comm. on Oversight & Accountability*, 118th Cong. (2023); *Infant Formula Crisis: Addressing the Shortage and Getting Formula on Shelves: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, 117th Cong. (2022).

300. *See* Consolidated Appropriations Act, 2023, tit. III, Food and Drug Omnibus Reform Act § 3401, Pub. L. 117-328 (Dec. 29, 2022) (codified as amended at 21 U.S.C.A. § 321(ss)).

301. Food and Drug Omnibus Reform Act § 3401(b), (j) (codified as amended at 21 U.S.C.A. § 350a–1(b), (j)).

302. NATIONAL STRATEGY, *supra* note 286.

303. *See* U.S. FOOD & DRUG ADMIN., ANALYTICAL RESULTS FOR ARSENIC IN FOOD INTENDED FOR BABIES AND YOUNG CHILDREN SAMPLED UNDER THE FDA'S TOXIC ELEMENTS IN FOOD AND FOODWARE, AND RADIONUCLIDES IN FOOD—IMPORT AND DOMESTIC COMPLIANCE PROGRAM (FY2009–FY2021) (2022), https://www.fda.gov/

A U.S. House subcommittee, following reports of heavy metals in baby foods, requested information from seven of the largest US manufacturers—four responded.[304] The report noted, "[i]nternal company test results obtained by the Subcommittee confirm that all responding baby food manufacturers sold baby foods tainted by high levels of toxic heavy metals."[305]

The presence of lead, cadmium, arsenic, and mercury in food results from their natural occurrence and human activity (e.g., mining, ore smelting, pesticides, and industrial and product uses).[306] These substances have been linked and associated with health concerns, and children are particularly vulnerable.[307] For example, there is no safe level of exposure to

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media/164564/download?attachment [https://perma.cc/PXB3-65JG]; Patrick Gray, *A Survey of Toxic Elements in Ready to Eat Baby Foods in the U.S. Market 2021*, 16 FOOD ADDITIVES & CONTAMINANTS: PART B 79 (2023).

304. BABY FOODS, *supra* note 2, at 2. The subcommittee expressed concern in its February 2021 report that three of the manufacturers "refused to cooperate with the Subcommittee's investigation." *Id.* A second report in September 2021, noted the "companies began cooperating to varying degrees," but "[t]he Subcommittee's investigation continues to reveal that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium." SUBCOMM. ON ECON. & CONSUMER POL'Y, COMM. ON OVERSIGHT & REFORM, U.S. HOUSE OF REPRESENTATIVES, NEW DISCLOSURES SHOW DANGEROUS LEVELS OF TOXIC METALS IN EVEN MORE BABY FOODS 1, 2, 25 (2021), https://oversight democrats.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby %20Food%20Report%209.29.21%20FINAL.pdf [https://perma.cc/N5W6-3KT9].

305. BABY FOODS, *supra* note 2, at 13.

306. *Arsenic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 2009), https://www.cdc.gov/biomonitoring/pdf/arsenic_factsheet.pdf [https://perma.cc/X7JP-3XCD]; *Cadmium Factsheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 7, 2017), https://www.cdc.gov/biomonitoring/Cadmium_FactSheet.html [https://perma.cc/5PLM-PRWX]; *Mercury Factsheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 7, 2017), https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html [https://perma.cc/K28R-JXPL]; *Lead Factsheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 7, 2017), https://www.cdc.gov/biomonitoring/lead_factsheet.html [https://perma.cc/7UH6-CYWE].

307. *Help Protect Children from Environmental Contaminants: Health Food Choices for Your Baby Aged 6-12 Months*, U.S. FOOD & DRUG ADMIN. (Jan. 24, 2023), https://www.fda.gov/food/environmental-contaminants-food/help-protect-children-environmental-contaminants-healthy-food-choices-your-baby-aged-6-12-months [https://perma.cc/2NYH-KMJ6]; *Mercury in Food and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2023), https://www.fda.gov/food/environmental-contaminants-food/mercury-food-and-dietary-supplements [https://perma.cc/FXN3-FZC3]; *Arsenic in Food and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (June 1, 2023), https://www.fda.gov/food/environmental-contaminants-food/arsenic-food-and-dietary-supplements [https://perma.cc/XRH8-G2TF] (same with respect to arsenic); *Lead in Food, Foodwares, and Dietary Supplements*, U.S. FOOD &

lead.[308] Lead can damage the ability of children to learn and, at higher levels, damage "kidneys, blood, and nervous system" and cause "coma, convulsions, or death."[309] "[Y]oung children face the most danger from exposure to lead because their growing bodies are more prone to harm and [they] absorb lead more easily than . . . adults . . . ."[310]

In 2021, to reduce children's exposure to these contaminants from food, FDA released a multi-phase action plan, "Closer to Zero," which is to culminate in final action levels for each element in baby foods.[311] FDA has indicated that once it has published final action levels, it "will establish a timeframe for assessing industry's progress toward meeting the action levels" and resume evaluating scientific data to determine whether to adjust the action levels.[312]

However, FDA's use of action levels to address contaminants in food has significant limitations. Action levels are not binding.[313] They are "a level of contamination at which a food *may* be regarded as adulterated" under FDCA § 402(a)(1).[314] FDA considers action levels in deciding whether to enforce the FDCA's adulteration provision.[315] Indeed, FDA is seeking "new authority [from Congress] to establish *binding* contamination limits in foods, including those consumed by infants and young children, via an administrative order process," noting that it currently "has limited tools to help reduce exposure to toxic elements in the food supply."[316]

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DRUG ADMIN. (Mar. 1, 2023), https://www.fda.gov/food/environmental-contaminants-food/lead-food-foodwares-and-dietary-supplements [https://perma.cc/SC5D-BJ4R] (same lead); *see also* sources cited *supra* note 306. *But see* Brenna M. Flannery, Heather R. Schaefer & Karlyn B. Middleton, *A Scoping Review of Infant and Children Health Effects Associated with Cadmium Exposure*, 131 REGUL. TOXICOLOGY & PHARMACOLOGY 1 (2022) ("[T]he adverse effects of cadmium exposure in infants and children are not well studied.").

308. *See, e.g.*, *Lead Factsheet*, *supra* note 306.

309. *Id.*

310. *Id.*

311. *Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods*, U.S. FOOD & DRUG ADMIN. (Aug. 10, 2023) [hereinafter *Closer to Zero*], https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods [https://perma.cc/H2LM-AH9L].

312. *Id.*

313. *Id.*

314. *Id.* (emphasis added).

315. *Id.*

316. U.S. FOOD & DRUG ADMIN., SUMMARY OF FY 2024 LEGISLATIVE PROPOSALS 3 (2023), https://www.fda.gov/media/166049/download [https://perma.cc/GVP7-HJH7] (emphasis added).

This is not the first time that FDA has proposed or used action levels for contaminants in food.[317] FDA's previous efforts have been subject to substantial delays. During delays, the risk assessments the action levels are based on may become outdated.[318]

FDA's efforts to reduce arsenic in certain foods are illustrative. There are two types of arsenic—organic and inorganic—both of which have been found in food, but current research suggests that inorganic arsenic is more toxic than organic.[319] While FDA has indicated that the levels of inorganic arsenic that have been reported in food are "not a concern in terms of immediate toxicity at the levels seen in food," they "may be a health concern when they are consumed long-term."[320] Long-term inorganic arsenic consumption is "associated with . . . cancer, skin lesions,

317. *See, e.g.*, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed*, U.S. FOOD & DRUG ADMIN. (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed [https://perma.cc/96M2-PZ3P]; *Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children*, U.S. FOOD & DRUG ADMIN. (Sept. 20, 2018) [hereinafter *Lead in Candy*], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children [https://perma.cc/NKU6-LF9C]; U.S. FOOD & DRUG ADMIN., INORGANIC ARSENIC IN RICE CEREALS FOR INFANTS: ACTION LEVEL GUIDANCE FOR INDUSTRY (2020) [hereinafter ARSENIC IN RICE CEREALS], https://www.fda.gov/media/97234/download [https://perma.cc/EBM3-CRD3]; U.S. FOOD & DRUG ADMIN., ACTION LEVEL FOR INORGANIC ARSENIC IN APPLE JUICE: GUIDANCE FOR INDUSTRY (2023), https://www.fda.gov/media/86110/download [https://perma.cc/637N-RDYH].

318. *See, e.g.*, Tom Neltner, *A Closer Look at FDA's "Closer to Zero" Plan to Reduce for Heavy Metals in Children's Food*, ENV'T DEF. FUND (Apr. 21, 2021), https://blogs.edf.org/health/2021/04/21/a-closer-look-at-fdas-closer-to-zero-plan-to-reduce-for-heavy-metals-in-childrens-food/ [https://perma.cc/2GJ7-KZCH] ("[T]he draft action levels were proposed in 2016 and 2013 respectively. It took so long that the risk assessment on which the proposals were based is already outdated. In the intervening years, the evidence of arsenic exposure and neurological harm which were deemed insufficient to quantify the risk five years ago has become even more compelling.").

319. *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants [https://perma.cc/FG3R-GXKA]; FDA CTR. FOR FOOD SAFETY & APPLIED NUTRITION, ARSENIC IN RICE AND RICE PRODUCTS RISK ASSESSMENT REPORT 2 (2016), https://www.fda.gov/media/96071/download [https://perma.cc/GB3T-Y37Q].

320. FDA CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 319, at 2.

cardiovascular disease, neurodevelopmental toxicity, adverse pregnancy outcomes, non-malignant lung disease, and diabetes."[321]

In July 2013, FDA announced draft guidance that proposed an action level for inorganic arsenic in apple juice.[322] FDA did not finalize the non-binding guidance until almost a decade later in June 2023.[323] Between the draft and final guidance, FDA "identified some apple juice samples with inorganic arsenic levels above 10 [parts per billion]"—the action level in the draft and final guidance—although FDA noted its "testing results reflect a trend in reductions in the amount of inorganic arsenic in apple juice."[324] In April 2016, FDA proposed an action level of 100 ppb for inorganic arsenic in infant rice cereal, stating that inorganic arsenic exposure early in life is associated with adverse neurological effects.[325] FDA also noted that it "recognizes that infant rice cereal is a common 'starter' food for infants and notes that the American Academy of Pediatrics specifically encourages consumption of iron-fortified cereals for infants and toddlers."[326] FDA reported that sampling after the draft guidance showed that 76% of samples were at or below the proposed action level of 100 ppb, which means nearly a quarter exceeded it.[327] FDA did not finalize the guidance and the 100 ppb action level, which are not binding, until August 2020.[328]

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321. *Id.* at 19.

322. 78 Fed. Reg. 42,086 (July 15, 2013).

323. 88 Fed. Reg. 36,319 (June 2, 2023).

324. *FDA Issues Final Guidance to Industry on Action Level for Inorganic Arsenic in Apple Juice*, U.S. FOOD & DRUG ADMIN. (June 1, 2023) [hereinafter *Arsenic in Apple Juice*], https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-guidance-industry-action-level-inorganic-arsenic-apple-juice [https://perma.cc/C2QG-R8N8]; *see also* 78 Fed. Reg. 42,086 (July 15, 2013).

325. *See* Press Release, U.S. Food & Drug Admin., FDA Proposes Limit for Inorganic Arsenic in Infant Rice Cereal (Apr. 19, 2016), https://www.fda.gov/news-events/press-announcements/fda-proposes-limit-inorganic-arsenic-infant-rice-cereal [https://perma.cc/3CKJ-JZEA] (discussing draft guidance on inorganic arsenic in infant rice cereal).

326. *Id.*

327. *FDA Makes Available Results from Testing of Infant Rice Cereal for Inorganic Arsenic*, U.S. Food & Drug Admin. (Mar. 6, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-makes-available-results-testing-infant-rice-cereal-inorganic-arsenic [https://perma.cc/9ZJ3-FHTG]. FDA did note in 2020 that sample results showed progress in meeting the proposed action level. *Id.*

328. ARSENIC IN RICE CEREALS, *supra* note 317; Press Release, U.S. Food & Drug Admin., FDA In Brief: FDA Takes Action to Limit Inorganic Arsenic Levels in Infant Rice Cereal (Aug. 5, 2020), https://www.fda.gov/news-events/fda-newsroom/fda-brief-fda-takes-action-limit-inorganic-arsenic-levels-infant-rice-cereal [https://perma.cc/7NH6-RAH4].

To date, FDA has not proposed action levels for arsenic in baby foods, and a chart of FDA's planned action items lists "develop action levels and submit draft guidance for interagency review" for 2024.[329] FDA appears to have fallen behind the timeline it announced previously for its Closer to Zero action.[330]

Thus, while FDA indicated in a recent press release that "protecting one of our most vulnerable populations, babies and young children, is among [its] highest priorities," much remains to be done.[331] Groups have critiqued the proposed action levels as being too limited, for example, expressing concern that "FDA did not set action levels for lead in [baby] snack foods like teething biscuits and puffs, which some tests have shown have higher lead levels than other baby foods" and that limits for some foods may not be strict enough.[332]

*4. Asking the Child Question About Cosmetics Regulation*

FDA's cosmetics mission is to "protect[] the public health . . . by

329. *Closer to Zero*, *supra* note 311.

330. *Compare Closer to Zero: Action Plan for Baby Foods*, U.S. FOOD & DRUG ADMIN. (Oct. 8, 2021), https://web.archive.org/web/20211018071615/https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods#Introduction (listing April 2021-April 2022 for proposing draft action levels for lead in "categories of foods consumed by babies and young children"), *with Closer to Zero*, *supra* note 311 (indicating draft guidance was issued in January 2023).

331. Press Release, U.S. Food & Drug Admin., FDA Releases Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies, Young Children (Apr. 8, 2021), https://www.fda.gov/news-events/press-announcements/fda-releases-action-plan-reducing-exposure-toxic-elements-foods-babies-young-children [https://perma.cc/S7L2-PGK8]; *see Closer to Zero*, *supra* note 311 (including a chart of planned action items with dates).

332. Kevin Loria, *FDA Proposes New Limits for Lead in Baby Foods*, CONSUMER REPS. (Jan. 24, 2023), https://www.consumerreports.org/babies-kids/baby-food/fda-proposes-new-limits-for-lead-in-baby-foods-a2167994237/ [https://perma.cc/G63N-8QTN]; *see also* Neltner, *supra* note 318; *Summary of FY 2024 Legislative Proposals*, *supra* note 316, at 3 (seeking to amend the FDCA and stating that allowing FDA to establishing binding limits thorough the administrative order process "would improve the efficiency, timeliness, and predictability of issuing binding limits to reduce exposure to toxic elements by these vulnerable populations, and updating limits as new scientific information becomes available"); Press Release, U.S. Food & Drug Admin., FDA Announces New Actions Aimed at Further Reducing Toxic Elements in Food for Babies, Young Children (Mar. 5, 2021), https://www.fda.gov/news-events/press-announcements/fda-announces-new-actions-aimed-further-reducing-toxic-elements-food-babies-young-children [https://perma.cc/V28F-Z6MS].

ensuring the safety of . . . cosmetics,"[333] which includes the safety of cosmetics marketed to and used by children. The FDCA defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance," as well as components of such articles.[334] Cosmetics include shampoos, conditioners, body washes and cleansers, diapers and baby wipes, lotions, baby powders, and makeup.[335]

Children are exposed to cosmetics, often from birth.[336] For example, newborns are bathed with "liquid soap" before leaving the hospital following birth.[337] The cosmetics that children use or are exposed to and the frequency of that exposure may differ, but cosmetic use on or by children is widespread.[338] Thus, cosmetic safety implicates children's safety.

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333. *What We Do*, *supra* note 6.

334. FDCA § 201(i), 21 U.S.C. § 321(i) (2012). "Cosmetics" excludes soap, which is defined narrowly, but many products that are commonly referred to as soap do not meet the legal definition of soap and are "cosmetics." *Id.* at 201(i)(2); *see also* 21 C.F.R. § 701.20. The term "personal care products" while not identical to "cosmetics" includes "cosmetics" as defined by the FDCA. *Are All "Personal Care Products" Regulated As Cosmetics?*, U.S. FOOD & DRUG ADMIN. (June 16, 2022), https://www.fda.gov/industry/fda-basics-industry/are-all-personal-care-products-regulated-cosmetics [https://perma.cc/TD7A-CGKR].

335. *See Cosmetic Products*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetic-products-ingredients/cosmetic-products [https://perma.cc/Q86U-JP5U]; *Talc*, U.S. FOOD & DRUG ADMIN. (Dec. 7, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/talc [https://perma.cc/U3SE-SQ53].

336. *See, e.g.*, Xiangmei (May) Wu, Deborah H. Bennett, Beate Ritz, Diana L. Cassady, Kiyoung Lee & Irva Hertz-Picciotto, *Usage Pattern of Personal Care Products in California Households*, 48 FOOD & CHEM. TOXICOLOGY 3109 (2010) (reporting on cosmetic use in children ages zero to one); Julia A. Wisniewski, Carrie A. Phillipi, Neera Goyal, Anna Smith, Alice E.W. Hoyt, Elizabeth King, et al., *Variation in Newborn Skincare Policies Across United States Maternity Hospitals*, 11 HOSP. PEDIATRICS 1010 (2021). Indeed, exposure often begins before birth. *See* Andrea L. Deierlein, Alexis R. Grayon, Xiaotong Zhu, Yanwen Sun, Xun Liu, Kaelyn Kohlasch, et al., *Personal Care and Household Cleaning Product Use among Pregnant Women and New Mothers during the COVID-19 Pandemic*, 19 INT'L J. ENV'T RSCH. & PUB. HEALTH 5645 (2022).

337. Wisniewski et al., *supra* note 336, at 1013.

338. Eleanor A. Medley, Kendall E. Kruchten, Miranda J. Spratlen, Maricela Ureño, Anabel Cole, Rashmi Joglekar, et al., *Usage of Children's Makeup and Body Products in the United States and Implications for Childhood Environmental Exposures*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Feb. 2023, at 1–2, 13–15 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9915933/pdf/ijerph-20-02114.pdf; Wu et al., *supra* note 336; Samantha Critchell, *Girls' Interest in Makeup Fades with Age*, TODAY (Aug. 5, 2010, 9:22 AM), https://www.today.com/

Children's cosmetic use and exposure also vary, for example, by age, gender, race, and ethnicity.[339] In prior work, I examined cosmetics as a gendered product category often associated with women and argued that the risks that cosmetics may pose may disproportionately impact women.[340] This Article builds on that work and considers the impacts of cosmetics on children, including girls. A higher percentage of teen girls use some categories of cosmetics than women ages eighteen to thirty-four.[341] For example, one survey found that 77% of teen girls ages twelve to seventeen use nail polish/nail care products compared with 71% of women aged eighteen to thirty-four.[342] Young girls often use these products as well, with one study finding that 45% of girls under five use nail polish.[343] While boys use cosmetics, studies have found that a higher percentage of girls use them,[344] and the types of cosmetics girls and boys use differ. For example, a significantly higher percentage of girls aged six to eight report using lipstick and lip gloss than boys the same age: 45% versus 5%.[345] Additionally, usage of and exposure to cosmetics differ among children of different racial and ethnic groups.[346] For example, in one survey, "almost half of the

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news/girls-interest-makeup-fades-age-wbna38566212 [https://perma.cc/28ML-D86H]; *Beauty is Child's Play: 80% of US Tweens Use Beauty and Personal Care Products*, MINTEL (July 28, 2016) [hereinafter *Child's Play*], https://www.mintel.com/press-centre/beauty-and-personal-care/beauty-is-childs-play-80-of-us-tweens-use-beauty-and-personal-care-products [https://perma.cc/2QBQ-RBN8].

339. *See infra* notes 341–348 and accompanying text; Boyd, *Gender, Race & Inadequate Regulation of Cosmetics*, *supra* note 49, at 289.

340. Boyd, *Gender, Race & Inadequate Regulation of Cosmetics, supra note* 49, at 284.

341. TEEN AND TWEEN BEAUTY AND PERSONAL CARE CONSUMER U.S., MAY 2016, MINTEL (2016) [hereinafter TEEN AND TWEEN BEAUTY AND PERSONAL CARE CONSUMER] (on file with author).

342. *Id.*

343. Wu et al., *supra* note 336.

344. *Child's Play*, *supra* note 338. "[90%] of girls aged [nine to seventeen] are beauty product users," compared with 69% of boys the same age. *Id.* Similarly, studies have found that a higher percentage of women use cosmetics than men and they may use more of them. *See* Peter Moore, *Poll Results: Getting Ready*, YOUGOV (Sept. 12, 2013, 6:26 PM), http://cdn.yougov.com/cumulus_uploads/document/ypg8eyjbsv/tabs_skincare_0910112013.pdf [https://perma.cc/9JG7-4KCC]; *Exposures Add Up –Survey Results*, ENV'T WORKING GRP. (Dec. 15, 2004), https://www.ewg.org/news-insights/news/2004/12/exposures-add-survey-results [https://perma.cc/437L-YGR5].

345. *See also Child's Play*, *supra* note 338 (tween and teen beauty routines).

346. Medley et al., *supra* note 338; Jessica S. Helm, Marcia Nishioka, Julia Green Brody, Ruthann A. Rudel & Robin E. Dodson, *Measurement of Endocrine Disrupting and Asthma-Associated Chemicals in Hair Products Used by Black Women*, 165 ENV'T RSCH. 448, 448–49 (2018).

parents/guardians reported first application of chemical relaxers to their [Black daughter's] hair between the ages of [four] and [eight]."[347] Another survey found that a higher percentage of Hispanic teens aged nine to seventeen reported using beauty or personal care products than non-Hispanic white or Black teens.[348]

Congress gave FDA the authority to regulate cosmetics in the 1938 FDCA.[349] In late 2022, Congress enacted the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).[350] Cosmetics law had long lagged behind that of other FDA-regulated products, and MoCRA expanded FDA's cosmetics authority. For example, it requires adverse event reporting, facility registration, and product listing.[351] It also gave FDA mandatory recall authority over cosmetics, requires FDA to establish good manufacturing practice regulations for cosmetic facilities, and gives FDA access to cosmetic product records under certain conditions.[352] MoCRA also requires that cosmetic manufacturers ensure that a cosmetic product has "adequate substantiation of safety" and that producers maintain reports supporting this.[353] Safe is defined to "mean[] that the cosmetic product, including any

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347. *See* Ami R. Zota & Bhavna Shamasunder, *The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as a Health Disparities Concern*, 217 AM. J. OBSTETRICS & GYNECOLOGY 418, 419 (2017); Dakara Rucker Wright, Raechele Gathers, Alissa Kapke, Dayna Johnson & Christine L.M. Joseph, *Hair Care Practices and Their Association With Scalp and Hair Disorders in African American Girls,* 64 J. AM. ACAD. DERMATOLOGY 253, 256 (2011); Symielle A. Gaston, Tamarra James-Todd, Quaker Harmon, Kyla W. Taylor, Donna Baird & Chandra L. Jackson, *Chemical/Straightening and Other Hair Product Usage During Childhood, Adolescence, and Adulthood Among African-American Women: Potential Implications for Health*, 30 J. EXPOSURE SCI. & ENV'T EPIDEMIOLOGY 86, 89 (2019).

348. CLARE HENNIGAN, MINTEL, COLOR COSMETICS - U.S. - 2021 43 (2021); TEEN AND TWEEN BEAUTY AND PERSONAL CARE CONSUMER, *supra* note 341, at 17, 25, 47, 50.

349. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

350. Consolidated Appropriations Act of 2023, Pub. L. No. 117-328 §§ 3501–3508. For an analysis and critique of MoCRA, see Janet Nudelman, *Modernization of Cosmetics Regulation Act of 2022 (MOCRA): Section-by-Section Analysis*, CAMPAIGN FOR SAFE COSMS. (2023), https://www.safecosmetics.org/wp-content/uploads/2023/01/Cosmetic-Safety-Law-Reform_CSC-Section-by-Section-Analysis-1_10_23.pdf [https://perma.cc/9ZZX-B592].

351. Consolidated Appropriations Act of 2023, Pub. L. No. 117-328 sec. 3502 (FDCA §§ 605, 607, 21 U.S.C. 364a, 364c).

352. *Id.* (FDCA §§ 606, 610, 611, 21 U.S.C. 364b, 364f, 364g).

353. *Id.* (FDCA § 608(a), 21 U.S.C. § 364d(a)). This requirement does not apply to coal-tar hair dye that complies with § 608(a). *Id.* (FDCA § 608(b), 21 U.S.C. § 364d(b)).

ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling . . . or . . . as are customary or usual."[354] However, a product or ingredient will not be considered injurious "solely because it can cause minor and transient reactions or . . . skin irritations in some users."[355] MoCRA also includes labeling requirements as well as provisions concerning talc-containing cosmetics and perfluoroalkyl and polyfluoroalkyl substances (PFAS).[356] While Congress has required that some FDA-regulated products be approved before they can be lawfully sold, there is no comparable requirement for cosmetics.[357] Instead, even with MoCRA, FDA's cosmetics regulation is largely post-market regulation, based on the FDCA's adulteration and misbranding provisions.[358]

When this Article was written, MoCRA—effective December 29, 2023—had not yet gone into effect.[359] Accordingly, its effects and implementation remain to be seen. The issues discussed in this Article occurred before the Act was effective. While MoCRA makes some important changes to the law that will likely help FDA advance cosmetic safety, gaps will likely remain.

As discussed above, children may be uniquely vulnerable to toxins because of their small size, behavioral patterns, and rapid growth and development.[360] These usage differences may have health implications.[361] One challenge in the cosmetic area is that safety information is often limited and focused on short-term reactions rather than long-term health problems.[362] MoCRA is

354. *Id.* (FDCA § 608(c), 21 U.S.C. § 364d(c)).

355. *Id.* (FDCA § 608(c)(2), 21 U.S.C. § 364d(c)(2)).

356. *Id.* sec. 3502, 3505–06 (FDCA § 609, 21 U.S.C. § 364e).

357. *See, e.g.*, FDCA § 409, 21 U.S.C. § 348 (food additives); FDCA § 505, 21 U.S.C. § 355 (drugs); FDCA § 515, 21 U.S.C. § 360e (devices); PHSA § 351, 42 U.S.C. § 262 (biologics). *But see supra* note 73 (regarding color additives).

358. *See* FDCA chpt. VI (cosmetics).

359. Consolidated Appropriations Act of 2023, Pub. L. No. 117-328 § 3503(b).

360. *Why Are Children Often Especially Susceptible to the Adverse Effects of Environmental Toxicants?*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY (May 25, 2023), https://www.atsdr.cdc.gov/csem/pediatric-environmental-health/why_children.html [https://perma.cc/T8T6-8WSD]; Maria J. Carroquino, M. Posada & P.J. Landrigan, *Environmental Toxicology: Children at Risk*, *in* ENVIRONMENTAL TOXICOLOGY 239, 244–45 (Edward A. Laws ed., 2012); Medley et al., *supra* note 338.

361. *See* Gaston et al., *supra* note 347.

362. Rajiv Shah & Kelly E. Taylor, Note, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENV'T. L. REV. 203, 204 (2011); *see* Ivan J. Boyer, Wilma F. Bergfeld, Bart Heldreth, Monice M. Fiume & Lillian J. Gill, *The Cosmetic Ingredient Review Program—Expert Safety Assessments of Cosmetic Ingredients in an Open*

unlikely to resolve this issue because it does not clearly require that cosmetic ingredients be tested for long-term health effects.[363]

Cosmetics may contain toxic chemicals as ingredients or contaminants.[364] For example, asbestos, lead,[365] mercury,[366] and other contaminants have been reportedly found in cosmetics.[367] Questions have been raised about the safety of cosmetics ingredients, including diethanolamine (DEA) and DEA-related ingredients, parabens, phthalates, and nanomaterials.[368]

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*Forum*, 36 INT'L J. TOXICOLOGY (SUPP. 2) 5S, 7S–10S (2017); *Toxic Beauty*, HARV. HEALTH PUB. (Apr. 1, 2020), https://www.health.harvard.edu/womens-health/toxic-beauty [https://perma.cc/YUA5-72CN]; *see also* Nicole M. Niehoff, Mandy Goldberg & Alexandra J. White, *The Importance of Addressing Early Life Environmental Exposures in Cancer Epidemiology*, 9 CURRENT EPIDEMIOLOGY REP. 49 (2022).

363. Nudelman, *supra* note 350.

364. *See Probing Personal Care Products: Look Out for Harmful Ingredients*, NIH NEWS IN HEALTH (Aug. 2022), https://newsinhealth.nih.gov/2022/08/probing-personal-care-products [https://perma.cc/5CUA-KBZQ].

365. *Lead in Cosmetics*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/lead-cosmetics [https://perma.cc/TVX8-E9KY].

366. This is even though mercury is largely prohibited in cosmetics. *See* 21 C.F.R. § 700.13; *see also FDA's Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content, Potential Contaminants in Cosmetics*, U.S. FOOD & DRUG ADMIN. (Mar. 3, 2022) [hereinafter *Potential Contaminants*], https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/fdas-testing-cosmetics-arsenic-cadmium-chromium-cobalt-lead-mercury-and-nickel-content [https://perma.cc/962T-PHNW].

367. *Potential Contaminants*, *supra* note 366.

368. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS (2014) https://www.fda.gov/media/83957/download [https://perma.cc/37AH-PPYX]; *Cosmetic Ingredients*, U.S. FOOD & DRUG ADMIN. (May 19, 2022), https://www.fda.gov/cosmetics/cosmetic-products-ingredients/cosmetic-ingredients [https://perma.cc/X5PG-ZK56]. For discussions of cosmetics and their risks, see, for example, Morgan G. Egeberg, *Beauty is Pain*, 23 QUINNIPIAC HEALTH L.J. 303, 322–25 (2000); Shah & Taylor, *supra* note 362, at 212 (permanent hair relaxers); Jessica C. Dixon, *The Perils of Body Art: FDA Regulation of Tattoo and Micropigmentation Pigments*, 58 ADMIN. L. REV. 667, 682 (2006) (tattoo and micropigmentation inks); Carrie Griffin Basas, *Henna Tattooing: Cultural Tradition Meets Regulation*, 62 FOOD & DRUG L.J. 779, 791 (2007) (henna and henna containing PPD and lead); Sarah A. Walsh, Note & Comment, *Beyond the Polish: An Examination of Hazardous Conditions in Nail Salons and Potential Solutions for the Industry in New York City*, 21 J.L. & POL'Y 243, 256–60 (2012) (nail salon products); Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1340–44 (2008); Donald R. Johnson, *Not in My Makeup: The Need for Enhanced Premarket Regulatory Authority over Cosmetics in Light of Increased Usage of Engineered Nanoparticles*, 26 J. CONTEMP. HEALTH L. & POL'Y 82, 94–102 (2009);

Asking the child question about the regulation of contaminants in cosmetics highlights its limitations. Children may be exposed to lead by cosmetics.[369] For example, FDA has warned consumers to avoid "traditional eye cosmetics containing kohl" as they may present a risk of lead poisoning in adults and children.[370] FDA has issued draft guidance with a recommended maximum lead level in cosmetic lip products and externally applied cosmetics.[371] Like FDA's guidance on heavy metals in food, as guidance, it is not binding.[372] And, like FDA's guidance regarding arsenic in infant rice cereal and apple juice, it has been subject to substantial delay.[373] When this Article was written, FDA had not finalized the 2016 draft guidance.

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Robin Fretwell Wilson, *Nanotechnology: The Challenge of Regulating Known Unknowns*, 34 J.L. MED. & ETHICS 704, 705–06, 708–09 (2006) (nanoparticles); Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 PACE ENV'T L. REV. 595, 607–11 (2014); Anastasia De Paz, *The Cosmetic Regime Needs A Makeover: Advocating to Empower the FDA Through the Safe Cosmetics Act of 2011*, 31 TEMP. J. SCI. TECH. & ENV'T L. 337, 340–42 (2012) (chemicals that may disrupt the endocrine system); Sharon E. Jacob, Tamar Zapolanski, Pamela Chayavichitsilp, Elizabeth Alvarez Connelly & Lawrence F Eichenfield, Commentary, *p-Phenylenediamine in Black Henna Tattoos: A Practice in Need of Policy in Children,* 162 ARCHIVES PEDIATRICS & ADOLESCENT MED. 790, 791 (2008); Grace Wallack, Note, *Rethinking FDA's Regulation of Cosmetics,* 56 HARV. J. ON LEGIS. 311, 324 (2019) (various); Emily Jones, Note, *Stripped from Sunscreen, But Fine for Foundation: How the Regulatory Dichotomy of Topically Applied Skin Products Endangers Women*, 35 WIS. J.L. GENDER, & SOC'Y 143, 154 (2020) (triclosan and other ingredients); Jessica M. Dugdale, Note, *A Plea for Consumer Protection: The Potential Human Health Hazards of the Spray Tanning Epidemic,* 11 IND. HEALTH L. REV. 347, 359–60 (2014) (spray tan solutions).

369. *See Health Effects of Lead Exposure*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2, 2022), https://www.cdc.gov/nceh/lead/prevention/health-effects.htm [https://perma.cc/RGP9-M7GE]; *see also supra* Part II.2.3.b. (discussing lead in food).

370. *Kohl, Kajal, Al-Kahal, Surma, Tiro, Tozali, or Kwalli: By Any Name, Beware of Lead Poisoning, Cosmetic Products,* U.S. FOOD & DRUG ADMIN. (Feb. 28, 2022) [hereinafter *Lead Poisoning*], https://www.fda.gov/cosmetics/cosmetic-products/kohl-kajal-al-kahal-surma-tiro-tozali-or-kwalli-any-name-beware-lead-poisoning [https://perma.cc/9ENC-GTKD]; Ron V. Sprinkle, *Leaded Eye Cosmetics: A Cultural Cause of Elevated Lead Levels in Children,* 40 J. FAM. PRAC. 358, 358–61 (1995). FDA has regulated these products under its color additives authority, which requires color additives to be approved for use. *See* 21 U.S.C. § 321(t); 21 U.S.C. § 379e.

371. *See supra* Part II.D.3; U.S. FOOD & DRUG ADMIN., LEAD IN COSMETIC LIP PRODUCTS AND EXTERNALLY APPLIED COSMETICS: RECOMMENDED MAXIMUM LEVEL: GUIDANCE FOR INDUSTRY (DRAFT GUIDANCE) (2016) [hereinafter COSMETIC LIP PRODUCTS], https://www.fda.gov/media/99866/download [https://perma.cc/B4YR-KM63].

372. *See* COSMETIC LIP PRODUCTS, *supra* note 371; *see also supra* Part II.D.2.b.

373. COSMETIC LIP PRODUCTS, *supra* note 371.

The issue of asbestos in certain talc-containing cosmetics highlights both the potential hazards that cosmetics can pose to children and some of the challenges FDA has faced ensuring safety of cosmetics.[374] In 2017, FDA "became aware of reports of asbestos contamination in certain cosmetic products sold by Claire's and Justice retailers."[375] Asbestos is a "known carcinogen" whose "health risks are well-documented."[376] FDA announced that four products tested positive for asbestos.[377] Justice had recalled its product in 2017, and "FDA requested that Claire's recall the [three other] products."[378] According to FDA, "Claire's . . . refused to comply with the FDA's request," highlighting the limits of FDA's cosmetic authority at the time.[379] The company later recalled the product.[380] MoCRA requires FDA to propose regulations "to establish and require standardized testing methods for detecting and identifying asbestos in tact-containing cosmetic products" and finalize such regulations within 180 days of the comment period, but it remains to be seen how FDA will implement those talc provisions.[381]

## III. CREATING AN FDA OFFICE OF CHILDREN'S HEALTH

There is a need for FDA to comprehensively examine the impact of its regulatory actions—and inaction—on children. To do so, this Article argues that as an initial step, FDA and Congress should create a children's health office at FDA to work *across product categories* to assess the impact FDA's regulatory actions have on children and to help ensure that children have not been left out of consideration in the pursuit of FDA's mission. Where children have been left out, the office should work to correct that omission to protect and better promote public health.

While an office of children's health would help elevate children's issues at FDA, it is important to note that the agency alone cannot solve the issues related to the products it regulates and children's health. Others, including

374. The regulation of talc-containing cosmetics also has implications for women's health. *See* Marie Boyd, *Preemption & Gender & Racial (In)equity: Why State Tort Law is Needed in the Cosmetic Context*, 102 B.U. L. Rev. 167, 214–30 (2022).

375. Statement of Commissioner & CFSAN Director, *supra* note 3.

376. *FDA Advises*, *supra* note 90.

377. Statement of Commissioner & CFSAN Director, *supra* note 3.

378. *Id.*

379. *Id.* At the time, FDA had no authority to mandate a recall, although MoCRA has since given FDA the authority to do so. *See* Consolidated Appropriations Act of 2023 § 3502, Pub. L. No. 117-328 (FDCA § 611, 21 U.S.C. § 364g).

380. Statement of Commissioner & CFSAN Director, *supra* note 3.

381. *See* MoCRA § 3505.

the regulated industries, must also work to address these issues.

As an administrative agency, FDA derives its authority to regulate from Congress, and its limited authority may hinder its ability to respond to issues involving children and FDA-regulated products. For example, in *FDA v. Brown & Williamson Tobacco Corp.*,[382] the United States Supreme Court held that Congress had not given FDA the authority to regulate tobacco products.[383] At issue in that case was FDA's assertion of jurisdiction over tobacco products and its promulgation of "regulations intended to reduce tobacco consumption among children and adolescents."[384] The Court noted,

> By no means do we question the seriousness of the problem that the FDA has sought to address. The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to the public health in the United States. Nonetheless, . . . an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.[385]

And even when FDA has jurisdiction over a product category, its authority may be limited in ways that hinder its ability to address issues involving children's health.[386] Forces and factors outside of FDA's

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382. 529 U.S. 120 (2000).

383. *Id.* at 161. Congress later gave FDA the authority to regulate tobacco products. *See* Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

384. 529 U.S. at 161; *see also* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996).

385. 529 U.S. at 161.

386. *See, e.g.*, Press Release, U.S. Food & Drug Admin., *supra* note 331 (noting FDA's proposal to amend the FDCA to grant it authority to issue binding limits for heavy metals in foods for infants and young children); Statement of Commissioner & CFSAN Director, *supra* note 3 (noting, in a statement made before MoCRA, FDA's lack of authority to order a cosmetics recall). FDA's ability to address children's health issues involving regulated products also may be limited because FDA may share jurisdiction over the products with another agency, for example. *See, e.g.*, 15 U.S.C. §§ 45, 52; Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration (May 1971), https://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration [https://perma.cc/7HHC-RRS8] ("With exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics."); Jennifer L. Pomeranz, *Federal Trade Commission's Authority to Regulate Marketing to Children: Deceptive vs. Unfair*

control,[387] including resource limitations, may hinder FDA's ability to address issues impacting children's health.[388] Nevertheless, this Article contends that creating an FDA office of children's health would help the agency better address issues impacting children.

This Part considers how FDA's OWH and OMHHE, and EPA's OCHP might inform the creation of an FDA office of children's health. Then, building on Part II, the current Part discusses how many issues involving children's health and FDA-regulated products cut across product categories and involve therapeutic and non-therapeutic products. Accordingly, this Article contends it may benefit children's health for FDA to undertake a broader examination of how food and drug law impacts children across product categories.

### *A. Potential Models*

While there is not currently an office at FDA that focuses on how FDA-regulated products across the product categories impact children, there are offices focused on how FDA-regulated products impact other specific populations: OWH and OMHHE, which address issues involving products

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*Rulemaking*, 21 HEALTH MATRIX 521, 526 (2011) (analyzing "the [Federal Trade Commission's] authority to regulate food marketing directed at children").

387. *See, e.g.*, ROOT CAUSES, *supra* note 132, at 5 (identifying "economic forces" as "the root causes of drug shortages"); Sharon LaFraniere, *Vaccines for Young Children Are Being Delayed by Incomplete Data, A Top F.D.A. Official Suggests*, N.Y. TIMES (Apr. 26, 2022), https://www.nytimes.com/2022/04/26/us/politics/vaccine-children-fda-pfizer-moderna.html [https://perma.cc/V8PH-3TEW] (suggesting that FDA had not authorized a COVID-19 vaccine for children under five because manufacturers had not completed their applications).

388. *See, e.g.*, JANE E. HENNEY, FRANCISCO DIEZ-GONZALEZ, JAMES JONES, BARBARA KOWALCYK, SHIRIKI KUMANYIKA & JOHN TAYLOR, OPERATIONAL EVALUATION OF THE FDA HUMAN FOODS PROGRAM: A REPORT OF THE HUMAN FOODS INDEPENDENT EXPERT PANEL 26 (2022), https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf ("The FDA's Human Foods Program is significantly under-resourced and additional resources . . . are critical to future success."); LAUREN SILVIS, JANE AXELRAD, KEITH FLANAGAN, CHARLENE FRIZZERA & ALBERTO GUTIERREZ, REAGAN-UDALL FOUND., OPERATIONAL EVALUATION OF CERTAIN COMPONENTS OF FDA'S TOBACCO PROGRAM 26 (2022), https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf [https://perma.cc/7CD9-A623] (noting the Center for Tobacco Product's "deep concerns about resources" and stating that "[a]dditional resources should be sought"); Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 432 (2008) (arguing that given its responsibilities, FDA has been chronically underfunded).

across the FDA-regulated product categories, could inform the creation of a children's health office.[389]

The Commissioner of Food and Drugs established OWH in 1994 within FDA's Office of External Affairs.[390] OWH was created "to facilitate [FDA] coordination and communication of women's health issues and initiatives."[391] Its mission includes advising the Commissioner "on scientific, ethical, and policy issues relating to women's health," "coordinat[ing] efforts to establish and advance a women's health agenda for the Agency," "[p]romot[ing] the inclusion of women in clinical trials" and "completion of sex/gender analysis," "[i]dentify[ing] and monitor[ing] the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission"; and serving as FDA's "liaison with other agencies, industry, professional associations and advocacy groups" on women's health.[392] The Affordable Care Act (ACA) later codified the establishment of OWH within the Commissioner's office.[393] OWH's work is not limited to a specific product category or categories. Instead, its work focuses on women's health and includes all the major FDA-regulated product categories.[394] The mission of a children's

389. *See* Pub. L. No. 111-148, § 3509, § 10334, 124 Stat. 119, 536, 972 (2010) (FDCA § 1011, 21 U.S.C. § 399b; PHSA § 1707A(b); 42 USC § 300u-6a); *see also FDA Overview Organization Chart*, *supra* note 11.

390. 59 Fed. Reg. 38,482, 38,482 (July 28, 1994); *see also* U.S. FOOD & DRUG ADMIN., ORAL HISTORY INTERVIEW WITH RUTH B. MERKATZ, PHD, RN, FAAN DIRECTOR OF THE OFFICE OF WOMEN'S HEALTH 1994–1996 (2019), https://www.fda.gov/media/165295/download?attachment [https://perma.cc/37WH-MWQA] (stating in a footnote that OWH "was established as a delegation of HHS authority in July 1994").

391. 59 Fed. Reg. at 38,482.

392. *Office of Women's Health*, U.S. FOOD & DRUG ADMIN. (Dec. 2, 2019), https://www.fda.gov/about-fda/office-commissioner/office-womens-health [https://perma.cc/ZHB6-6PVH]; 59 Fed. Reg. at 38,482.

393. Pub. L. No. 111-148, § 3509, 124 Stat. at 536 (FDCA § 1011, 21 U.S.C. § 399b); *see also FDA Overview Organization Chart*, *supra* note 11. The Affordable Care Act (ACA) also codified the establishment of several other Offices of Women's Health at HHS. *See* Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. at 531–36 (codifying the establishment of offices focused on women's health, including Offices of Women's Health within the Office of the Secretary of HHS, the Office of the Director of the Centers for Disease Control and Prevention, Office of the Administrator of the Health Resources and Services Administration).

394. *Timeline of FDA Accomplishments in Women's Health: 1993–Present*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://www.fda.gov/consumers/free-publications-women/timeline

health office could be modeled on that of OWH, except child-focused.

The ACA established the FDA's OMHHE in 2010.[395] Like OWH, its director reports directly to the Commissioner.[396] OMHHE's mission is "to promote and protect the health of diverse populations through research and communication of science that addresses health disparities."[397] While much of OMHHE's work focuses on clinical trials and information about specific diseases, its work is broader.[398] It aims to "strengthen FDA's ability to respond to minority health concerns" and "promote health and safety communication to minority populations."[399] For example, it has provided consumers information about cosmetics and tobacco products.[400]

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-fda-accomplishments-womens-health-1993-present [https://perma.cc/J2RF-7UVC]; *Women's Health Research*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2020), https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research [https://perma.cc/F84G-X4A6]. For a critique of the OWH, and suggestions to strengthen it, see Genevieve Grabman & Cara Tenenbaum, *FDA Regulation Must Uphold Women's Health*, 77 FOOD & DRUG L.J. 318, 338 (2022). *See also* Lisa C. Ikemoto, *In the Shadow of Race: Women of Color in Health Disparities Policy*, 39 U.C. DAVIS L. REV. 1023, 1045 (2006).

395. § 10334, 124 Stat. at 972 (PHSA § 1707A(b); 42 U.S.C §§ 300u-6a). And, like was the case with the women's health offices, the ACA provided for minority health offices at several agencies at HHS. *Offices of Minority Health at HHS*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=7 [https://perma.cc/W7PS-MBUT].

396. *See* 124 Stat. at 973.

397. *Office of Minority Health and Health Equity*, U.S. FOOD & DRUG ADMIN. (May 16, 2023), https://www.fda.gov/about-fda/office-commissioner/office-minority-health-and-health-equity [https://perma.cc/EH6J-M9B2].

398. *Minority Health and Health Equity Resources*, U.S. FOOD & DRUG ADMIN. (Jun. 15, 2023), https://www.fda.gov/consumers/minority-health-and-health-equity/minority-health-and-health-equity-resources [https://perma.cc/G959-78DJ].

399. *Office of Minority Health and Health Equity*, *supra* note 397.

400. *Commercial Tobacco Use in American Indian and Alaska Native Populations*, U.S. FOOD & DRUG ADMIN. (Oct. 31, 2022), https://www.fda.gov/consumers/minority-health-and-health-equity-resources/commercial-tobacco-use-american-indian-and-alaska-native-populations [https://perma.cc/T7QP-B7EF]; *Skin Facts! What You Need to Know About Skin Lightening Products*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2022), https://www.fda.gov/consumers/minority-health-and-health-equity/skin-facts-what-you-need-know-about-skin-lightening-products [https://perma.cc/Z5VP-MDHC]; *see also* Jovonni Spinner & Richardae Araojo, *FDA's Strategies to Close the Health Equity Gap Among Diverse Populations*, 12 J. PRIMARY CARE & CMTY. HEALTH, Jan–Dec. 2021; Christine Lee, Melanie J. McLean, Caroline J. Huang, Anh Nguyen Zarndt, Kathryn J. Aikin, Paula Rausch, et al., *The FDA's Diverse and Dynamic Activities in the Social and Behavioral Sciences: Advancing and Supporting Health*

OWH and OMHHE are outside the product centers and the Office of Regulatory Affairs, enabling them to work outside the confines of specific product categories and regulatory activities.[401] The first director of FDA's OWH, Ruth Merkatz, recalled in an oral history that the proposal for a women's health office came up because "there were pieces [issues impacting women] all over the agency, but there wasn't a central focus to try to bring them together in a cohesive manner."[402] The current situation concerning issues impacting children is similar. There are issues affecting children's health across the agency, but there is no central structure to bring them together more cohesively. Indeed, even within a single product center, efforts to address children's health issues may be fragmented.[403]

In addition, while there are organizational structures within FDA that focus on children's health issues, these structures are not set up to cut across the product centers and the divide between therapeutic and non-therapeutic products. As discussed in Part II, each product center deals with topics and issues that impact children related to specific categories of products. The Office of Pediatric Therapeutics (OPT) and the Division of Pediatric and Maternal Health (DPMH) also deal with topics and issues that impact children, but they focus on medical products.[404] OPT, which is within the Office of the Commissioner, focuses on therapeutic products for pediatrics patients.[405] Similarly, DPMH, within the Office of New Drugs

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*Equity*, 12 J. PRIMARY CARE & CMTY. HEALTH, Jan–Dec. 2021; U.S. Food & Drug Admin., *Minority Health Playlist*, YOUTUBE (May 24, 2023), https://www.youtube.com/playlist?list=PLey4Qe-UxcxbdJTzbekD712YosmrV78uE [https://perma.cc/E24Y-2GZF].

401. *FDA Overview Organization Chart*, *supra* note 11; *see also Office of Regulatory Affairs*, U.S. FOOD & DRUG ADMIN. (May 11, 2023), https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs [https://perma.cc/TLZ2-UCL6].

402. ORAL HISTORY INTERVIEW WITH RUTH B. MERKATZ, *supra* note 390.

403. *See supra* note 298.

404. *Office of Pediatric Therapeutics*, *supra* note 12 ("The Office of Pediatric Therapeutics (OPT) helps assure access for children to innovative safe and effective medical products."); *Division of Pediatric and Maternal Health*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2023), https://www.fda.gov/drugs/development-resources/division-pediatric-and-maternal-health [https://perma.cc/MZJ3-8B4M] ("The Division of Pediatric and Maternal Health (DPMH) is located in the Office of New Drugs. DPMH oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population and to improve pregnancy and lactation-related information in product labeling."); *see also Pediatric Advisory Committee*, U.S. FOOD & DRUG ADMIN. (Apr. 13, 2022), https://www.fda.gov/advisory-committees/committees-and-meeting-materials/pediatric-advisory-committee [https://perma.cc/WE46-XYXP].

405. 21 U.S.C.A. § 393a; U.S. FOOD & DRUG ADMIN., SMG 1113B.5, FDA STAFF

and the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, focuses on drugs and biologics.[406] Other organizational structures dealing with pediatric topics and issues are similarly focused. For example, the Pediatric Oncology Program works "to promote the development of safe and effective new drugs and biologics to treat cancer in children."[407] Moreover, the Pediatric Advisory Committee "[a]dvises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which [FDA] has regulatory responsibility."[408]

FDA could also look to EPA's OCHP, within EPA's Office of the Administrator, as a potential model.[409] OCHP was created as part of EPA's efforts to implement its National Agenda to Protect Children's Health from Environmental Threats and Executive Order 13,045 on the Protection of Children from Environmental Health Risks and Safety Risks.[410] OCHP's goals include "reduc[ing] negative environmental

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MANUAL GUIDES: ORGANIZATIONS & FUNCTIONS (2018), https://www.fda.gov/media/83753/download [https://perma.cc/292B-CM7W]; U.S. FOOD & DRUG ADMIN., SMG 1113B.1, FDA STAFF MANUAL GUIDES: ORGANIZATIONS & FUNCTIONS (2018) https://www.fda.gov/media/136706/download [https://perma.cc/KF8X-ETYP]; *Office of Clinical Policy and Programs*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2021), https://www.fda.gov/about-fda/office-commissioner/office-clinical-policy-and-programs [https://perma.cc/GWR3-2MJT].

406. *Division of Pediatric and Maternal Health*, *supra* note 404 ("DPMH oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population and to improve pregnancy and lactation-related information in product labeling."). The Office of New Drugs is within the Center for Drug Evaluation and Research. *See CDER Offices and Divisions*, U.S. FOOD & DRUG ADMIN. (Sept. 7, 2023), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-offices-and-divisions [https://perma.cc/9FP8-XSF2].

407. *Pediatric Oncology*, U.S. FOOD & DRUG ADMIN. (Apr. 14, 2023), https://www.fda.gov/about-fda/oncology-center-excellence/pediatric-oncology [https://perma.cc/S3JN-96TL].

408. 21 C.F.R. § 14.100(a)(2)(ii) (2022); *Charter of the Pediatric Advisory Committee to the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN. (July 21, 2022), https://www.fda.gov/advisory-committees/pediatric-advisory-committee/charter-pediatric-advisory-committee-food-and-drug-administration [https://perma.cc/D4QA-QFFP].

409. *About the Office of Children's Health Protection (OCHP)*, U.S. ENV'T PROT. AGENCY (Oct. 11, 2023), https://www.epa.gov/aboutepa/about-office-childrens-health-protection-ochp [https://perma.cc/GF2B-7DU4].

410. *History of Children's Environmental Health Protection at EPA*, U.S. ENV'T PROT. AGENCY (Oct. 11, 2023), https://www.epa.gov/children/history-childrens-environmental-health-protection-epa [https://perma.cc/55E8-D7QM]; *see also* Exec. Order No. 13,045, 62 Fed.

impacts on children through involvement in EPA rulemaking, policy, enforcement actions, research and applications of science that focuses on prenatal and childhood vulnerabilities;" "protect[ing] children through safe chemicals management;" and "coordinat[ing] community-based programs to eliminate threats to children's health where they live, learn and play."[411] OCHP's aim is "to ensure that all EPA actions and programs address the unique vulnerabilities of children,"[412] vulnerabilities which may also be relevant in the food and drug law context.[413]

### *B. Proposal*

Asking the child question about FDA-regulated products shows how FDA has fallen short in protecting and promoting children's health. It also helps demonstrate why a broader child-health-focused lens is needed to supplement FDA's existing work in this area.

A crucial part of asking the child question is considering how those shortcomings might be corrected and what difference it would make.[414] As a first step, this Article proposes the creation of a central office of children's

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Reg. 19,885 (Apr. 23, 1997) [hereinafter EO 13,045]; ENV'T PROT. AGENCY, EPA 175-F-96-001, ENVIRONMENTAL HEALTH THREATS TO CHILDREN (1996), https://www.epa.gov/system/files/documents/2022-10/national_agenda_to_protect_childrens_health_from_environmental_threats_508%20%281%29.pdf. Executive Order 13,045 provides that "each Federal agency . . . shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children and . . . shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health or safety risks." EO 13,045, supra note 410. It requires that, for certain covered regulatory actions, the issuing agency must provide "an evaluation of the environmental health or safety effects of the planned regulation on children" and "an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency." *Id.*; *see also* Devon Payne-Sturges & Debra Kemp, *Ten Years of Addressing Children's Health Through Regulatory Policy at the U.S. Environmental Protection Agency*, 116 ENV'T HEALTH PERSPS. 1720 (2008) (considering the limitations of EO 13,045). EO 13,045 also created a Task Force on Environmental Health Risks and Safety Risks to Children. *Id.*

411. *About OCHP*, *supra* note 409.

412. *Id.* (stating that "[c]hildren may be more vulnerable to environmental exposures than adults because: . . . their bodily systems are still developing; . . . they eat more, drink more, and breathe more in proportion to their body size; and . . . their behavior can expose them more to chemicals and organisms").

413. *See supra* Part I.B.

414. I plan to return to this question in the context of food and drug law in future scholarship.

health at FDA within the Commissioner's office to advise the Commissioner on matters related to children's health outside of the silos of a specific product center or regulatory focus. This Article does not argue that a children's health office should replace the existing organizational structures that focus on children's health. Instead, it suggests a children's health office should supplement and build on the agency's current child-health-related work. Creating a children's health office would not eliminate all the issues that hinder the agency's ability to protect and promote children's health, but it could help to advance its mission. The success of any such office would depend on several factors.[415]

A central office focused on children's health may help to reduce the fragmentation and increase the integration of FDA's existing work related to children's health, as many of the topics and issues involving children's health and FDA-regulated products cut across product categories.[416] For example, FDA has tried to prevent and ameliorate shortages of products in different categories—drugs, biologics, medical devices, and food (infant formula). Some of FDA's learnings from its work addressing drug shortages could help the agency avoid or mitigate future shortages in other categories. Indeed, FDA Commissioner Robert M. Califf noted that "[r]ecommendations from the White House's 100-day supply chain review report with regard to pharmaceutical and active pharmaceutical ingredient supply chain resiliency may prove insightful" in the context of the issues with the infant formula supply chain.[417]

Another example of a crosscutting issue is how to reduce "heavy metals" (e.g., lead, arsenic, cadmium, and mercury) in FDA-regulated products. These metals have been found in cosmetics,[418] foods,[419]

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415. *See* Grabman & Tenenbaum, *surpa* note 394 (discussing potential improvements for OWH).

416. *See supra* Part II.

417. *Infant Formula Crisis: Addressing the Shortages and Getting Formula on Shelves: Hearing Before the Comm. on Health, Educ., Lab. & Pensions (U.S. Senate)*, 117th Cong. 10 (2022), https://www.help.senate.gov/imo/media/doc/Califf4.pdf (Testimony of Robert M. Califf, M.D., Comm'r of Food & Drugs).

418. *Lead Poisoning*, *supra* note 370 (lead); *FDA Advises*, *supra* note 90 (asbestos); *see also* CONNIE ENGEL, JANET NUDELMAN, SHARIMA RASANAYAGAM, MAIJA WITTE & KATIE PALMER, BREAST CANCER FUND, PRETTY SCARY 2: UNMASKING TOXIC CHEMICALS IN KIDS' MAKEUP 7 (2016), https://www.bcpp.org/wp-content/uploads/2017/03/Report_Pretty-Scary-2_October_2016.pdf [https://perma.cc/Y7DZ-TFGC] (reporting that testing found lead in nearly 20% of the Halloween face paints tested and cadmium in nearly 30%); *Mercury Poisoning Linked to Skin Products*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2022),

medical devices,[420] drugs,[421] and tobacco products,[422] including products used by children.[423] Exposure to heavy metals may harm

https://www.fda.gov/consumers/consumer-updates/mercury-poisoning-linked-skin-products [https://perma.cc/XBF6-YJ6D] (mercury); *Testing*, *supra* note 366.

419. *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants*, *supra* note 319, at 3; *Arsenic in Apple Juice*, *supra* note 324; *Mercury in Food and Dietary Supplements*, *supra* note 307; *Advice About Eating Fish*, U.S. FOOD & DRUG ADMIN. (Sept. 28, 2022), https://www.fda.gov/food/consumers/advice-about-eating-fish [https://perma.cc/RH7U-RK2H] (mercury); *Testing Results for Arsenic, Lead, Cadmium and Mercury, Environmental Contaminants in Food*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2023), https://www.fda.gov/food/environmental-contaminants-food/testing-results-arsenic-lead-cadmium-and-mercury [https://perma.cc/FV5W-SPAJ] (lead, cadmium, and mercury); *Lead in Candy*, *supra* note 317; *see also* U.S. FOOD & DRUG ADMIN., TOTAL DIET STUDY REPORT 4-5 (2022), https://www.fda.gov/media/159745/download?attachment; *Closer to Zero*, *supra* note 311.

420. *Dental Amalgam Fillings*, U.S. FOOD & DRUG ADMIN. (Feb. 18, 2021), https://www.fda.gov/medical-devices/dental-devices/dental-amalgam-fillings [https://perma.cc/674W-TWCS] (mercury).

421. *FDA Warns Four Manufacturers of Unapproved Injectable Drugs Labeled as Homeopathic*, U.S. FOOD & DRUG ADMIN. (June 16, 2020), https://www.fda.gov/news-events/press-announcements/fda-warns-four-manufacturers-unapproved-injectable-drugs-labeled-homeopathic [https://perma.cc/5JF2-RWRL] (mercury and lead); *Frequently Asked Question on Children's Cough and Cold Medicines*, U.S. FOOD & DRUG ADMIN. (Oct. 25, 2021), https://www.fda.gov/drugs/information-drug-class/frequently-asked-question-childrens-cough-and-cold-medicines [https://perma.cc/YJ77-TY5L]; *see also* John F. Kauffman, Benjamin J. Westenberger, J. David Robertson, James Guthrie, Abigail Jacobs & Susan K. Cummins, *Lead in Pharmaceutical Products and Dietary Supplements*, 48 REGUL. TOXICOLOGY & PHARMACOLOGY 128, 128–29 (2007).

422. *Chemicals in Tobacco Products and Your Health*, U.S. FOOD & DRUG ADMIN. (May 1, 2020), https://www.fda.gov/tobacco-products/health-effects-tobacco-use/chemicals-tobacco-products-and-your-health [https://perma.cc/3XAS-FSJL]; Di Zhao, Atul Aravindaksha, Markus Hilpert, Pablo Olmedo, Ana M. Rule, Ana Navas-Acien, et al., *Metal/Metalloid Levels in Electronic Cigarette Liquids, Aerosols, and Human Biosamples: A Systematic Review*, 128 ENV'T HEALTH PERSP. 036001–10 (2020) ("Several studies have reported that exposure to secondhand snoke increases blood Pb [(lead)] levels in U.S. children."); Andria Apostolou, Esther Garcia-Esquinas, Jeffrey J. Fadrowski, Pat McLain, Virginia M. Weaver & Ana Navas-Acien, *Secondhand Tobacco Smoke: A Source of Lead Exposure in U.S. Children and Adolescents*, 102 AM. J. PUB. HEALTH 714, 716–17 (2012).

423. *See* PRESIDENT'S TASK FORCE ON ENV'T HEALTH RISKS & SAFETY RISKS TO CHILD., FEDERAL ACTION PLAN TO REDUCE CHILDHOOD LEAD EXPOSURES AND ASSOCIATED HEALTH IMPACTS (2018), https://ptfcehs.niehs.nih.gov/sites/niehs-ptfceh/files/resources/lead_action_plan_508.pdf [https://perma.cc/BBH8-5J7L] (listing objectives, including to reduce lead in food and cosmetics, and actions to be taken by FDA).

children's health.[424]

As a third example, "accidental" ingestion of FDA-regulated products, including drugs, dietary supplements (foods), cosmetics, and tobacco products, by children results in many emergency department visits. For example, each year, there are an estimated 57,928 emergency department visits for children five and under for medication overdoses, and of those, 82.2% are from unsupervised ingestions.[425] An estimated 4,877 emergency department visits are due to unsupervised ingestions of dietary supplements by children.[426] An estimated 4,312 children under five are treated for a cosmetic-related injury, with ingestion accounting for approximately 76% of the exposures.[427] An estimated 900 visits for children under five were due to ENDS liquid nicotine exposure with ingestion being the most common route of exposure (99.4%).[428]

As a fourth example, issues related to addiction have arisen with drugs (i.e., opioids) and tobacco products (specifically nicotine)—as well as issues regarding how others' (including parents and caregivers') use of these products impacts children.[429]

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424. *See, e.g.*, Muwaffak Al osman, Fei Yan & Isaac Yaw Massey, *Exposure Routes and Health Effects of Heavy Metals*, 32 BIOMETALS 563, 565–68 (2019).

425. Sarah F. Schillie, Nadine Shehab, Karen E. Thomas & Daniel S. Budnitz, *Medication Overdoses Leading to Emergency Department Visits Among Children*, 37 AM. J. PREVENTIVE MED. 181, 185 (2009); *see also* G. Randall Bond, Randall W. Woodward & Mona Ho, *The Growing Impact of Pediatric Pharmaceutical Poisoning*, 160 J. PEDIATRICS 265 (2012).

426. Andrew I. Geller, Nadine Shehab, Nina J. Weidle, Maribeth C. Lovegrove, Beverly J. Wolpert, Babgaleh B. Timbo, et al., *Emergency Department Visits for Adverse Events Related to Dietary Supplements*, 373 NEW ENG. J. MED. 1531 (2015).

427. Jordan Vajda, Rebecca J. McAdams, Kristin J. Roberts, Motao Zhu & Lara B. McKenzie, *Cosmetic-Related Injuries Treated in U.S. Emergency Departments: 2002 to 2016*, 58 CLINICAL PEDIATRICS 1493, 1495–96 (2019).

428. Joanne T. Chang & Brian L. Rostron, *Electronic Nicotine Delivery System (ENDS) Liquid Nicotine Exposure in Young Children Presenting to U.S. Emergency Departments, 2018*, 6 INJ. EPIDEMIOLOGY, art. no. 43 (2019); *see also* Joanne T. Chang, Baoguang Wang, Cindy M. Chang & Bridget K. Ambrose, *National Estimates of Poisoning Events Related to Liquid Nicotine in Young Children Treated in U.S. Hospital Emergency Departments, 2013–2017*, 6 INJ. EPIDEMIOLOGY, art no. 10 (2019); Scott Appleton, *Frequency and Outcomes of Accidental Ingestion of Tobacco Products in Young Children*, 61 REGUL. TOXICOLOGY & PHARMACOLOGY 210 (2011) (reporting on tobacco product related poison events); Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, 130 Stat. 3 (2016). For Poison Prevention Packaging Act (PPPA) special packaging requirements, see Poison Prevention Packaging Act of 1970, Pub. L. 91-601 and 16 C.F.R. § 1700.14.

429. *FDA Acts to Protect Kids from Serious Risks of Opioid Ingredients Contained in Some*

In addition, a children's health office whose work is not limited to a specific product category or categories (e.g., therapeutic or medical products) may be beneficial because the lines between categories can be blurry, and so much is often at stake in how a product is categorized.[430]

Furthermore, a children's health office within the Commissioner's office could increase the prominence of FDA's children's health work and play a crucial role in communicating science-based educational material to parents and caregivers about children's health and FDA-regulated products.[431] Indeed, in response to the infant formula shortage, FDA has said that it will "improve accessibility" of its education materials on its website.[432] A child-focused office could help streamline and promote FDA's message.

Despite the potential benefits of creating a children's health office, it is also important to consider potential costs.[433] FDA's resources are limited,[434] and creating a new children's health office would have costs.

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*Prescription Cough and Cold Products by Revising Labeling to Limit Pediatric Use*, U.S. FOOD & DRUG ADMIN. (Jan. 11, 2018), https://www.fda.gov/news-events/press-announcements/fda-acts-protect-kids-serious-risks-opioid-ingredients-contained-some-prescription-cough-and-cold [https://perma.cc/ZP5N-65ZR]; *Youth and Tobacco*, U.S. FOOD & DRUG ADMIN. (June 29, 2022), https://www.fda.gov/tobacco-products/public-health-education/youth-and-tobacco# [https://perma.cc/94M9-9BPB]; BRUNDAGE & LEVINE, *supra* note 159; Palumbo et al., *supra* note 158.

430. Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357, 358, 372 (1997); Jones, *supra* note 368, at 154 (triclosan and other ingredients); Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 177, 181–86 (2005).

431. *See* U.S. FOOD & DRUG ADMIN. OFF. OF WOMEN'S HEALTH, 10 YEARS AND BEYOND (2006), https://www.fda.gov/media/75826/download [https://perma.cc/ZEX7-EPJG] (discussing the FDA OWH's science program, health outreach program, and educational materials); *Office of Minority Health and Health Equity Brochure*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/93154/download [https://perma.cc/66Q3-8K2T] (highlighting FDA OMHHE's outreach and communication and language access programs); *see also* Jordan Paradise & Elise Fester, *FDA Publicity and Enforcement in the COVID-19 Era*, 60 WASHBURN L.J. 77, 105 (2020) (stating "the FDA promotes transparency through the utilization of timely publication and updating of information on its website, as well as providing the means for the public to search the agency website and databases").

432. NATIONAL STRATEGY, *supra* note 286, at 23.

433. HENRY B. HOGUE, CONG. RSCH. SERV., R44909, EXECUTIVE BRANCH REORGANIZATION 15–16 (2017), https://crsreports.congress.gov/product/pdf/R/R44909 (listing potential benefits and drawbacks of governmental reorganizations).

434. Barry Leonard, FDA Sci. Bd., FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology 4 (2007).

Nevertheless, the increased coordination and integration that could result from a children's health office could result in cost savings for FDA, due to possible synergies and efficiencies, for example. Furthermore, the potential for better health outcomes for children could result in substantial benefits, including cost savings.[435]

FDA could possibly create a children's health office administratively like it did initially with OWH.[436] The Commissioner has the authority to approve first echelon reorganizations, which include offices, subject to the limitations discussed in FDA's policy regarding organizational changes and HHS clearance.[437] There are some exceptions to the Commissioner's ability to approve such reorganizations, which require approval from the Secretary.[438] FDA must formally notify Congress thirty days before a reorganization proposal is effective.[439] Congress could also direct FDA to create an office of children's health like it did when it directed FDA to create the OMHHE and when it codified the OWH.[440]

## CONCLUSION

FDA's mission is to protect and promote public health, and children's health is an integral part of that mission.[441] Modifying the woman question to ask how food and drug law impacts children's health shows how vital FDA regulation is to that health as well as the limitations of that regulation. Congress and FDA should create a children's health office within the Commissioner's office. The creation of a children's health office at FDA would be consistent with Executive Order 13,045 on the Protection of

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435. *See, e.g.*, THERESA M. WIZEMANN & KAREN M. ANDERSON, INST. OF MED. & NAT'L RSCH. COUNCIL, FOCUSING ON CHILDREN'S HEALTH: COMMUNITY APPROACHES TO ADDRESSING HEALTH DISPARITIES: WORKSHOP SUMMARY chpt. 3 (2009).

436. *See supra* Part III.A.

437. 2 FDA Staff Manual Guides, Delegations of Authority, SMG 1415.5 (2013); 1 FDA Staff Manual Guides, Organizations & Functions, SMG 1005.1 (2022).

438. 2 FDA Staff Manual Guides, Delegations of Authority, SMG 1415.5 (2013); 1 FDA Staff Manual Guides, Organizations & Functions, SMG 1005.1 (2022).

439. *Id.*

440. ACA § 3509, 124 Stat. at 536 (FDCA § 1011, 21 U.S.C. § 399b); ACA § 10334, 124 Stat. at 972 (PHSA § 1707A(b); 42 U.S.C §§ 300u-6a).

441. *See supra* note 6; *see also* Lennart Kohler, *Child Public Health: A New Basis for Child Health Workers,* 8 EUR. J. PUB. HEALTH 253, 254 (1998) (discussing "why children's health and well-being is of special importance in public health"); T. Cresswell, *What is Child Public Health?*, 14 CURRENT PEDIATRICS 612 (2004).

Children from Environmental Health Risks and Safety Risks.[442] A children's health office may help FDA decrease fragmentation, increase integration, and better protect and promote children's health. Failing to elevate children's health issues at the agency may jeopardize FDA's ability to advance its public health mission and may ultimately make the products that it regulates less safe and beneficial for us all.

442. *See supra* note 408.