REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by John T. Carlo, MD, Chair:

1. CANNABIS THERAPEUTIC CLAIMS IN MARKETING AND ADVERTISING

Reference committee hearing: see report of Reference Committee K.

HOD ACTION: ADOPTED AS FOLLOWS
REMAINDER OF THE REPORT FILED
See Policy D-95.958

At the 2023 American Medical Association (AMA) Interim Meeting, the House of Delegates (HOD) referred recommendation 6 of the Council on Science and Public Health (CSAPH) Report 6-I-23, "Marketing Guardrails for the 'Over-Medicalization' of Cannabis Use." Recommendation 6 asked that "[o]ur AMA support and encourage state regulation of therapeutic claims in cannabis advertising." This report represents the Council's findings and recommendations.

CSAPH has issued seven previous reports that include research on cannabis including synthetic cannabinoids:

1. CSAPH Report 6-A-01, "Medical Marijuana"
2. CSAPH Report 3-I-09, "Use of Cannabis for Medical Purposes"
3. CSAPH Report 2-A-17, "Emerging Drugs of Abuse Are a Public Health Threat"
4. CSAPH Report 5-I-17, "Clinical Implications and Policy Considerations of Cannabis Use"
5. CSAPH Report 3-I-19, "Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals"
6. CSAPH Report 5-I-20, "Public Health Impacts of Cannabis Legalization"
7. CSAPH Report 6-I-23, "Marketing Guardrails for the 'Over-Medicalization' of Cannabis Use"

In CSAPH Report 6-I-23, the Council studied the marketing practices of cannabis companies. The policies that stemmed from the report state that our AMA will request more direct oversight from the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) on the marketing of cannabis, generate a letter for use by state medical societies requesting more oversight by state governments, and support research on the effects of cannabis marketing to identify best practices (D-95.958). The report also explained the categories of cannabis marketing regulations, including medium restrictions (e.g., radio, television, print media, internet) and physical restrictions (e.g., proximity to schools, signs visible to the public, signs on public transportation).

Generally, cannabis content restrictions can be divided into six categories: (1) therapeutic claims, (2) safety claims, (3) content targeting children, (4) validity of statements, (5) gifts, and (6) product warnings.[4] This report will focus on health claim content restrictions, with an emphasis on therapeutic and curative claims, addressing the specifications and limitations placed on content within cannabis advertisements. While the Council is aware of additional cannabis content restrictions such as product warnings and prohibitions on content targeting children, these are outside the scope of this report and already included in AMA policy.

METHODS

English-language reports, peer-reviewed articles, white papers, government publications, and grey literature was selected from PubMed and an Internet search, using the text terms "cannabis," "marijuana," "claims," "advertising," and "marketing." Additional information was obtained from state government websites and organizations that specialize in public health law or cannabis regulation to identify current cannabis marketing and advertising laws.

BACKGROUND

Marketing is categorized as "any commercial communication or other activity, including advertising, promotion, and sponsorship, that is designed to increase the recognition, appeal and/or consumption" of the product being marketed.[1] States have varying approaches to the marketing of cannabis and tetrahydrocannabinol (THC) containing products. While federal regulatory agencies oversee the marketing and advertising of hemp (including cannabidiol or CBD), the regulation of cannabis and cannabis-derived products varies by state. The challenges of cannabis

products are accentuated by the lack of research and guidance on dosing and adverse effects, leading consumers to rely on potentially inaccurate marketing sources like dispensary staff or online sites, emphasizing the need to ensure accurate and consistent information in marketing.

In most states where the adult-use or medical use of cannabis is legal, states have established regulatory bodies, officers, and/or departments that provide licensing and industry oversight to ensure compliance with existing cannabis laws, the development of marketing and advertising guidelines, and the enforcement of violation penalties. However, there are no federal standardized regulations, guidelines, or laws for non-FDA-approved cannabis or cannabis-based products. The marketing and advertising landscape has changed over time as states have implemented legislation granting state-based regulatory bodies the authority to enforce cannabis marketing guardrails.

Marketing can lead to changes in patient or consumer attitudes, beliefs, and behavior. In some cases a "positive halo effect" can be seen when medical benefits are highlighted, leading consumers to perceive all cannabis products as beneficial, safe, and health-promoting, even in adult use contexts.[2] Conversely, a "negative halo effect" may occur following negative press or reports on cannabis-related incidents, causing consumers to view all cannabis products or uses as harmful or risky, regardless of the specific circumstances or evidence.[3] This psychological phenomenon is one of many broader public health and regulatory concerns.

DISCUSSION

According to the FDA, a claim says something about the advertised drug or what it does.[5] Claims usually relate to benefits and are made directly by stating, for example, “Brand X treats heartburn.” Claims also can be made indirectly by the use of pictures or other graphics.”[5] Additionally, “the truthfulness of claims must be supported by ‘substantial evidence’ or substantial clinical experience.”[5] However, because cannabis companies are not regulated by the FDA, they may make claims that are not supported by rigorous research (as required by the FDA). Therapeutic claims are usually made in relation to the products usefulness, are supported by expert medical opinion or controlled clinical studies, and encompass phrases such as “for,” “in the treatment of,” and “indicated.”[6] FDA’s drug approval process includes an analysis of the benefits and risks from clinical data, and strategies for managing risks.[7] AMA policy details our support of the FDA evaluation and approval process based on sound scientific and medical evidence derived from controlled trials (H-100.992, “FDA”).

In early 2017, the National Academies of Sciences, Engineering, and Medicine released a report based on over 10,000 scientific abstracts from cannabis health research.[8] In an evaluation of the therapeutic effects of cannabis and cannabinoids, they conclude there is evidence to support the therapeutic effect of cannabis and cannabinoids in several conditions (See Table 1), but this evidence relates to the FDA approved cannabinoid products (dronabinol, nabilone, and nabiximols).[8] There is limited evidence to support claims for non-FDA approved cannabis products.[8–10] Uncertainty about the appropriate use, risks, and benefits of cannabis necessitates ongoing research to support claims and inform clinical practice. As varying cannabis products and consumption methods remain under-studied, making evidence-based recommendations on cannabis is challenging.

Cannabis Therapeutic Claims Research

While cannabis claims are regulated on a state-by-state basis, the FDA has noted common drug promotion issues that could potentially relate to marketing and advertising of cannabis therapeutic claims. Common drug promotion issues include, exaggerating the drug’s benefit, missing or de-emphasizing risk, failing to offer a “fair balance: of risk and benefit information, misrepresenting data from the studies, creating claims that are not appropriately backed, omitting material facts about the drug, misbranding and investigational medication, and making misleading medication comparisons.”[11] Current research on cannabis therapeutic claims, including industry practices, state regulations, and enforcement, is limited in both scope and content.

A 2015-2016 cross-sectional study examined recreational dispensary compliance with advertising regulations in Washington state (i.e., Washington Administrative Code (WAC) § 314-55-155).[12] The law states advertising must not contain any statement or illustration that is false or misleading, promotes overconsumption, represents the use of cannabis as having curative or therapeutic effects, or depicts a person under legal age consuming cannabis.[13] The study analyzed 1,027 posts from 12 cannabis business pages on Facebook and Twitter, representing six companies equally across rural and urban areas.[12] Out of the 1,027 posts, 137 (13.3 percent) highlighted curative or therapeutic

benefits, with 121 (11.8 percent) focusing on stress relief and 16 (1.6 percent) promoting treatment for medical conditions.[12] Examples included posts like "#Cannabis Used To Ease PTSD." Notably, a majority (69 percent) came from one company.[12]

A separate state-based analysis compared 94 cannabis medical and adult-use dispensary websites across Nevada, Oregon, Arizona, California, Colorado, Illinois, Michigan, Montana, New Mexico, and Washington.[14] Of the 94 dispensaries, 63 (67 percent) included health claims related to medical conditions treatable by cannabis products on their menus.[14] Over half of the 94 dispensaries claimed their products could address issues such as pain, stress/relaxation, appetite, anxiety/panic attacks, insomnia/sleep problems, depression, nausea/stomach ailments, and muscle spasms (See Table 2).[14] Additionally, 35 dispensaries (37 percent) made health claims on other than the menu page.[14] Claims made by at least 20 percent of dispensaries on these pages included treatment for pain, appetite, anxiety/panic attacks, insomnia/sleep problems, depression, nausea, muscle spasms, and epilepsy/seizures.[14] Less common health claims included treatments for autism, Hepatitis C, Alzheimer's disease, AIDS, and autoimmune disorders.[14] The prevalence of health claims did not significantly differ based on whether the dispensary was medical only or adult-use and medical (54/70, 77 percent vs. 19/23, 83 percent; p=0.772).[14] A small percentage of dispensaries (8/94, 9 percent) included specific comparisons of cannabis to other prescription or over-the-counter drugs, such as prescription painkillers.[14]

In a similar study researchers found that 23 out of 94 (24 percent) of dispensaries provided citations from scientific journals, links to medical literature (18 dispensaries), and/or endorsements from medical professionals (eight dispensaries) to support their health claims.[14] This practice was more common among medical dispensaries compared to those offering both medical and adult-use cannabis (23/70, 33 percent vs. 0/23, 0 percent; p=0.001).[14] The authors concluded that most dispensaries made health claims pertaining to medical conditions that could be treated by their cannabis products.[8,14] However, claims regarding the treatment of symptoms related to epilepsy, anorexia, Parkinson's Disease, and ALS have limited or insufficient scientific evidence.[8,14] While these health claims may align with state-approved conditions for cannabis use for medical purposes, it is important for dispensaries to distinguish between scientifically validated treatments and those not yet supported by empirical evidence to avoid misleading patients.[14]

From 2022-2023, researchers examined the online practices of 175 non-medical cannabis retailers in five cities (Denver, Colorado; Seattle, Washington; Portland, Oregon; Las Vegas, Nevada; Los Angeles, California).[15] They found that content claiming any health benefits of cannabis use declined from 105 (60 percent) in 2022 to 93 (47.4 percent) in 2023.[15] Of the total online cannabis retailers reviewed, 93 retailers (52.6 percent) had no health claims. Conversely, 83 retailers (47.4 percent) included health claims; among these seven retailers (4 percent) specified only medical claims, 14 retailers (eight percent) specified only mental health claims, and 62 retailers (35.4 percent) contained both medical and mental health claims (See Table 3).[15] In 2022, a similar study came to the same conclusions finding that among 195 cannabis retailers, 59.0 percent posted some unsubstantiated health claims, and 44.6 percent indicated physical and mental health benefits.[16] Although Colorado, Washington, and Oregon prohibit health claims, 51.2–53.8 percent of retailers posted them in these states.[16]

Overall, online cannabis retail presents health risks by emphasizing health benefit claims that lack sufficient evidence. In a 2022 mystery shopper study of 140 cannabis retailers in Denver, Seattle, Portland, Las Vegas, and Los Angeles researchers found despite health claim prohibitions in Colorado, Washington, and Oregon, over 90 percent of retailers in these states endorsed cannabis for anxiety, insomnia, and pain. Additionally, 54.3 percent endorsed its use for pregnancy-related nausea (ranging from 23.3 percent in Denver to 76.7 percent in Seattle), while 26.4 percent warned against use during pregnancy (most often in Denver at 46.7 percent, and least often in Seattle and Portland at 13.3 percent).[17] Likewise, a study conducting point-of-sale audits found that among 150 cannabis retailers in the same cities 28.7 percent posted health claims, 72 percent posted pregnancy/breastfeeding warnings, and 38 percent posted health risks.[18] Findings emerging from cannabis research show associations between exposure to marketing and use.[14,17,19,20] As the cannabis retail market expands in the U.S., surveillance of retail practices is crucial to inform regulations and protect consumers..

Cannabis Therapeutic Claims in Marketing and Advertising: Regulatory Landscape

It is important to understand how jurisdictions utilize laws to regulate cannabis therapeutic claims in both adult-use and medical use programs. Thirty-three states and territories have some law either on claim restrictions or untrue statements in cannabis marketing and advertising; however, there are 11 states and one territory that have no laws

prohibiting false claims or statements. Further, nine states have claim restrictions where the evidence standard is stated in the law. State's cannabis regulatory authority can be found in Table 4.

Cannabis therapeutic claim laws can be split broadly into five categories (See Table 5). The description below gives an overview of the varying laws across U.S states and territories:

No Claim Restrictions. Eleven states do not have a law on cannabis advertising/marketing claim restrictions. *State Examples:* Arizona, Vermont, and Montana have laws on cannabis advertising; however, the laws do not mention claims. Neither Arizona nor Montana laws detail claim restrictions, false or untrue statements, or any evidence standard. Vermont's law states that advertisements must be submitted to the state Cannabis Control Board prior to dissemination of the advertisement. The Board then determines if the advertisement requires a specific disclosure based on if the advertisement would be "false or misleading without such a disclosure," or they may require changes that are "necessary to protect the public health, safety, and welfare."

Claim Restrictions. Sixteen states have cannabis advertising/marketing claim restrictions or false/unsubstantiated statement prohibitions, but do not detail any evidence standard. *State Examples*: New York law notes "explicit rules prohibiting advertising that makes medical claims or promotes adult-use cannabis for a medical or wellness purpose." Washington, D.C. (D.C.) law prohibits false or misleading health benefit statements. California law specifically prohibits false or misleading therapeutic claims.

Claims are Restricted and Substantiated**.** Nine states have cannabis advertising/marketing claim restrictions with additional details to substantiate the claim restriction such as scientific evidence. *State Examples:* New Mexico law requires claims to be supported by evidence and data. Oregon law requires any claim to be supported by "the totality of publicly available scientific evidence." On the other hand, New Jersey law states that claims must be demonstrated by substantial scientific or clinical evidence consisting of two or more studies; there is no specification regarding which type of study counts towards this requirement.

Claim Restrictions Refer to Federal Law or Agency. Four states have cannabis laws that refer to federal agency standards or federal law on drugs. *State Examples:* Utah law states no statement, claim, or information that would violate the Food, Drug, and Cosmetic Act, while Missouri law states that unverified claims cannot be made unless the statement has been evaluated and approved by the FDA.

Not Applicable (N/A). Eleven states have no law on cannabis advertising/marketing because medical and adult-use cannabis are illegal.

Furthermore, forty-six states/territories have a regulatory body to oversee state cannabis policies. Generally, state law either dictates who should be appointed to the regulatory body or leaves the appointment rules to the regulatory body; however, not every state requires a physician to be on the board. In 13 states, the Department of Health (DOH) or a body within the DOH is designated as the cannabis regulatory body. In 17 states and three territories there is a cannabis commission, board, or administration that typically encompass individuals with varied expertise in health, policy, and medicine. Four states and D.C. have a duo alcohol and cannabis regulatory body, and seven states have relegated control to agencies outside the state DOH. For example, in New Mexico, the regulatory body designated is the Regulation and Licensing Department and in Utah the regulatory body is the Department of Government Operations (Table 6). Overall, every state with medical or adult-use cannabis has a regulatory body that may oversee therapeutic claims in marketing and advertising.

EXISTING AMA POLICY

Our AMA has significant policy on cannabis, including encouraging state regulatory bodies to enforce cannabis marketing laws, social media platforms to set a threshold age of 21 for exposure to advertising and support physician education on the health risks of cannabis (D-95.958, "Marketing Guardrails for the 'Over-Medicalization' of Cannabis Use"). AMA policy supports the traditional federal drug approval process for assessing the safety and efficacy of cannabis-based products for medical use and notes that cannabis products that have not been approved by the FDA, but are marketed for human ingestion in many states, should carry a warning label that this product has not been approved by the FDA for preventing or treating any disease process (D-95.969, "Cannabis Legalization for Medicinal Use").

Our AMA also has policy on cannabis addressing marketing and advertising, public health and safety messaging, prevention, harm reduction, education, treatment, research, regulation, and claims related to FDA-approved drugs. In 2022, AMA submitted a letter to the FDA and FTC relaying concern of the lack of federal regulation of cannabis and encouraging additional action to protect consumers by combating marketing of unapproved medical claims.[23] The AMA is currently working on a letter to request more oversight by state regulators. On May 16, 2024, the Drug Enforcement Administration (DEA) submitted a notice of proposed rulemaking to consider rescheduling cannabis from Schedule I to Schedule III under the Controlled Substances Act. In response, our AMA submitted a letter to the DEA highlighting several key considerations including the need to ensure public health and safety, additional research and data, consistent regulatory oversight, and protective measures for historically vulnerable populations.[24] Emphasis is placed on the clear need for more effective regulatory boundaries and guidelines concerning cannabis marketing and promotion.

CONCLUSION

There is a vast range of how states address health or medical claims for cannabis, including therapeutic claims, misleading statements, and substantial evidence. In some cases, the therapeutic claims for certain state-legalized cannabis products are unsupported, misleading, or false. In other cases, therapeutic claims are marketed by cannabis companies with sparse evidence and without medical consensus. These practices extend to both states with medical use only and both medical and adult use cannabis.

False and inaccurate claims can confuse consumers about the safety and effectiveness of cannabis products, misleading many that cannabis products (whether purchased from medical or non-medical legal markets or from illicit sellers) are less risky and more beneficial than they actually are.[21] Cannabis companies that promote the medical benefits of cannabis through these claims can create this "health halo effect," which leads to positive perceptions of adult use.[2] Such misinterpretations could increase medical and adult-use of cannabis, and prompt patients to use cannabis products to treat certain medical conditions when there is either no evidence of benefit, clear evidence that they will do more harm than good, or when conventional medicines or treatments would be safer or more effective.[8,21,22] Lastly, the lack of consistent marketing guidelines could expose youth and populations made vulnerable to false and misleading cannabis advertisements.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That our AMA:
    a. Oppose cannabis and cannabis-based product advertising that includes claims or statements that are not supported by peer reviewed scientific evidence.
    b. Will continue to monitor regulatory approaches to cannabis marketing.

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TABLE 1. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE REPORT BOX 4-1 SUMMARY OF CHAPTER CONCLUSIONS

National Academies of Sciences, Engineering, and Medicine. 2017. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. Washington, D.C.: The National Academies Press. https://doi.org/10.17226/24625.

BOX 4-1
Summary of Chapter Conclusions*

There is conclusive or substantial evidence that cannabis or cannabinoids are effective:

- For the treatment of chronic pain in adults (cannabis) (4-1)
- As antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids) (4-3)
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids) (4-7a)

There is moderate evidence that cannabis or cannabinoids are effective for:

- Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols) (4-19)

There is limited evidence that cannabis or cannabinoids are effective for:

- Increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabis and oral cannabinoids) (4-4a)
- Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids) (4-7a)
- Improving symptoms of Tourette syndrome (THC capsules) (4-8)
- Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol) (4-17)
- Improving symptoms of posttraumatic stress disorder (nabilone; a single, small fair-quality trial) (4-20)

There is limited evidence of a statistical association between cannabinoids and:

- Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage (4-15)

There is limited evidence that cannabis or cannabinoids are *ineffective* for:

- Improving symptoms associated with dementia (cannabinoids) (4-13)
- Improving intraocular pressure associated with glaucoma (cannabinoids) (4-14)
- Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis (nabiximols, dronabinol, and nabilone) (4-18)

There is no or insufficient evidence to support or refute the conclusion that cannabis or cannabinoids are an effective treatment for:

- Cancers, including glioma (cannabinoids) (4-2)
- Cancer-associated anorexia cachexia syndrome and anorexia nervosa (cannabinoids) (4-4b)
- Symptoms of irritable bowel syndrome (dronabinol) (4-5)
- Epilepsy (cannabinoids) (4-6)
- Spasticity in patients with paralysis due to spinal cord injury (cannabinoids) (4-7b)
- Symptoms associated with amyotrophic lateral sclerosis (cannabinoids) (4-9)
- Chorea and certain neuropsychiatric symptoms associated with Huntington's disease (oral cannabinoids) (4-10)
- Motor system symptoms associated with Parkinson's disease or the levodopa-induced dyskinesia (cannabinoids) (4-11)
- Dystonia (nabilone and dronabinol) (4-12)
- Achieving abstinence in the use of addictive substances (cannabinoids) (4-16)
- Mental health outcomes in individuals with schizophrenia or schizophreniform psychosis (cannabidiol) (4-21)

* Numbers in parentheses correspond to chapter conclusion numbers.

TABLE 2. HEALTH CLAIMS MADE ABOUT CANNABIS WHEN DESCRIBING THE EFFECTS OF THEIR PRODUCTS

Cavazos-Rehg PA, Krauss MJ, Cahn E, et al. Marijuana Promotion Online: An Investigation of Dispensary Practices. Prev Sci. 2019;20(2):280-290. doi:10.1007/s11121-018-0889-2

Table 2 Health claims made about marijuana when describing the effects of their products ($N = 94$)

Health claims made within menu				
≥ 50% of dispensaries	11–49% of dispensaries		≤ 10% of dispensaries	
Anxiety/Panic attacks	ADHD	Glaucoma	Alzheimer's disease	Fibromyalgia
Appetite[b]	Arthritis	Inflammation	AIDS	Hepatitis C
Depression	Cancer	Mental illness	Anorexia nervosa	Menstrual problems
Insomnia	Epilepsy	Migraine/Headaches	Asthma	Neuropathy
Muscle spasms[a]	Fatigue	***Multiple sclerosis***	Autism	Parkinson's disease
Nausea	Gastrointestinal disorders	PTSD	Autoimmune disorders	Sjögren's syndrome
Pain			Colitis	Trauma
Stress/Relaxation			Crohn's disease	Urinary systems condition
Health claims observed within the website, but outside of their menu				
≥ 20% of dispensaries	11–19% of dispensaries		≤ 10% of dispensaries	
Anxiety/Panic Attacks	ADHD	Glaucoma	ALS	High blood pressure
Appetite[b]	*AIDS*	Inflammation	Alzheimer's disease	Hydrocephalus
Depression	Anorexia nervosa	Mental illness	Asthma	Menstrual problems
Epilepsy	Arthritis	Migraine/Headaches	Autism	Neuropathy
Insomnia	Cancer	Multiple sclerosis	Autoimmune disorders	Opioid dependence
Muscle Spasms[a]	Fatigue	Stress/Relaxation	Colitis	Parkinson's disease
Nausea	Gastrointestinal disorders		Crohn's disease	*PTSD*
Pain			Diabetes	*Tourette syndrome*
			Fibromyalgia	Trauma
			Hepatitis C	Urinary systems condition

Italics and bold represent conditions that have conclusive/substantial evidence or moderate evidence. *Italics* represent conditions that have limited evidence associated with marijuana therapies. Non-italics represent conditions that have little or no evidence associated with marijuana therapies (National Academies of Sciences, Engineering, and Medicine 2017)

ADHD attention-deficit/hyperactivity disorder, *PTSD* post-traumatic stress disorder, *AIDS* acquired immunodeficiency syndrome, *ALS* amyotrophic lateral sclerosis, Lou Gehrig's disease

[a] Evidence for muscle spasms as a symptom of Multiple Sclerosis

[b] Evidence for increasing appetite in individuals with HIV/AIDS

TABLE 3: SUPPLEMENTAL TABLE 5 MARKETING STRATEGIES AMONG CANNABIS RETAILER WEBSITES IN 5 US CITIES

Cui Y, Duan Z, LoParco CR, et al. Changes in online marketing and sales practices among non-medical cannabis retailers in 5 US cities, 2022 to 2023. *Preventive Medicine Reports*. 2024;42:102755. doi:10.1016/j.pmedr.2024.102755

Supplementary Table 5. Marketing strategies among cannabis retail websites in 5 US cities in 2023, N=175

Variable	Total N=175 (100%) n (%)	Denver N=31 17.7% n (%)	Seattle N=37 (21.1%) n (%)	Portland N=36 (20.6%) n (%)	Las Vegas N=34 (19.4%) n (%)	LA N=37 (21.1%) n (%)	p-value
Content claiming health benefits of cannabis use							
Not indicated	92 (52.6)	9 (29.0)	27 (73.0)	21 (58.3)	10 (29.4)	25 (67.6)	**<.001**
Any benefits indicated	83 (47.4)	22 (71.0)	10 (27.0)	15 (41.7)	24 (70.6)	12 (32.4)	
Medical benefits only	7 (4.0)	1 (3.2)	3 (8.1)	0 (0.0)	2 (5.9)	1 (2.7)	
Mental health benefits only	14 (8.0)	1 (3.2)	1 (2.7)	7 (19.4)	5 (14.7)	0 (0.0)	
Both medical and mental health benefits	62 (35.4)	20 (64.5)	6 (16.2)	8 (22.2)	17 (50.0)	11 (29.7)	
Content targeting/representing specific populations							
Youth or young adults	53 (30.3)	23 (74.2)	4 (10.8)	6 (16.7)	17 (50.0)	3 (8.1)	**<.001**
Veterans	39 (22.3)	11 (35.5)	4 (10.8)	3 (8.3)	15 (44.1)	6 (16.2)	**.001**
LGBTQ+	10 (5.7)	7 (22.6)	0 (0.0)	1 (2.8)	1 (2.9)	1 (2.7)	**.001**
Racial/ethnic minorities	37 (21.1)	9 (29.0)	2 (5.4)	4 (11.1)	16 (47.1)	6 (16.2)	**<.001**
Content themes							
Party/cool/popularity imagery	62 (35.4)	23 (74.2)	6 (16.2)	7 (19.4)	22 (64.7)	4 (10.8)	**<.001**
Celebrity/influencer endorsement	36 (20.6)	11 (35.5)	4 (10.8)	0 (0.0)	14 (41.2)	7 (18.9)	**<.001**
Exclusivity/luxury imagery	66 (37.7)	25 (80.6)	2 (5.4)	10 (27.8)	18 (52.9)	11 (29.7)	**<.001**

TABLE 4. STATE LAW GOVERNING CANNABIS CLAIM RESTRICTIONS EXCEL SHEET

State	Medical	Adult-Use	Claim Restrictions	State Regulator	Marketing/Advertising Law
Alabama	Yes	No	Restricted unless supported by substantial clinical data	Alabama Medical Cannabis Commission	Ala. Admin. Code r. 538-X-4-.17
Alaska	Yes	Yes	Restricted	The director, an enforcement agent, an employee of the board, or a peace officer acting in an official capacity	Alaska Admin. Code tit. 3, § 306.770
American Samoa	No	No	N/A	N/A	N/A
Arizona	Yes	Yes	No Restriction	Arizona Department of Health Services	Ariz. Rev. Stat. § 36-2859
Arkansas	Yes	No	Restriction on false statements	Arkansas Alcoholic Beverage Control Board	Arkansas Medical Marijuana Amendment of 2016
California	Yes	Yes	Prohibits false or misleading therapeutic claims	Department of Cannabis Control	Cal. Bus. & Prof. Code § 26150
Colorado	Yes	Yes	Restricted	Colorado Marijuana Enforcement Division	1 Colo. Code Regs. § 212-3
Connecticut	Yes	Yes	Restricted unless substantiated or conveyed by medical professional	The Department of Consumer Protection	Conn. Gen. Stat. § 21a-421bb
Delaware	Yes	Yes	No Restriction	The Marijuana Commissioner	Delaware Marijuana Control Act
District of Columbia	Yes	Yes	Prohibits false or misleading health benefit statements	Alcoholic Beverage and Cannabis Administration	D.C Municipal Regulations Title 22-C 5801.2
Florida	Yes	No	No Restriction	Florida Department of Health	381.986. Medical Use of Marijuana
Georgia	Yes*	No	No Restriction	Georgia Access to Medical Cannabis Commission	Ga. Comp. R. & Regs. 351-6-.07
Guam	Yes	No	Cannot represent a curative or therapeutic effect	Guam Cannabis Control Board	11 Guam Code §§ 8101 - 8120
Hawaii	Yes	No	No unsubstantiated, false, or misleading claims	Director of the Hawaii Department of Health	Haw. Code R. § 11-850-145
Idaho	No	No	N/A	N/A	N/A
Illinois	Yes	Yes	Restricted	Illinois Department of Public Health	410 Ill. Comp. Stat. Ann. 705/55-20
Indiana	No*	No	N/A	N/A	N/A
Iowa	Yes*	No	Prohibits unsubstantiated medical claims and business website false, misleading, or unsubstantiated statements.	Iowa Department of Public Health	Iowa Admin. Code R.641-154.44
Kansas	No	No	N/A	N/A	N/A
Kentucky	No*	No	N/A	N/A	N/A
Louisiana	Yes	No	No Restriction	Louisiana Department of Health	Louisiana HB 524
Maine	Yes	Yes	Restricted	Maine Department of Administrative and Financial Services - Office of Cannabis Policy	CMR 18-691-001
Maryland	Yes	Yes	Claims must be supported by competent and reliable scientific evidence	Maryland Cannabis Administration	2023 Md. ALS 254, 2023 Md. Laws 254, 2023 Md. Chap. 254, 2023 Md. HB 556
Massachusetts	Yes	Yes	Claims must be supported by substantial evidence or substantial clinical data with reasonable scientific rigor	Massachusetts Cannabis Control Commission	935 CMR 500.105

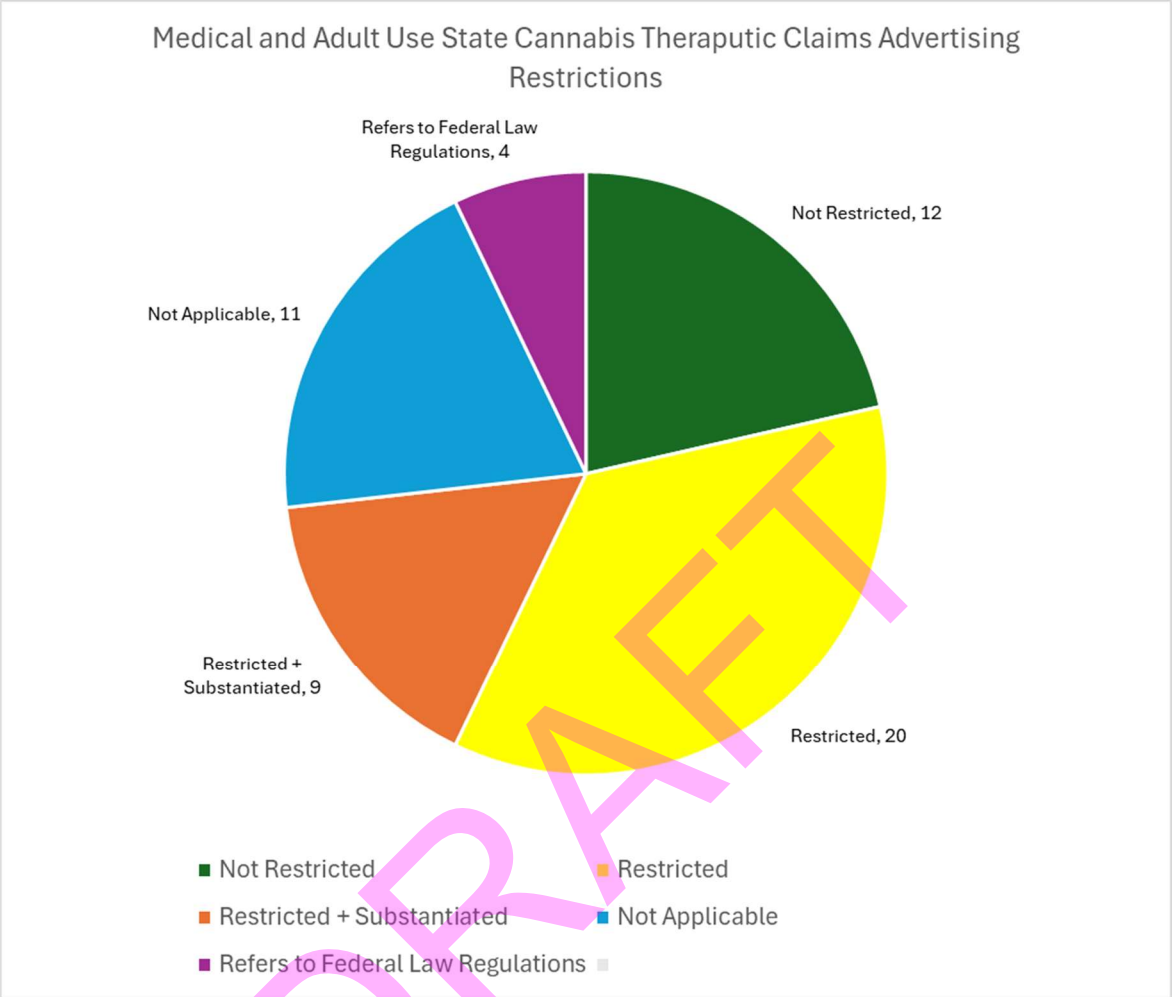
State	Medical	Adult-Use	Claim Restrictions	State Regulator	Marketing/Advertising Law
Michigan	Yes	Yes	Restricted unless complies with FDA Letter of Enforcement Discretion or other FDA approval	The Marijuana Regulatory Agency	Mich. Admin. Code r. 420.507
Minnesota	Yes	Yes	Cannot make unverified claims	The Office of Cannabis Management	Chapter 121, Article 2, Section 131
Mississippi	Yes	No	Restricted	Mississippi State Department of Health	15 Miss. Code R. § 22-6.1
Missouri	Yes	Yes	Cannot make unverified claims unless such statement has been evaluated and approved by the FDA	Missouri Department of Health and Senior Services	19 CSR 100-1.010
Montana	Yes	Yes	No Restriction	Montana Cannabis Control Division	Mont. Admin. R. 42.39.123
Nebraska	No	No	N/A	N/A	N/A
Nevada	Yes	Yes	No Restriction	NV Cannabis Compliance Board	Nev. Rev. Stat. Ann. § 678B.520
New Hampshire	Yes	No	Prohibition on Misrepresentation	NH Department of Health and Human Services	Section 126-X:6
New Jersey	Yes	Yes	Claim must be demonstrated by substantial scientific or clinical evidence consisting of two or more studies.	New Jersey Cannabis Regulatory Commission	N.J. Admin. Code § 17:30-17.2
New Mexico	Yes	Yes	Cannot make unproven claims. Claims must be supported by substantial evidence or substantial clinical data	New Mexico Regulation and Licensing Department, Cannabis Control Division	N.M. Code R. § 16.8.3.8
New York	Yes	Yes	Restricted	NY Cannabis Control Board	N.Y. Can. 86
North Carolina	No	No	N/A	N/A	N/A
North Dakota	Yes	No	No Restriction	ND Department of Health	N.D. Admin. Code 33-44-01-23
Northern Mariana Islands	Yes	Yes	No false or misleading statements	Commonwealth of the Northern Mariana Islands Cannabis Commission	§ 180-10.1-1110
Ohio	Yes	No	Under medical marijuana laws, cannot make therapeutic claims about recreational marijuana	Ohio Department of Commerce	Ohio Admin. Code Rule 3796:5-7-01
Oklahoma	Yes	No	No statements that are statements that are deceptive, false, or misleading, or "represents that the use of marijuana has curative or therapeutic effects"	Oklahoma Medical Marijuana Authority	Okla. Admin. Code § 442:10-7-3
Oregon	Yes	Yes	Claim must be supported by the totality of publicly available scientific evidence.	The Oregon Liquor and Cannabis Commission	OAR 845-025-8040
Pennsylvania	Yes	No	Advertising and Marketing must be consistent with federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1	Pennsylvania Department of Health	28 Pa. Code § 1141a.50

State	Medical	Adult-Use	Claim Restrictions	State Regulator	Marketing/Advertising Law
			(relating to prescription-drug advertisements)		
Puerto Rico	Yes	No	No Restriction	The Medicinal Cannabis Regulatory Board within Puerto Rico's Department of Health	§ 2625 Regulations
Rhode Island	Yes	Yes	No Restriction	An Independent Three Member Commission	R.I. Gen. Laws Section 21-28.11-5
South Carolina	No	No	N/A	N/A	N/A
South Dakota	Yes	No	Prohibits deceptive false or misleading statements. Prohibits curative or therapeutic effect claims. Cannot claim any health or physical benefits	South Dakota Department of Health	Admin. Code R. ARSD 44:90:10:17-19
Tennessee	No*	No	N/A	N/A	N/A
Texas	Yes*	No	No Restriction	Texas Department of Public Safety	37 Tex. Admin. Code 1, Chap.12
Utah	Yes	No	No statement, claim, or information that would violate the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301	Department of Government Operations	4-41a-403
Vermont	Yes	Yes	No Restriction	Cannabis Control Board	Vt. Stat. Ann. tit. 7, § 864
Virgin Islands	Yes	Yes	No false or misleading statements	Office of Cannabis Regulation	2024 VICUA
Virginia	Yes	Yes	No advertisements that are "misleading, deceptive, or false"	Virginia Cannabis Control Authority	Virginia § 4.1-1401
Washington	Yes	Yes	Restricted	Washington State Liquor and Cannabis Board	Wash. Admin. Code § 314-55-155
West Virginia	Yes	No	No statements that are statements that are deceptive, false, or misleading	West Virginia Bureau for Public Health within the WV Department of Health and Human Resources	W. Va. Code R. § 64-109-23
Wisconsin	No	No	N/A	N/A	N/A
Wyoming	No	No	N/A	N/A	N/A

* As of July 3, 2024, CBD Oil with THC has an ingredient is illegal, but subject to state limits e.g., CBD oil may be legal to 0.5% THC.

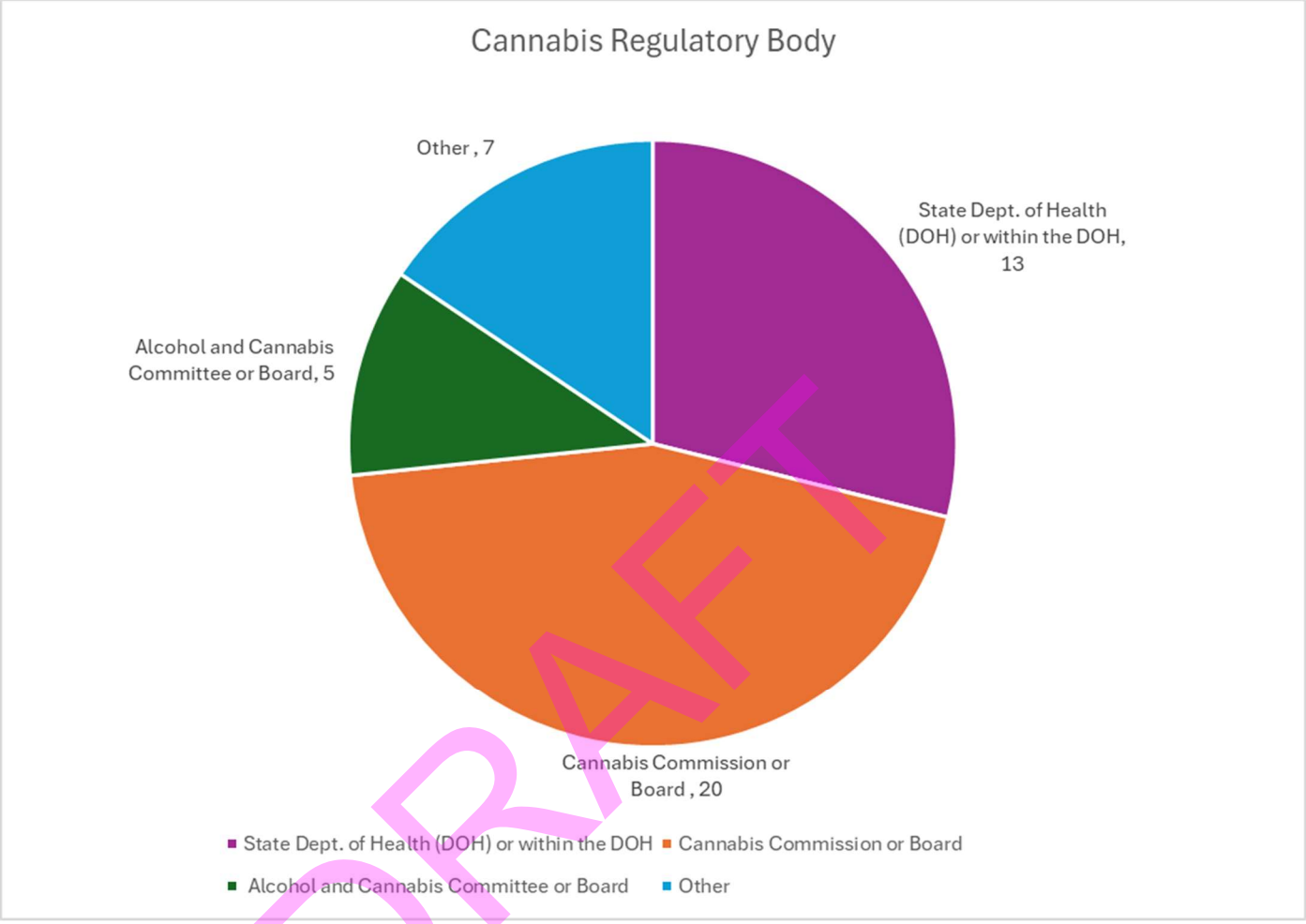
** Medical Cannabis Legal in 2025

TABLE 5. STATE CLAIM RESTRICTION DATA CHART



Not Restricted	Restricted	Restricted + Substantiated	Not Applicable	Refers to Federal Law Regulations
Arizona	Alaska	Alabama	American Samoa	Michigan
Delaware	Colorado	Connecticut	Idaho	Missouri
Florida	Guam	Iowa	Indiana	Pennsylvania
Georgia	Illinois	Maryland	Kansas	Utah
Louisiana	Maine	Massachusetts	Kentucky	
Montana	Mississippi	Minnesota	Nebraska	
Nevada	New York	New Jersey	North Carolina	
North Dakota	Ohio	New Mexico	South Carolina	
Puerto Rico	Oklahoma	Oregon	Tennessee	
Rhode Island	Washington		Wisconsin	
Vermont	Arkansas		Wyoming	
Texas	California			
	District of Columbia			
	Hawaii			
	New Hampshire			
	Northern Mariana Islands			
	South Dakota			
	US Virgin Islands			
	Virginia			
	West Virginia			

TABLE 6. STATE CANNABIS REGULATORY BODY DATA CHART



State Dept. of Health (w/i) Department of Health	Cannabis Commission or Board	Alcohol and Cannabis Committee or Board	Other
Arizona	Alabama	Alaska	Connecticut
Florida	California	Arkansas	Maine
Hawaii	Colorado	District of Columbia	New Mexico*
Illinois	Delaware	Oregon	Ohio
Iowa	Georgia	Washington	Rhode Island**
Louisiana	Guam		Utah
Mississippi	Maryland		Texas*****
Missouri	Massachusetts		
New Hampshire	Michigan		
North Dakota	Minnesota		
Pennsylvania	Montana		
South Dakota	Nevada		
West Virginia***	New Jersey		
	New York		
	Northern Mariana Islands		
	Oklahoma		
	Puerto Rico****		
	Vermont		
	US Virgin Islands		
	Virginia		

*New Mexico Regulation and Licensing Department, Cannabis Control Division
**R.I. Gen. Laws § 21-28.11-2
***West Virginia Bureau for Public Health within the WV Department of Health and Human Resources
**** The Medicinal Cannabis Regulatory Board within Puerto Rico's Department of Health
***** Texas Department of Public Safety

2. DRUG SHORTAGES: 2024 UPDATE

Reference committee hearing: see report of Reference Committee K.

HOD ACTION: **ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 922-I-23**
See Policies D-100.961, D-110.987, H-100.956, H-120.920, and H-120.923

American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. Drug shortages are defined by the Food and Drug Administration (FDA) as "a period of time when the demand or projected demand for the drug within the United States (U.S.) exceeds the supply of the drug." This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

Additionally, Resolution 922-I-23, "Prescription Drug Shortages and Pharmacy Inventories" was referred for study. Resolution 922-I-23 asked that our AMA:

> work with the pharmacy industry to develop and implement a mechanism to transfer prescriptions without requiring a new prescription [and] advocate for legislation and/or regulations permitting pharmacies to transfer prescriptions to other pharmacies when prescription medications are unavailable at the original pharmacy or the patient requests the prescription be transferred.

Due to the similarity of their subject matter, these two reports have been combined.

CSAPH has issued 14 reports on drug shortages, with the most recent being at the 2023 Interim Meeting of the HOD. As such, this report will focus on developments that have occurred primarily in the last year and the near horizon.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2021 to June 2024, using the text terms "drug shortages" and "prescription transfers". Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine, U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), and Duke Margolis Center for Health Policy, and contemporary media reporting.

DISCUSSION

Current Trends in Drug Shortages

The year 2024 marked the worst year on record for drug shortages, with 323 individual drug shortages reported in Q1, more than any year with data collected.[1] Several drugs in shortage received significant media attention, such as mixed amphetamine salts (MAS) for the treatment of attention-deficit hyperactivity disorders, where only approximately 42 percent of prescriptions were filled in 2023.[2] While there appears to be some positive movement on this front, such as reports that brand-name MAS products are in-stock, problems sourcing lower cost generic medications still persist.[3] Similarly, a National Comprehensive Cancer Network study found that platinum-based chemotherapy shortages were easing, with only seven percent of surveyed centers reporting a shortage of cisplatin, down from 70 percent in 2023.[4] However, that same report found that 89 percent of cancer centers reported a shortage of at least one critical anti-cancer agent, demonstrating that while progress can be made on individual drug shortages, systemic issues in drug procurement remain.[4]

According to ASHP statistics (see Appendix 1), trends in drug shortages have gotten worse in the last year.[5] Continuing the trend from 2023, new drug shortages are continuing to rise, and existing drug shortages take longer to resolve. When combined, these two factors have resulted in the worst year of drug shortages recorded. For the first quarter of 2024, there have been 48 new drugs in shortage. If that trend were to continue for the remainder of the calendar year, 2024 would have the most new drug shortages since 2012. So far in 2024, the five classes of drugs facing the largest number of shortages are: central nervous system therapies (66), antimicrobials (43), hormones (34), chemotherapies (32), and fluids/electrolytes (25), placing significant burden on physicians and patients across all health care settings, including urban, rural, and outpatient and inpatient.

More optimistically, the number of high-profile drugs, such as chemotherapy agents, and overall severity of current shortages has resulted in a marked increase in activity from lawmakers, regulators, and stakeholder groups, including the AMA, in addressing and alleviating drug shortages. Drug shortage developments in the past year can broadly be divided into three categories described in this report: controlled substances, generic drugs, and on-patent drugs.

Controlled Substances and Artificial Shortages

Controlled substances, such as MAS and opioids, have been a topic of interest in several of the past drug shortages reports, and persist as a class of interest. In previous reports, the Council has described how manufacturing quotas

from the Drug Enforcement Administration (DEA) have unnecessarily created drug shortages for some controlled substances, including MAS. The AMA continues to monitor this issue and act where appropriate, as described later in this report.

The national opioid litigation settlement agreements have created issues for accessing controlled substances. In 2021, nationwide settlements were reached between state attorneys general and a series of opioid manufacturers and distributors. In 2022, additional settlements were reached with several pharmacy chains. These settlements represented significant negotiations and included billions of dollars in payments and substantial changes to policies regarding the production, distribution, and marketing of opioids and other controlled substances. While most of the topics covered by the settlements are outside the scope of this report, there have been changes to distributors' risk mitigation and suspicious order surveillance and reporting which may have artificially created or otherwise exacerbated drug shortages.

Under the distributors settlement agreement, Exhibit P requires, among other things, that distributors and pharmacies abide by a series of new "red flag" regulations regarding the fulfillment, ordering, and dispensing of controlled substances.[6] These red flag policies include requirements to monitor and identify pharmacies and prescribers' "ordering ratio" of controlled substances to non-controlled substances, "excessive" ordering of controlled substances, orders to fill prescriptions of patients traveling more than 50 miles from the pharmacy, and multiple different metrics for "top prescribers" of controlled substances. Any one of these metrics (or others) are further influenced by—and most relevant to this report—extensive requirements for distributors to set "thresholds" on the amount and type of medication it will supply to a pharmacy. In the event a pharmacy exceeds its threshold limit for the procurement of controlled substances, its orders of controlled substances may be canceled, held for further inquiry or reported to the DEA as a suspicious order report. Unlike production quotas which are calculated by the DEA and made public, distributors and pharmacies implementing the red flag and threshold policies are not subject to any measure of transparency or review of implications on patients' access to care. Further, these thresholds may vary widely between distributors, impacting some pharmacies more than others, which is of particular concern when patients may have limited choice for pharmacies they can utilize.

In May 2024, the AMA joined the American Pharmacists Association (APhA), the American Society of Addiction Medicine, and ASHP in writing to the DEA and other federal stakeholders with concerns about this approach.[7] The letter described reports of pharmacies choosing not to keep adequate stock of controlled substance medications out of fear that suspicious order reports will be filed against them, or that they will be cut off from purchasing other critical controlled substance medications. As such, individual pharmacies are unable to fill prescriptions not due to a lack of supply or demand, but rather an artificial barrier that acts like a shortage for patients and physicians. Through its work with these and other physician and pharmacy organizations, the AMA has learned of physicians and/or pharmacies being cut off from ordering medication or being able to prescribe medication, including opioids, stimulants, and medications for opioid use disorder, in multiple states.

These pharmacy-specific shortages are further amplified by the electronic prescription regulatory landscape. Historically, when prescriptions were handwritten, the transference of a prescription from one pharmacy to another was a simple affair – if there was a lack of stock at one pharmacy, the patient could simply bring their written prescription to a new pharmacy. With the ubiquity of electronic prescriptions, however, concerns over multiple fillings (either accidental or intentional) of a single prescription by different locations has hampered this process. For example, if an electronic prescription has been received and begun to be processed by a pharmacy after it has closed for the day, it cannot be transferred to another, open pharmacy and the patient would be required to go back to their original prescriber to cancel the current prescription and then file a new one. Additionally, some pharmacies maintain policies where they do not disclose to patients if they have controlled substances in stock, meaning that the prescribing physician can often be further tasked with calling the pharmacy directly to inquire if a prescription can be filled.

Prior to August 28th, 2023, it was also illegal to transfer any prescription from one pharmacy to another for a Schedule II through V controlled substance. This rule was only recently modified to allow a single, one-time-only transfer for the initial filling for these drugs. The entire prescription, including any authorized refills, must all be filled at the same pharmacy, and must otherwise comply with state laws. It should be noted that some states may have stricter laws around pharmacy transfers than those proposed by the DEA, and as such would not benefit from this rule-change. Additionally, prescriptions may be required to be transferred by other entities, such as payers who have changed their in-network requirements for coverage. In those instances, a patient may have a prescription

already filled at one pharmacy, but are unable to pay for it, meaning it may be impossible to re-prescribe, and then have payers cover a new prescription.

Currently, our AMA maintains two policies on prescription transfers: H-120.923, "Legalization of Interpharmacy Transfer of Electronic Controlled Substance Prescriptions" and H-120.920, "Access to Medications" (full text available at the end of this report). Briefly, they outline our AMA's support for legislative and regulatory changes which increase the ease of transferring prescriptions, particularly when prescriptions are for controlled substances. When combined with policy changes from the opioid settlement, these restrictions on prescription transfers can result in wholly artificial, localized drug shortages that prevent patients from accessing critical medications, even if the manufacturers have adequate supply.

Pharmacy Benefit Managers

Artificial drug shortages are further exacerbated by the increasing consolidation of power in intermediaries, such as pharmacy benefit managers (PBMs), who use their purchasing power to dictate the drugs patients can access. In last year's report, the practice of PBMs only including drugs in shortage on their formularies, while excluding available alternatives, was discussed. AMA policy opposes this practice. In July of this year, the Federal Trade Commission (FTC) released an interim report into their investigation into PBM practices.[8]

While much of the focus was on PBMs increasing prices for costly, branded medications, several alarming trends emerged regarding PBM practices creating artificial drug shortages. For example, CVS Caremark, the largest PBM in the country, processed 34 percent of U.S. prescriptions in 2023, and owns its own chain of retail pharmacies. In their report, the FTC found that CVS Caremark forced patients to use CVS pharmacies, which causes smaller pharmacies to become financially unviable. This lack of choice further ingrains artificial drug shortages, particularly when an individual pharmacy may be choosing to not stock a certain drug, or prescription transfers are blocked. While CVS Caremark was the only PBM with a retail pharmacy chain, all major PBMs analyzed utilized their own pharmacies for mail-order and specialty products.

Of particular relevance to this report is the experience described by a patient's public comment received by the FTC, which describes their experience being required to utilize a PBM-owned pharmacy:

> *I generally have to place around 20 phone calls, often spending upwards of 10 hours on the phone with Accredo, before my medication finally gets shipped. In total I am waiting 3+ weeks to receive my medication [...] I have explained to my insurance company that the requirement to use Accredo results in delays receiving my medication, but they refuse to authorize me to use an alternative pharmacy [...] in my community that could provide me my medication the same day.*[9]

Similarly, manufacturer GSK halted production of its asthma medication Flovent (fluticasone propionate) in January 2024.[10] The company claimed that due to restrictions on sudden price increases, the product was no longer financially viable, but they only left the market once a generic version was available. However, reporting suggests that these generic products are not available on formularies, in part due to the inability for generic manufacturers to provide rebates to PBMs, effectively removing access to these critical medications.[11]

These changes coincided with the removal of the cap on Medicaid rebates in the American Rescue Plan Act of 2021. Previously, Medicaid drug rebates were calculated based on a percentage of the historic average price. For example, Flovent (fluticasone) HFA and Diskus, which had recently been increasing prices at a much higher rate than inflation, were thus faced with significantly higher rebates owed.[12] By authorizing a new generic product that did not have the same pricing history as the original branded product, GSK was able to escape paying these higher Medicaid rebates. As a result, PBMs may choose to not add the generic to their formulary despite its lower list price due to its net price (list price minus rebate) being higher than the previously available branded product.

In response to the FTC's report, members of Congress have indicated support for PBM regulations to address vertical consolidation and several of the practices which lead to artificial drug shortages, such as the skirting of Medicaid rebates.[13,14]

GENERIC DRUGS, COST CONTROL, AND STOCKPILES

Congressional Proposals

As described in detail in previous drug shortage reports, one of the persistent sources of drug shortages are poor manufacturer incentives to produce low-cost generic drugs. One of the leading risk factors for a drug being under shortage is the age of the drug.[15] This may seem counterintuitive – the longer a drug has been on the market, the better understanding we should have of expected demand, and have had more time to improve manufacturing yields. However, age has a significant impact on profit margins and thus market supply. Since cisplatin and carboplatin are available as generic medications, the profit incentives for their manufacturing dramatically decreases. The unit price of cisplatin and carboplatin are estimated to be $15 and $23 USD, respectively.[16] For several generic drugs, there may only be one or two manufacturers that have been able to produce the drug with a razor-thin profit margin, and any disruption, such as an FDA quality inspection, a natural disaster, or a change in ingredient prices, may cause manufacturers to halt manufacturing entirely rather than invest further.

One of the proposed legislative solutions is to require hospitals or other procurers to pay more for generic drugs. For example, the currently proposed version of the Drug Shortage Prevention and Mitigation Act contains provisions which would exclude generic drugs in shortage from the 340B Drug Pricing Program, and/or waive inflation rebates under the Medicaid Drug Rebate Program if it were to pass.[17] Under the proposed law, generic drugs in shortage would see their purchasing prices increase, with the intention of incentivizing more manufacturers to begin producing the generic drug in question at increased profit.

However, by increasing profit margins only on drugs in shortage, it creates a financial incentive for manufacturers to allow for their drugs to slip into dangerously short supply rather than invest in more efficient manufacturing practices. If the drug supply is then stabilized and the financial incentive goes away, there is no guarantee that the same manufacturers will simply again choose to opt-out of manufacturing a low-profit drug, creating the shortage all over again. The AMA has sent comment on record to the Senate Finance Committee expressing concerns over the bill and a willingness to work towards actionable legislation addressing drug shortages.[18]

To incentivize manufacturers to invest in efficient manufacturing, the FDA maintains an Advanced Manufacturing Technologies (AMT) Designation program.[19] In the AMT program, manufacturers can obtain this initial designation by demonstrating to the FDA that their drug manufacturing uses new technologies, or utilizes older technologies in innovative ways to increase quality and/or quantity of drugs produced. Beyond improvements in yield, the FDA details that manufacturers will gain other benefits, such as increased priority for communications, although these benefits are more targeted to New Drug Applications, with lesser benefit to those seeking to upgrade ongoing processes or generic drug manufacturing. As such, a financial incentive, either through direct grant or adjustment of user fees, may be necessary for those manufacturing generic medications to increase uptake of AMT. The initial guidance for the AMT Designation program is anticipated to be finalized in late 2024 or early 2025 and will be continued to be monitored for its impact on mitigating drug shortages.

Health and Human Services Proposal

A separate approach to stabilizing the generic medication supply chain has gained traction over the last few years, as described in a white paper released from the HHS, “Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States”.[20] The HHS white paper outlines two major policy proposals: (1) the Manufacturer Resiliency Assessment Program (MRAP), and (2) the Hospital Resilient Supply Program (HRSP).

Under MRAP, HHS would contract with a private entity to evaluate manufacturers based on their expected resilience against shortages and provide a publicly available “scorecard.” The criteria manufacturers will be judged upon has not been decided but could include the ability to acquire ingredients from multiple sources, regional geopolitical stability, level of investment in innovation, and frequency of communication with U.S. regulators. It is believed that by having the scorecard available, hospitals and group purchasing organizations would be able to evaluate multiple manufacturers and may be willing to pay a premium for drugs that come from facilities with a lower risk of supply disruption. This approach is aligned with current AMA policy H-100.956, “National Drug Shortages,” regarding manufacturer quality.

HRSP, however, would focus on rewarding and penalizing hospitals for their purchasing behaviors. Briefly, health systems, hospitals or even individual practices, would be incentivized to enter into longer-term, fixed volume purchasing agreements, and thus maintain an individual stockpile of drugs that are at high risk for having a shortage. Theoretically, these stockpiles would minimize disruptions to care during an active shortage, while also giving manufacturers a steadier, more reliable stream of income by entering into longer-term contracts with easily anticipated demand. In its current proposal, HHS seeks to emulate the Promoting Interoperability program they leveraged for electronic health record uptake.[21] Briefly, the Promoting Interoperability program scores participants on a number of criteria regarding their use of electronic medical records, such as electronic prescriptions, provider-to-patient information communication, and information exchange with public health and other clinical entities. To encourage initial uptake, eligible participants received incentive payments for achieving a certain score, but those incentives have since been phased out and instead replaced with a penalty in Medicare payment for non-participation.
Under HRSP, hospitals would have Medicare payments and penalties linked to activities intended to promote a healthier generic drug manufacturing ecosystem. For example, hospitals would be rewarded for (or punished for not) maintaining their own stockpiles of essential medicines, entering in longer-term contracts, having minimum volume purchasing requirements, or purchasing from entities with higher MRAP-administered scores.

Under the current proposal, HRSP would only apply to inpatient hospitals. Incentives and penalties would apply for the first five years of the program and would aim to move to a penalty-only model after year six. While there is no current AMA policy describing an approach such as that described in HSRP, when a similar punitive approach was taken towards EHR interoperability, the AMA opposed it in part due to the physician's inability to control the EHR products on the market.[22] Similarly, physicians may have limited influence on the contracts which drug manufacturers are willing to enter into, particularly for smaller practices with limited purchasing power.

Beyond the punitive approach the proposed HSRP would have on physicians and hospitals, it is also not necessarily a proven strategy for addressing many common causes of drug shortages. For example, penicillin is currently experiencing a shortage in part due to a surge of syphilis cases.[23] While stockpiles may help initially with lapses in supply, they do little to buffer against surges in demand. HRSP is currently very narrowly targeted at generic sterile injectables, in part to address this. Additionally, buffer supplies may place a significant administrative burden on hospitals for managing a drug stockpile, promote waste, and could exacerbate the stark divide between well-funded academic centers and rural hospitals competing for essential medicines.

ON-PATENT DRUGS AND QUESTIONABLE MARKET PRACTICES

By contrast, drugs which are on-patent and highly profitable but otherwise experiencing a shortage have the inverse problem to generic drugs: it is so enticing for market actors to source these drugs that they may skirt regulations or best practices.

For example, in previous versions of this report, the advertising practices of semaglutide and other glucagon-like peptide-1 (GLP-1) agonists were discussed. Unlike many other drugs under shortage, semaglutide's increase in popularity can largely be attributed to a massive advertising presence, particularly through social media. For example, one report suggests that by November 2022, one hashtag (#Ozempic) was viewed over 273 million times on the social media platform TikTok.[24] Since then, the semaglutide shortage has persisted, with demand expected to continue to grow as more uses for GLP-1 agonists emerge. Prolonged shortages combined with ultra-high demand have attracted several bad actors, including significant concerns over counterfeit products being sold to pharmacies struggling to keep up with patient needs.[25]

Due to the highly profitable nature of semaglutide sales, several online companies, such as Hims & Hers Health, have begun to utilize a rule in the Food, Drug & Cosmetics Act which allows for compounding pharmacies to prepare compounded forms of drugs experiencing a shortage, even if they are not the patent holder.[26] This rule was intended for instances where the precursors or active ingredients for these drugs are readily available on the market, but the manufacturers are experiencing difficulty with final-stage processes, commonly known as fill-finish. In those instances, compounding pharmacies could serve as a valuable, temporary stop-gap solution to getting patients a useable form of the drug.

However, the FDA has reported that compounders may be using non-approved forms of semaglutide, such as its salts, which are a different active ingredient, have a different safety profile, and have not been evaluated for safety

and efficacy by the FDA.[27] In July 2024, the FDA released a warning around compounded semaglutide and an increased risk for overdose.[28] Additionally, marketing these products designed for continuous, chronic use, to new patients amidst a shortage may be irresponsible. In its report to investors, Hims & Hers Health disclosed that in the quarter after they started offering compounded semaglutide, they saw a 45 percent increase in online revenue, a record 172,000 new subscribers to their platform, and expect their weight loss offerings to result in over $100 million in sales.[29]

When utilized appropriately, rules that allow for compounders to bolster the supply of drugs in shortage are a useful tool for ensuring that patients have continuous access to the medications they need. However, when they are utilized as an attempt to accrue market share for popular drugs that still retain patent protections, patient safety and unfair market practices should be investigated.

Telemedicine prescribing, particularly for controlled substances, has been an area of increased scrutiny from federal regulators in the past years. Since COVID-19 flexibilities allowed for expanded access and comfort with telemedicine, there have been increases in demand for some medications, particularly for those which may carry stigma such as MAS. In some instances, telemedicine companies have abused these new flexibilities for profit rather than for patient wellbeing. In June 2024, a telehealth company CEO was indicted by the Department of Justice for fraudulent reimbursement claims for prescriptions of MAS.[30] In the indictment, the company was accused of using deceptive marketing practices to drive individuals to their service, where they would prescribe MAS even when not medically necessary, resulting in an estimated $100 million in profit and flooding the market with unnecessary demand, exacerbating shortages. The resulting surge in demand resulted in the Centers for Disease Control and Prevention issuing a Health Advisory Notice for potential treatment disruptions.[31]

Newly utilized and expanded flexibilities on telemedicine and prescribing have been an ongoing tension between access and drug shortages. Bad actors have utilized deceptive marketing practices to drive profits over patient wellbeing and made it challenging for patients with valid prescriptions to source the medications they need. The AMA has been in regular communication with the DEA and other regulators overseeing telemedicine prescribing flexibilities, including a 2023 letter on prescriptions for patients that have not had an in-person examination with their physician.[32] Amongst its other recommendations, the AMA recommended that the DEA focus its enforcement efforts on outlier practices, such as companies using deceptive advertising, rather than placing additional barriers to care on legitimate telemedicine encounters.

ADDITIONAL AMA ACTIVITIES

The AMA has been active in combatting drug shortages. Advocacy efforts have been targeted at both legislators and regulators to create impactful policies that could help alleviate drug shortages. The AMA also served as a subject matter expert for the Government Accountability Office's ongoing review of the federal government's response to drug shortages.

Beyond advocacy, the AMA is a founding member of the Task Force on Preventing and Mitigating Drug Shortages, a national group including the US Pharmacopeia, the Association for Clinical Oncology, APhA, ASHP, the American Cancer Society Action Network, the National Consumers League, the Susan G. Komen Foundation, and more. For drug-specific shortages, such as those observed with buprenorphine, other AMA groups such as the Substance Use and Pain Care Taskforce, which includes many members from the Federation of Medicine, have also convened to discuss challenges and engaged in advocacy outreach. The AMA continues to build upon its profile as a thought leader and advocate in this space, including initiating new research projects on the impacts of drug shortages on physician practices, and speaking at academic conferences on the subject.

As drug shortages will continue to be studied and reported on with an annual cadence, some topics relevant to drug shortages are currently being monitored but may be included in a future report, such as Section 804 importation programs, wherein individual states may directly contract with Canadian manufacturers for drug importation, a recently announced study by the Department of Commerce on the health of the precursor supply chain, and the roll-out of compulsory licensing and march-in rights for drugs developed with significant public investment.[33-35]

CONCLUSIONS

Drug shortages continue to be a persistent problem for patient safety and the quality of health care patients receive. Due to the increase in highly visible drugs experiencing a shortage, along with advocacy from groups such as the AMA, there has been an increase in both urgency and action from legislators and regulators. In the past year, new proposals have included a report-card system for drug manufacturers, an emphasis on buffer supplies, and multiple strategies for stabilizing the generic drug supply chain. However, given the significant implications of some of the proposed programs, a more nuanced approach may be required to achieve the desired outcomes. To that end, updates have been recommended to the AMA's existing drug shortage policy to reflect the current landscape. Additionally, artificial barriers to drug access, procurement thresholds and restrictions on pharmacy choice, were examined. Given the subtle distinction between these practices and a traditional drug shortage, in which supply does not meet demand, a new standalone policy is recommended. Finally, existing AMA policy regarding inter-pharmacy prescription transfers and pharmacy benefit managers was reviewed and found to be supportive and synergistic with current drug shortage policy and is thus recommended for reaffirmation.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 922-I-23, and that the remainder of the report be filed:

1. That Policy H-100.956, "National Drug Shortages," be amended by addition and deletion to read as follows:

1. Our American Medical Association considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the U.S. Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations and pharmacy benefit managers on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges continued analysis of the root causes of drug shortages that includes consideration of federal actions, evaluation of manufacturer, Group Purchasing Organization (GPO), pharmacy benefit managers, and distributor practices, contracting practices by market participants on competition, access to drugs, pricing, and analysis of economic drivers, and supports efforts by the Federal Trade Commission (FTC) to oversee and regulate such forces.
7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market or caused to stop production due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.

10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the FTC consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers and distributors to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, any unpredicted changes in product demand, and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA supports the collection and standardization of pharmaceutical supply chain data in order to determine the data indicators to identify potential supply chain issues, such as drug shortages.
13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as expansion of global reporting requirements for indicators of drug shortages.
14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing~~.~~, and supports the use of incentives such as prioritized regulatory review, reduction of user fees, and direct grant opportunities for manufacturers seeking to invest in manufacturing processes.
15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.
16. Our AMA encourages electronic health records vendors to make changes to their systems to ease the burden of making drug product changes.
17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
18. Our AMA urges DHHS and the U.S. Department of Homeland Security to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.
19. Our AMA urges the Drug Enforcement Agency and other federal agencies to regularly communicate and consult with the FDA regarding regulatory actions which may impact the manufacturing, sourcing, and distribution of drugs and their ingredients.
20. Our AMA supports innovative approaches for diversifying the generic drug manufacturing base to move away from single-site manufacturing, increasing redundancy, and maintaining a minimum number of manufacturers for essential medicines.
21. Our AMA supports the public availability of FDA facility inspection reports to allow purchasers to better assess supply chain risk.
22. Our AMA opposes the practice of preferring drugs experiencing a shortage on approved pharmacy formularies when other, similarly effective drugs are available in adequate supply but otherwise excluded from formularies or coverage plans.
23. Our AMA shall continue to monitor proposed methodologies for and the implications of a buffer supply model for the purposes of reducing drug shortages and will report its findings as necessary.
24. Our AMA opposes increasing drug prices or waiving fee exemptions in a manner that incentivizes a drug manufacturer to have its drug be declared in shortage.
25. Our AMA opposes the use of punitive fees on physician practices that do not maintain buffer supplies of drugs.
26. Our AMA encourages the FDA, the FTC, or other relevant oversight entities, to examine the practice of compounding pharmacies and the entities that utilize them advertising drugs actively in shortage, particularly when targeted to new patients. (Modify Current Policy)

2. That the following new HOD policy be adopted:

Artificial Drug Shortages Limiting Access to Medications

Our AMA will:
1. Oppose laws, regulations, or business practices which create artificial scarcity of drugs, such as limitations on pharmacy procurement or restrictions on which pharmacies a patient can use, which prevent the filling of an otherwise valid prescription from their physician;

2. Advocate for pharmacies and distributors subject to the national opioid litigation settlement to make public the specific metrics, formulas, data sources, algorithms, thresholds and other policies and analyses that are used to delay or deny orders to pharmacies, restrict physicians' prescribing privileges and other actions that impede patients' access to medication; and
3. Advocate for pharmacies and distributors to provide physicians with all due process rights and opportunities to contest any decision to restrict a physician's prescribing privileges based on a pharmacy or distributor metric, formula, algorithm or other policy before such restriction is put into effect. (New HOD Policy)

3. That policies H-120.923, "Legalization of Interpharmacy Transfer of Electronic Controlled Substance Prescriptions", H-120.920, "Access to Medications", and D-110.987, "The Impact of Pharmacy Benefit Managers on Patients and Physicians" be reaffirmed. (Reaffirm HOD Policy)

CITED POLICIES

Legalization of Interpharmacy Transfer of Electronic Controlled Substance Prescriptions H-120.923
Our AMA will advocate for the removal of state, federal and other barriers that impede interpharmacy transfers of valid electronic prescriptions for Schedule II-V medications.

Access to Medication H-120.920
Our AMA will advocate against pharmacy practices that interfere with patient access to medications by refusing or discouraging legitimate requests to transfer prescriptions to a new pharmacy, to include transfer of prescriptions from mail-order to local retail pharmacies.

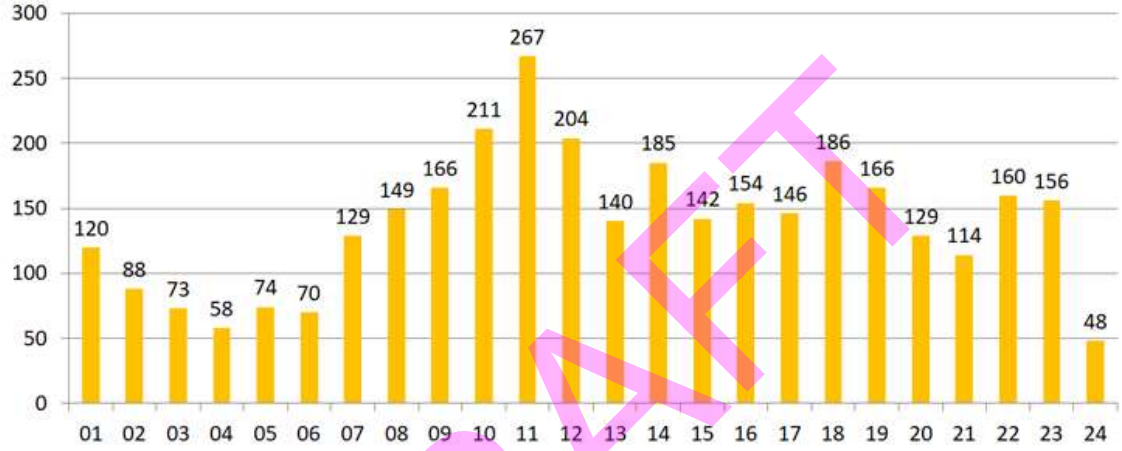
The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987
1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. Our AMA supports improved transparency of PBM operations, including disclosing:
- Utilization information;
- Rebate and discount information;
- Financial incentive information;
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
- Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
- Percentage of sole source contracts awarded annually.
6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.

Box 1. Resources available to assist in mitigation of drug shortages.

1. ASHP Resource Center
2. ASHP list of current shortages
3. FDA Drug Shortages Page (includes current shortages list, extended use dates, mobile app, and additional information)

APPENDIX 1

Figure 1. National Drug Shortages: New Shortages by Year: January 2001 to March 31, 2024

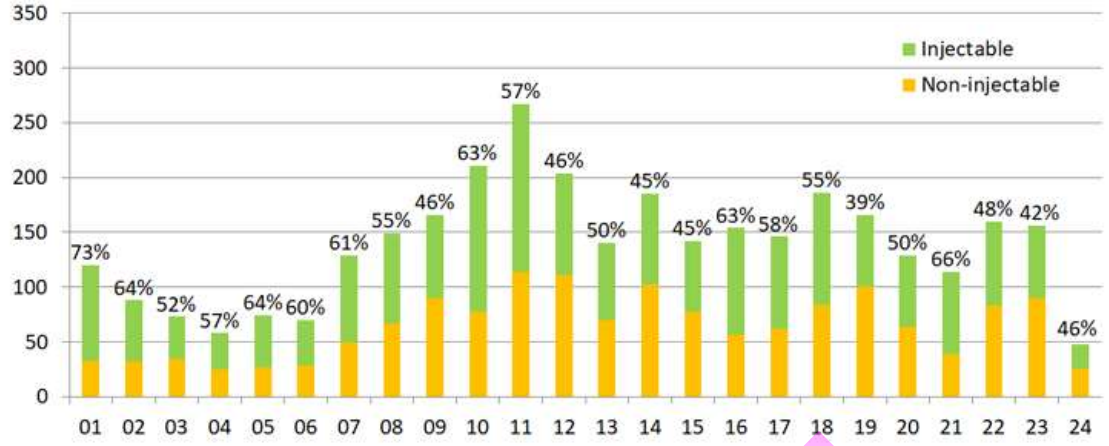


Note: Each column represents the number of new shortages identified during that year.

University of Utah Drug Information Service

Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

Figure 2. National Drug Shortages: New Shortages by Year
Percent Injectable: January 2001 to March 31, 2024, % Injectable



Note: Each column represents the number of new shortages identified during that year.
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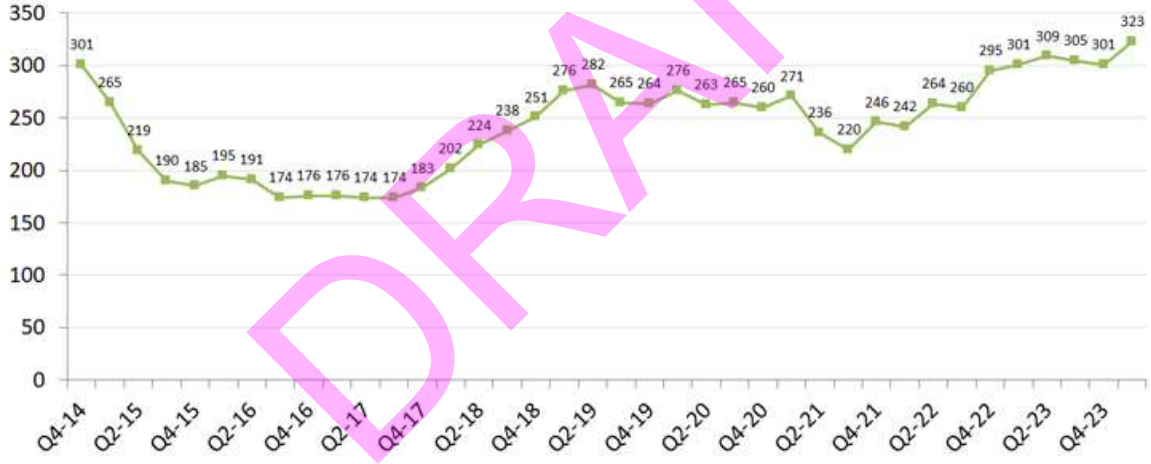
Figure 3. National Drug Shortages: Active Shortages by Quarter: 5 Year Trend



Note: Each point represents the number of active shortages at the end of each quarter.
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Figure 4. National Drug Shortages: Active Shortages Top 5 Drug Classes

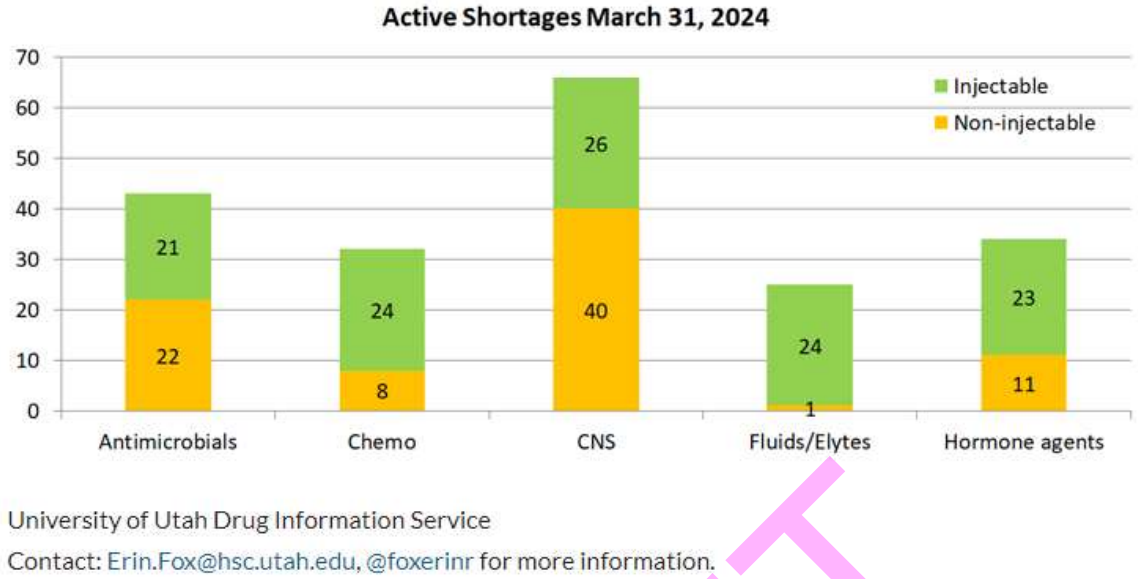

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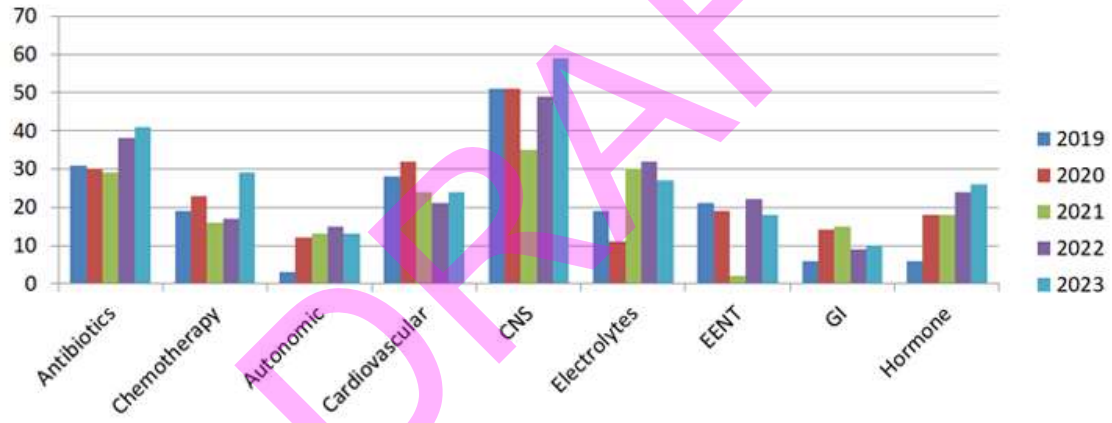
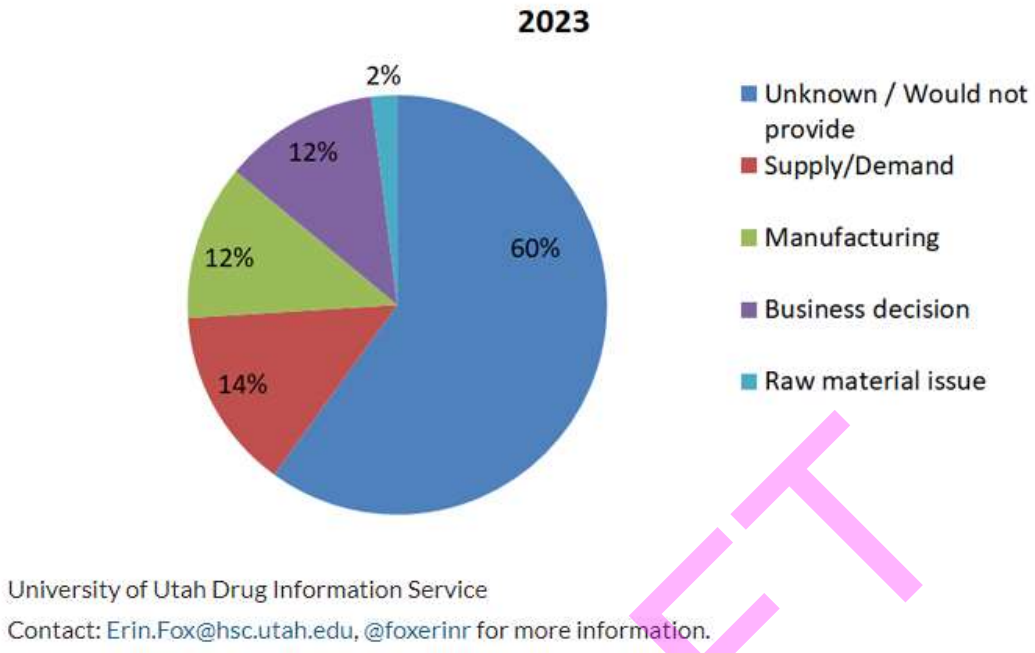
Figure 5. National Drug Shortages: Common Drug Classes in Short Supply: 5 Year Trend



University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

Figure 6. National Drug Shortages: Reasons for Shortages as Reported by Manufacturers During UUDIS Investigation — 2023



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3. HPV-ASSOCIATED CANCER PREVENTION

Reference committee hearing: see report of Reference Committee K.

HOD ACTION: **ADOPTED**
See Policies H-60.969, H-440.872, and H-440.970

INTRODUCTION

American Medical Association (AMA) Policy H-440.872 "HPV-Associated Cancer Prevention," asked that our AMA study requiring HPV vaccination for school attendance and report its findings to the AMA House of Delegates by the 2023 Interim Meeting. CSAPH Report 3-I-23, which reported the findings and recommendations of that study, was referred for further study.

BACKGROUND

Human papillomavirus (HPV) is a group of more than 200 related viruses, some of which are spread through vaginal, anal, or oral sex.[1] The majority of HPV infections are self-limited and are asymptomatic. Sexually transmitted HPV types fall into two groups, low and high risk.[6] Low-risk HPVs generally cause no disease.[6] However, a few low-risk HPV types can cause warts on or around the genitals, anus, mouth, or throat. High-risk HPVs can cause several types of cancer.[6] There are about 14 high-risk HPV types including HPV16 and HPV18, which are responsible for most HPV-related cancers.[6] Nearly all people are infected with HPV, with low malignant potential, within months to a few years after becoming sexually active. Around half of these infections are with a high-risk HPV type.[6] HPV can infect anyone regardless of their sex, gender identity, or sexual orientation. HPV vaccination is the best method to prevent infection with disease-causing HPV types, preventing many HPV-related cancers and cases of genital warts. Before HPV vaccines were introduced, approximately 355,000 new cases of ano-genital warts occurred every year.[2]

Prevalence of HPV-associated cancers

Long-lasting infections with high-risk HPVs can cause cancer in parts of the body where HPV infects cells, such as in the cervix, oropharynx, anus, penis, vagina, and vulva.[6] HPV infects the squamous cells that line the inner surfaces of these organs. For this reason, most HPV-related cancers are squamous cell carcinomas. Some cervical cancers come from HPV infection of gland cells in the cervix and are adenocarcinomas.[6] Each year, there are about 45,000 new cases of cancers in parts of the body where HPV is often found, and HPV is estimated to cause about 36,000 of these.[6]

Background on HPV Vaccines and Recommendations for Vaccination

The Food and Drug Administration (FDA) approved first-generation Gardasil®, produced by Merck, in 2006, which prevented infection of four strains of HPV – 6, 11, 16, and 18.[3] In December 2014, Gardasil®9 was approved by the FDA.[8] This vaccine protects against nine strains of HPV: the four strains approved in the previous Gardasil vaccine, as well as 31, 33, 45, 52, and

1 National Cancer Institute. *HPV and Cancer*. Accessed August 1, 2023. Available at https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer.
2 CDC. *Human Papillomavirus (HPV) Infection*. Accessed August 1, 2023. Available at https://www.cdc.gov/std/treatment-guidelines/hpv.htm.

3 CDC. *HPV Vaccine Information for Clinicians*. Accessed August 1, 2023. Available at https://www.cdc.gov/hpv/hcp/need-to-know.pdf.
58.[8] These strains are associated with the majority of cervical cancer, anal cancer, and throat cancer cases as well as most genital warts cases and some other HPV-associated ano-genital diseases.[1] The vaccine was initially approved for cervical cancer prevention, but in 2020 the FDA broadened its approval to include the prevention of oropharyngeal cancer and other head and neck cancers.[2]

HPV vaccination is recommended at age 11 or 12 years but can be started at nine years of age. The Centers for Disease Control and Prevention (CDC) also recommends vaccination for everyone through age 26 years if not adequately vaccinated when younger.[15] For adults ages 27 through 45 years, health care professionals, using shared clinical decision-making, can consider discussing HPV vaccination with people who are most likely to benefit.[15] HPV vaccination is given as a series of either two or three doses, depending on age at initial vaccination.[15] HPV vaccines are currently not recommended for use in pregnant persons.[15] HPV vaccines can be administered regardless of history of ano-genital warts, abnormal Pap test or HPV test, or ano-genital precancer.[15]

With over 120 million doses of HPV vaccines distributed in the United States (U.S.), robust data demonstrate that HPV vaccines are safe.[3] There have been relatively few adverse events reported after HPV vaccination. Commonly reported symptoms include injection-site reactions such as pain, redness and swelling, as well as dizziness, fainting, nausea, and headache.[4] Current research suggests the vaccine protection is long-lasting: more than 10 years of follow-up data indicate the vaccines are still effective and there is no evidence of waning protection, although it is still unknown if recipients will need a booster.[5] Further, HPV vaccination has not been associated with decreased age in the initiation of sexual activity or sexual risk behaviors.[6]

HPV vaccination remains the best method for preventing cancer-causing infections and precancerous lesions. HPV infections and cervical precancers have dropped since 2006, when HPV vaccines were first used in the U.S. For example, among teen girls, infections with HPV types that cause most HPV cancers and genital warts have dropped 88 percent and among young adult women they dropped 81 percent.7 Despite the benefits of vaccination, a 2022 analysis of data from the National Immunization Survey–Teen showed that for the first time since 2013, HPV vaccination initiation did not increase among adolescents aged 13–17 years.[8] Among all adolescents aged 13–17 years, 2022 HPV vaccination coverage levels did not differ from 2021 levels; however, initiation of the HPV vaccination series decreased among those who were insured by Medicaid.[35] In 2022, 89.9 percent of adolescents aged 13–17 years had received ≥1 HPV vaccine dose, and 62.6 percent were up to date with HPV vaccination (HPV UTD).[35] During 2015–2021, among adolescents aged 13–17 years, coverage with ≥1 HPV vaccine dose was higher among those insured by Medicaid than among those with private insurance; however, in 2022, coverage with ≥1 HPV vaccine dose among Medicaid beneficiaries declined by 3.3 percentage points compared with coverage in 2021, whereas ≥1-dose HPV coverage among those with private insurance was stable, resulting in similar coverage between the two groups in 2022.[35] Coverage with ≥1 HPV vaccine dose remains lowest among uninsured adolescents.[35]

HPV vaccination initiation fell among adolescents insured by Medicaid and remained lowest among the uninsured (two of the four groups that constitute the Vaccines for Children [VFC]–eligible population), highlighting the continued need for outreach among adolescents eligible for VFC.[35] VFC vaccine ordering data provide additional evidence that HPV vaccination coverage might be declining in VFC-eligible populations.[35] VFC provider orders for HPV vaccines decreased 24 percent during 2020, nine percent during 2021, and 12 percent during 2022 compared with 2019, while provider orders for non-HPV vaccines have rebounded to pre-pandemic levels.[35] The VFC program is vital to reach and administer vaccines to eligible adolescents to maintain vaccination coverage in underserved communities.[35] Children living in large central metropolitan areas (39.4 percent), large fringe metropolitan areas (41.1 percent), and medium and small metropolitan areas (39.4 percent) were more likely to have received one or more HPV vaccine doses, compared with children living in nonmetropolitan areas (30.0 percent).[9] Hispanic children (34.4 percent) were less likely than White non-Hispanic children (39.9 percent) to have received one or more HPV vaccine doses.[36] All other observed differences between Asian non-Hispanic, Black non-Hispanic, White, and Hispanic children were not significant.[36]

CDC vaccine recommendations, as informed by the Advisory Committee on Immunization Practices (ACIP), provide clinical guidance on how to use vaccines to control diseases in the U.S. School vaccination requirements are generally determined by state legislatures or state health departments. Few states require the HPV vaccine for school

attendance in part because HPV is considered a sexually transmitted infection (STI), and it is not likely to be transmitted in schools.10 Adding vaccines to the list required for school entry is viewed by some as putting up unnecessary roadblocks for school attendance. For the HPV vaccine, some have expressed moral objections related to a vaccination requirement for a STI.11 This report is specifically focused on the history of vaccine requirements for school entry, the legality of vaccine requirements, assessment on the effectiveness of HPV vaccine requirements on HPV vaccination rates, and other interventions to increase HPV vaccination rates.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "HPV vaccination", "HPV vaccine mandates," "HPV vaccine requirement," "mandated vaccines AND schools" and "school attendance AND HPV vaccine mandate". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

VACCINE REQUIREMENTS

Legality of Vaccination Requirements

In the early 19th century, smallpox was one of the largest threats to public health. Amid frequent smallpox outbreaks, Massachusetts passed the nation's first vaccine mandate in 1810. The Massachusetts law gave local health boards the authority to require vaccination when outbreaks occurred, imposing fines or quarantine for non-compliance.[12] In 1827, Boston enacted the first school vaccine requirement for smallpox; other cities and states soon followed.[13] Today, four common childhood vaccinations – DtaP, MMR, polio, and varicella – are required for children to enroll in kindergarten in every state,[1] with 44 states also requiring a hepatitis B vaccination before kindergarten and 30 states requiring a meningitis vaccination before entering later grades.[14]
Until the COVID-19 pandemic, vaccine requirements in the U.S. had mostly been enacted by state and local governments in relation to public venues, schools, and health care facilities, with the military also requiring certain vaccines.[15] Vaccine mandates require that individuals be vaccinated against certain illnesses, usually as a condition of entry to or participation in certain activities. The most common vaccine requirements are applied to enrollment in schools. However, vaccine requirements are not absolute. School vaccine requirements in every state allow for exemptions.

The legal basis for vaccine requirements typically lies within the police powers of a state. Police powers encompass the broad power of a state to regulate matters affecting the health, safety, and general welfare of the public, housed within the Tenth Amendment of the Constitution.[2,16] While school vaccination requirements are framed as conditional, courts often view them as compulsory; however, these compulsory requirements have been widely accepted and judicially sanctioned.[13] The legitimacy of compulsory vaccination programs depends on both scientific factors and constitutional limits. Scientific factors include the prevalence, incidence, and severity of the contagious disease; the mode of transmission; the safety and effectiveness of any vaccine in preventing transmission; and the nature of any available treatment. Constitutional limits include protection against unjustified bodily intrusions, such as forcible vaccination of individuals at risk for adverse reactions, and physical restraints and unreasonable penalties for refusal.[17] Vaccination programs have been legally challenged as inconsistent with federal constitutional principles of individual liberty and due process, an unwarranted governmental interference with individual autonomy, and an infringement of personal religious beliefs under First Amendment principles.[2]

The U.S. Supreme Court has addressed vaccine requirements in two cases. In 1905, the Court upheld the constitutionality of vaccine requirements in the seminal case *Jacobson v. Massachusetts*.[18] Jacobson challenged the Massachusetts law mentioned earlier that gave local health boards the authority to require vaccination when outbreaks occurred. The Court held that a vaccine requirement was valid so long as there was a danger to public health and safety and the requirement had a real or substantial relation to the goal of protecting public health. In 1922, the Court upheld vaccine requirements as a condition of school attendance in *Zucht v. King*.[19] In its brief, three paragraph opinion, the Court reaffirmed the broad discretion of the states to employ police powers and states' authority to delegate those powers to municipalities to determine under which conditions health regulations become operative.

[1] With the exception of Iowa, which does not require a mumps vaccine.

The most frequent arguments against compulsory vaccination are the religious clauses in the First Amendment. Supreme Court jurisprudence outside the realm of vaccination has clarified that the right of free exercise of religion does not relieve an individual of the obligation to comply with a valid and neutral law of general applicability.[2] The majority of states grant religious exemptions to school vaccine requirements, but even laws that do not provide for religious exemptions have been deemed constitutional.[20] Arguments have also been made under the Equal Protection Clause of the Fourteenth Amendment, but courts have rejected arguments that school vaccine requirements discriminate against school children to the exclusion of other groups because school children are not a constitutionally protected class.[2]

Other constitutional arguments have had less success. Constitutional rights are generally framed as the right to be free of some form of government intrusion or restriction. As such, courts have found that the Constitution does not guarantee "positive" rights, (e.g., any requirement that the government provide anything). This includes education, thus there is no limit on the sort of reasonable regulations that a state may choose to impose on the privilege of a public education.[2] Arguments that vaccine requirements are arbitrary, capricious, or unreasonable have also failed, as well as arguments that school vaccination laws constitute illegal searches and seizures that violate the Fourth Amendment.[2]

Vaccine Exemptions

Vaccine exemption laws vary by jurisdiction. All 50 states and Washington D.C. (D.C) allow for vaccine exemptions for medical reasons. There are 45 states and D.C. that grant religious exemptions.[21] Currently, 15 states allow philosophical exemptions for children whose parents object to immunizations because of personal, moral or other beliefs. How exemptions are enforced also varies among states. Examples of how states have addressed enforcement include: parental notarization or affidavit in the exemption process, and education about the benefits of vaccination and risk of being unvaccinated.[22] To reduce non-medical exemptions, the CDC recommends that states strengthen the rigor of the application process, frequency of submission, and enforcement as strategies to improve vaccination rates.[22]

There is a growing body of evidence regarding the impact of state vaccination requirements for school age children on vaccination coverage and the association of non-medical exemption rates with increased disease incidence. The use of philosophical exemptions and under immunization tends to cluster geographically, putting some communities at greater risk for outbreaks. This geographic clustering of exemptions is associated with increased local risk of vaccine-preventable diseases, such as pertussis and measles.[22]

Many of the vaccine-related bills introduced in state legislatures in 2023 reflect similarities to legislation enacted in 2021 and 2022, such as limitations on COVID-19 requirements for public and private sector employees and in schools, as well as requirements for vaccine exemptions based on medical, religious, and philosophical reasons.23 However, the vaccine-related bills enacted during the 2023 state legislative sessions have shifted in focus beyond COVID-19 to address routine immunizations and limitations on private entities.[28]

Possibility of HPV Vaccine Requirements

When discussion surrounding an HPV vaccine requirement first began, it was riddled with controversy. Being initially recommended only for females aged 11-12 years,[24] parents were uncomfortable with the idea of giving a vaccine for a STI to young girls, especially as the manufacturer mounted an expensive lobbying campaign to establish vaccine requirements.[25] The target age for vaccination was selected to capture youth prior to initiation of any sexual activity so that all children are protected.[26] However, a common misperception by parents is that the act of vaccination somehow conveys a message that sexual activity is permissible at that age.[27,28]

The traditional rationale of tying vaccination to school attendance, is to prevent the spread of a disease outbreak that would prevent large numbers of children from attending school. The traditional justification for tying vaccination to school entry not only fails to comprehensively weigh the risks and benefits of HPV vaccination, it also does not reflect the realities of vaccine requirements today. In *Boone v. Boozman*, an Arkansas court explained in the context of hepatitis B vaccines that the method of transmission is not the only factor by which a disease can be judged dangerous and thus require vaccination.[29] The caveat to *Boone* is that the court noted that the longevity of the virus on fomites added to the danger warranting a vaccination requirement for the high-traffic environment of a school setting, which may not be said of HPV. There is limited data assessing the role of fomites in the transmission of

HPV, however HPV-DNA positivity has been reported in health care settings such as on transvaginal ultrasound probes and colposcopes after routine disinfection.30

LESSONS FROM JURISDICTIONS WITH HPV VACCINE REQUIREMENTS

Since 2006, 46 states, D.C. and Puerto Rico (P.R.) have proposed legislation to require the HPV vaccine for school entry, fund HPV vaccine administration programs, or educate the public or school children about the benefits of HPV vaccination.31,32 However, only Virginia, D.C., and P.R. have enacted such legislation into law, with Rhode Island and Hawaii adopting the policy through an administrative ruling from their health departments.[38] In these five jurisdictions, the capacity to opt-out of HPV vaccination, and procedures to obtain an exemption vary by jurisdiction.[37,33,34] A limited number of studies have explored whether the enactment of school-entry requirement for HPV vaccine has impacted population-level vaccination rates, and these studies highlight the state-specific efforts that led to success or failures.[37] The findings suggest that sex-neutral, restrictive HPV vaccination requirements for school entry are associated with increased vaccination initiation among adolescents aged 13 to 17 years, however it should be noted that initiation does not mean completion of the HPV vaccine series.35,36,37,38 It should also be observed that most of the data collected from these studies do not assess the impact of the COVID-19 pandemic on HPV vaccination rates. Further, studies have cited that the socio-political differences, barriers and facilitators, including resources and political will, to adopt, implement, and enforce vaccine requirements may vary state by state.39

Rhode Island

Rhode Island continues to be a national leader in adolescent immunizations. In Rhode Island, teens are at or above the national averages for every vaccine type, due in large part to its unique infrastructure and vaccination funding.40 Rhode Island is the smallest state and does not have individual county health departments. Instead, the Rhode Island Department of Health (RIDOH) coordinates health care directly within the state and works with Rhode Island Vaccine Advisory Committee (RIVAC) regarding vaccination.41 Therefore, the RIDOH has the authority to set vaccination regulations without legislative action or approval. It should be noted that the recommendations made by RIVAC are subject to community review through a public hearing.[47] From start to finish, the process to include HPV vaccination in school requirements took about three years for the health department to implement, which is a little longer than normal due to the controversy surrounding the vaccine.[47] Even though Rhode Island was among the states with the highest levels of HPV vaccine coverage prior to enacting requirements, they still faced opposition.42,43,44 It should be noted that it is unclear whether states with lower uptake than Rhode Island would have the same outcome.[48,50]

Further, Rhode Island is one of the universal purchase vaccine states, meaning federal and other funding sources are used to provide vaccines to all children regardless of insurance status. All childhood and adolescent vaccines, and most adult vaccines, recommended by the ACIP are purchased by RIDOH from the CDC federal contract at a reduced price and distributed to immunization providers at no cost to the providers.[47,45] Federal and private insurer funding covers the cost of vaccine purchased. This eliminates the financial burdens of providers purchasing their own vaccine supply, reduces barriers, and improves equal access to all vaccines.[47] Through this program, HPV vaccines have been provided for girls since 2006 and boys since 2011.[47] During early implementation, the state promoted vaccine education by employing a physician consultant who advised pediatricians and expanded the in-school vaccination program to include middle schools.[47] Through these educational efforts, the discounted vaccine cost, and the use of programs such as “Vaccinate Before You Graduate”, the state enjoyed the highest vaccination rates in the country in 2014.[47,46]

In October 2013, the RIVAC voted to recommend HPV vaccination as a school requirement over three years with a graduated approach beginning in 2015.[37] The graduated integration was intended to ensure progress in vaccination, while also slowly increasing the logistical and administrative burdens for parents, students, and clinicians. After the measure was approved, RIDOH implemented a combined media and educational approach to provide factual information and raise awareness.[37] Rhode Island was the first state to enact a school-entry requirement for HPV vaccination that did not allow special exemptions and that applies to both males and females.[37] Rhode Island was well positioned for this challenge as they were leading the nation in HPV vaccination rates: 77 percent initiation for girls and 69 percent for boys in 2013.47,48 By including a HPV vaccine requirement after achieving high vaccination rates and broad public support, including having both males and females in the requirements, and not allowing opt-out provisions that do not apply to other vaccines, the Rhode Island HPV vaccine requirement

succeeded. As a result in 2015, it resulted in 68 percent of girls and 58 percent of boys aged 13 to 17 in Rhode Island having completed all three doses, up from 56.5 percent and 43.2 percent from 2013.[49,49] However, an analysis examining initiation rates identified an 11 percent increase in HPV vaccine initiation among boys in Rhode Island after the school-entry requirement was enacted, whereas no significant change was observed for girls.50 This set of findings indicates that school-entry requirements may reduce gender disparities and close the gap in HPV vaccine uptake.[57] It was noted that significant differences in HPV vaccine initiation among girls might not have been seen because of their already high HPV vaccination initiation rate (87.9 percent) in 2015.[49]

Washington D.C.

HPV vaccination requirements for school entry were successfully implemented in D.C. in 2009, which included liberal opt-out language and resulted in less public backlash.[53] In the case of the HPV vaccine requirements in D.C., legislation moved rapidly through the Council of the District of Columbia.[53] In the absence of public consensus about the vaccine's benefits, there were widely publicized debates about concerns that HPV vaccines were too new to be considered safe and effective, that pharmaceutical companies were untrustworthy, that the media had exaggerated the worries that the HPV vaccine would promote promiscuity, and that requirements were impinging on parental rights to make decisions for their children and forcing them to have conversations about sexuality before they believed their children were ready.[53,51,52,53] The requirement called for sixth grade girls in D.C. to: (1) receive the HPV vaccine or (2) submit a one-time opt-out form.54 According to an analysis of the 2009-2013 CDC National Immunization Survey (NIS)-Teen Vaccine Dataset, D.C.'s HPV vaccination school-entry policy was not associated with higher levels of HPV vaccination compared with non-policy jurisdictions.55 However, in 2014, the requirement was expanded to 6th grade boys and all students up through 12th grade.[60] Additionally, all those not vaccinated were required to opt-out annually. As such, the implications for teen girls was not a move from "no requirement" to an "HPV vaccine requirement," but rather a change from a one-time opt-out in 6th grade to an annual opt-out requirement through 12th grade.[60]

The sex- and age-inclusive policy was associated with increased rates of HPV vaccination.[61] In 2017, the level of HPV vaccination was higher in D.C. compared with that in non-policy states.[61] In addition, D.C. had higher levels of HPV vaccination compared with Virginia (another state with broad opt-out provisions), suggesting that the former's more inclusive and stricter policy (i.e., annual exemption filing requirements) was associated with greater increases in vaccination initiation than the latter.[61] Furthermore, the jurisdiction's school-entry policy appeared to increase post-policy HPV vaccination initiation among boys and younger girls.[61]

The D.C. policy change offers broader insights into the importance of how vaccine requirements are implemented. While respondents view vaccine school requirements more favorably if they contain broad opt-out provisions, these provisions likely reduce the requirement's efficacy.56

Virginia

In April 2007, Virginia became the first state to enact a law requiring HPV vaccination of girls before entry into the sixth grade.57 The requirement became effective in October 2008; however, given the timing of when the requirement went into effect, it did not change school admission requirements until the 2009 school year.[63] Virginia allows for both medical and religious exemptions for all vaccines recommended as part of the Advisory Committee on Immunization Practices recommended series. However, when the HPV requirement was added to the Code of Virginia, it allowed for an HPV-specific philosophic exemption.[63] The rationale for the exemption reads: "Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent or guardian's sole discretion, may elect for their child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board." [63,58]

The HPV vaccine requirement in Virginia (similar to the pre-2014 requirement in D.C.) moved rapidly through the legislature without input from key stakeholders.[53] Interviews with Virginia parents indicated that many parents did "opt-out" of vaccinating their daughters, and the data in other studies corroborate low-levels of compliance with requirements.[53,59] Studies found there was no effect on the rate of HPV vaccination in the five years since its enactment in Virginia.[63,60] Among a cohort of girls who sought well-child care, HPV vaccine uptake was noted to be higher among minorities and those with public insurance than White girls or those who were privately insured.[63,61] These findings are concordant with the pre-requirement vaccination data and with the rates of HPV

vaccine uptake, which was defined as ≥1 dose, within the NIS Teen Vaccine Dataset.[63,66] Understanding the implications of these findings requires a consideration of Virginia law against a broader context of compulsory vaccination in the U.S.[63] The philosophic exemption for HPV vaccination in Virginia is broad, easy to cite verbally, and is largely unenforced.[63] As a result, philosophic exemption was noted as likely a large contributor to the findings of these studies.[63] It was also noted that these findings are not explained entirely by the presence of a lax exemption.[63] Parental education and perceived susceptibility to HPV, physician recommendation, and the cost of vaccination are all factors involved in the parental decision to accept or opt-out of vaccination.[63]

Puerto Rico

In part due to P.R. having high HPV vaccination rates in adolescents ages 13-17, in June 2017, P.R.'s Department of Health (DOH) announced that the HPV vaccine would be added to the list of school-entry required vaccines for fall 2018.[45,62,63] Subsequently, in May 2018, the DOH formally announced that the HPV vaccine would be required for 11 to 12-year-old children starting during the 2018–2019 academic year.[45,68,69] As established by P.R.'s Immunization Law of 1983, only medical or religious exemptions are permitted. Similar to other vaccine school-entry requirements, not having the required vaccines would ultimately result in children not being permitted to attend school.[45,64] For the 2019–2020 academic year, the requirement was expanded to include adolescents up to 14 years old.[45,68] The adoption of this policy was influenced by stakeholders from medical professional organizations, academia, government staff, non-profit organizations, and the members of the private sector.[45,68] Adopting this policy took many years and much groundwork (i.e., legislation, education).[45] The epidemiologic impact of the disease was considered before the policy's adoption, as was the jurisdictions already high HPV vaccine initiation rates.[45] In 2016, before the implementation of the requirement, vaccination rates were 80.8 percent in girls and 71.1 percent in boys with one or more HPV vaccine doses.65 Another consideration was the initial cohort chosen (i.e., children aged 11 to 12 years), which requires only two doses of the vaccine, resulting in a more cost-efficient approach.66

Previous studies have documented that parents, primarily Latino or Spanish-speaking parents, perceive that the age of 11 is too early for HPV vaccination and also express concern that this could promote sexual activity.[68,67] Hence, prior to implementation, most of those who initiated vaccination were between 13 to 17 years old.[68,73] Post-implementation studies found significant evidence of improvement in vaccination rates associated with the HPV school-entry vaccination requirement.68 One year after implementation of the requirement, adolescents from 11 to 12 years old, , began to lead initiation rates (89.8 percent) compared to adolescents 13 to 17 years (82.6 percent).[74] Although adolescents aged 13 to 17 years lead HPV UTD vaccine coverage rates, the UTD vaccine coverage rates for adolescents between 11 and 12 years improved after policy implementation.[74] These findings support the notion that the way the school-entry vaccine requirement policy is designed and implemented impacts HPV vaccination uptake.

In P.R., the adoption of the HPV vaccine school-entry requirement can be evaluated, in part, through a bottom-up approach to policy making (i.e., driven by diverse sectors of society, not necessarily starting with the top level of policy makers/politicians).[45,69] Using the bottom-up approach allowed a more thorough understanding of policy creation and implementation by evaluating the 'network of actors' that participated in the process and focusing on local factors.[45,75] Empowered with local data, stakeholders created multisectoral collaborations to combine limited resources. Moreover, educational efforts and the publicized case of Rhaiza (a mother of three who died from cervical cancer) facilitated the adoption process. Rhaiza's case was a catalyst for increasing HPV-related and cervical cancer knowledge among the public.[45] It served to create a public face and champion that was relatable, as a mother, spouse, and daughter. Champions, usually studied at the organizational level, have been highlighted as a need for effective implementation.[45,70] Moreover, humanizing the impacts of disease proved useful among certain segments of the population who might have otherwise been hesitant to be vaccinated.

Vaccine policy adoption and implementation in P.R. benefited from the assessment and consideration of context-specific factors to help build trust and confidence among communities.[45,71] For instance, Hispanics show higher odds of support for HPV vaccine school-entry requirements compared to non-Hispanic Whites in the U.S.[45,72] In the case of P.R., perspectives on the implementation of the HPV vaccine school-entry requirement from parents of unvaccinated children were reported as mixed.[45,72] Half of the parents supported the policy, while those who were uncertain mentioned concerns related to the early age of vaccine administration, vaccine safety, and parental autonomy.[45,72] Therefore, it was important for individuals and organizations involved in vaccination efforts, such as local health departments, to adapt and tailor to context, including the politico-cultural context, when considering

vaccine policies and educational interventions.[45,73] In P.R., a broad coalition of individuals and organizations from multiple facets of society (i.e., physicians, non-profit organizations) convened to rally for support of the requirement.[45,72] Further, diverse perspectives were included when thinking about and implementing vaccine requirements that affect historically marginalized populations (e.g., groups with limited access to providers who can offer the required vaccine).[45] The HPV vaccine was also covered for eligible students, via the federal program Vaccines for Children, the government-funded insurance, or private insurance.[45,72]

BEST PRACTICES FOR IMPLEMENTING VACCINE REQUIREMENTS

Studies that examined school-entry requirements noted that they should be considered alongside other initiatives and policies for promoting HPV vaccine uptake.[56] In fact, it was found that a combination of policies, such as Medicaid expansion, policies allowing pharmacists to administer HPV vaccines, school-entry requirements, and sexual education requirements are associated with higher HPV vaccine uptake.[56,74] As seen through the successes in Rhode Island, P.R., and D.C., a multi-pronged approach that is state specific is necessary to ensure success.[45,47,61] This includes limiting broad opt-out provisions, collaborations with public health entities, schools, and the public, providing the HPV vaccine at no cost, understanding the socio-political differences, barriers and facilitators to adopt and implement vaccine requirements, educational efforts to address concerns about HPV vaccine safety and efficacy, and building confidence and trust with the public.75

In establishing a vaccine requirement, it is important to consider implementation with care and with regard to the context.76 Overly strict vaccine requirements can result in parents finding ways to avoid the vaccine, and selective requirements might damage the broader vaccination program.[82] Removing the choice of opting out entirely might simply induce parents to seek loopholes, and, worse, fuel negative attitudes towards vaccination.[82] For example, in 2015, California became the third U.S. state to eliminate all non-medical exemptions.[82] This change in the law was preceded by a 2014 administrative initiative to reduce the misuse of a school admission process involving 'conditional entrants' — children who have started the required vaccination schedule but have not completed it.[82,77] Following the elimination of non-medical exemptions, many parents with strong objections to vaccination simply acquired medical exemptions instead, educated their children at home, enrolled them in independent study programs that do not require classroom-based instruction, or found other loopholes.[82,83] Medical exemptions rose from 0.2 percent to 0.7 percent in the year following the bill.78

A requirement to vaccinate when the vaccine or primary-care service is difficult or impossible for many people to access creates further inequities.[81,79] Therefore, before even considering requirements, states must ensure that people from all sectors of society can get vaccines easily and safely. This includes ensuring a stable supply of vaccines. The following steps are considered essential best practices (also summarized in Appendix I Figure 1) before states assess if requirements are considered politically appropriate: (1) ensure access to the required vaccine which includes ensuring a stable supply of the vaccine at various locations of access; and (2) use multiple interventions to improve uptake which includes understanding the reasons for under-vaccination, using reminders, and providing vaccinations in communities.[81]

CURRENT BARRIERS TO IMPLEMENTING VACCINE REQUIREMENTS

The COVID-19 pandemic highlighted several barriers to vaccine requirements overall. There was speculation that rampant misinformation related to the COVID-19 vaccine would lead to a spillover of distrust into vaccination in general, potentially leading to a reduction in childhood vaccination rates.[35] Attitudes regarding school requirements for routine vaccinations became more negative, suggesting a spillover of anti-requirement sentiments more broadly.[80] During the 2020–21 school year, national coverage with state-required vaccines among kindergarten students declined from 95 percent to approximately 94 percent.81 Despite widespread return to in-person learning, COVID-19–related disruptions continue to affect vaccination coverage, preventing a return to pre-pandemic coverage levels among kindergarten students and adolescents. Compounding matters, a recent study evaluated the prevalence of vaccine hesitancy among parents about specific vaccines, including HPV. That study found that 55.9 percent of children had a parent hesitant about COVID-19 vaccine, 30.9 percent hesitant about influenza vaccine, 30.1 percent hesitant about HPV vaccine, and 12.2 percent had a parent hesitant about other vaccines such as measles, polio, and tetanus.82

Public support for school requirements for routine childhood vaccination dropped by 10 to 12 percentage points between 2019 and 2023 (down to only 70-74 percent support three years into the pandemic).[37] This left about one-

quarter of U.S. adults (25-28 percent) opposed to vaccine requirements in 2023, which is the highest level of opposition to routine childhood vaccination requirements in recent history.[37] Notable drops in support during this time occurred among specific political parties, as well as among adults who are not vaccinated against COVID-19.[80]

The vaccine requirement tension can be highlighted by recent attempts to add required vaccines for school kids in Wisconsin and California.83 AB 659 introduced during the California 2023-2024 legislative session originally required pupils to be fully immunized against HPV before admission or advancement to the 8th grade level of any private or public elementary or secondary school.84 The bill passed after being amended by removal of the requirement for middle schoolers.[87,88] Lawmakers stripped out that provision without any debate, reflecting the contentious nature of school vaccine requirements even in a state with some of the nation's strictest immunization laws.[87,88] Wisconsin is one of the only other states that attempted to enact any kind of vaccine requirement in 2023, through its health department.[87] What should have been a simple update — to put the state in line with federal recommendations requiring that 7th-graders be vaccinated against meningitis and 12th-graders be boosted for it — became a supercharged political issue as lawmakers blocked it from passing.[87]

INTERVENTIONS FOR INCREASING HPV VACCINATION RATES

One of the most effective interventions to increase vaccine uptake in individuals is strong recommendation for vaccination by their health care professional.[39,]85 Research documenting HPV vaccination inequities suggests low-income and Black (vs. White) girls are less likely to receive a strong health care professional recommendation for vaccination and the racial gap in recommendations has waned, but not disappeared, over time.86,87 Reminder-based interventions for health care professionals such as standing orders and social media campaigns have improved vaccination coverage.88 In addition to campaigns and interventions to improve health care professional recommendations for the HPV vaccine, statewide policies can lead to downstream impact on HPV vaccination.[56,80] A recent analysis of Medicaid expansion and HPV vaccine uptake supports improvements in vaccination in states that expanded Medicaid.[56,]89 Taking a comprehensive systems approach to HPV vaccination is needed. Further, a review of studies evaluating school entry requirements for other adolescent vaccines observed positive spillover effects for HPV vaccination. Federally funded programs related to VFC and Medicaid were consistently associated with higher HPV vaccination coverage.90 Finally, studies have found that environmental interventions, particularly school-based and childcare center-based vaccination programs were most effective in increasing vaccination coverage.91

The Community Preventive Services Task Force has also released the following findings on what works in public health to improve vaccination rates based on available evidence. The following interventions could be applied to increasing HPV vaccination rates:

- Home visits to increase vaccination rates.92
- Vaccination programs in schools and organized child-care centers.93
- Vaccination programs in (Women, Infants, Children) WIC settings.94
- Immunization information systems set up to create or support effective interventions, such as client reminder and recall systems, provider assessment and feedback, and clinician reminders for vaccination or missed vaccination opportunities.95

EXISTING AMA POLICY

AMA policy H-440.872 "HPV-Associated Cancer Prevention" urges physicians to educate themselves and their patients about HPV and associated diseases, HPV vaccination, as well as routine HPV related cancer screening. This policy also states that the AMA will intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public. Further, it recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination and encourages interested parties to investigate means to increase HPV vaccination rates by facilitating administration of HPV vaccinations in community-based settings including school settings.
AMA policy H-440.970, "Nonmedical Exemptions from Immunizations" states that the AMA believes that nonmedical (religious, philosophic, or personal belief) exemptions from immunizations endanger the health of the unvaccinated individual and the health of those in the community at large. It also supports the immunization recommendations of ACIP for all individuals without medical contraindications. It is of particular importance to

note is that this policy recommends that states have in place an established mechanism, which includes the involvement of qualified public health physicians, of determining which vaccines will be mandatory for admission to school and other identified public venues based upon the recommendations of the ACIP and policies that permit immunization exemptions for medical reasons only.

The AMA has not singled out specific vaccines for school entry requirements, beyond outlining conditions that should be met before decisions to mandate COVID-19 vaccination for school attendance for children and college/university students. Those considerations included:

a. After a vaccine has received full approval from the U.S. Food and Drug Administration through a Biological Licenses Application.
b. In keeping with recommendations of the Advisory Committee on Immunization Practices for use in the population subject to the mandate as approved by the Director of the Centers for Disease Control and Prevention.
c. When individuals subject to the mandate have been given meaningful opportunity to voluntarily accept vaccination.
d. Implementation of the mandate minimizes the potential to exacerbate inequities or adversely affect already marginalized or minoritized populations.

The AMA also continues to develop material and publish new stories on how doctors can effectively communicate with patients to help build vaccine confidence.96,97

CONCLUSION

HPV is a common virus, some types of which spread through sexual contact.98 Some sexually transmitted HPVs can cause genital warts, whereas others, called high-risk or oncogenic HPVs, can cause cancer.[102] High-risk HPVs cause virtually all cervical cancers, most anal cancers, and some vaginal, vulvar, penile, and oropharyngeal cancers.[6] Research has demonstrated that the HPV vaccine is a safe and effective way to decrease HPV-related cancers. However, the vaccination rate in the U.S. is suboptimal.

When first proposed, HPV school vaccine requirements were controversial. Some parents were uncomfortable with the idea of giving a vaccine for a STI to young girls age 11-12.[25] The U.S. has a long history of using school requirements to increase vaccination rates; these requirements have been consistently upheld by U.S. courts against claims that they violate individual rights.99 Currently, Hawaii, Rhode Island, Virginia, P.R, and D.C. have laws that require HPV vaccination for school entry. The requirement and opt-out provisions vary by state/territory as well as the success of the school entry requirement on HPV vaccine series initiation and completion. Findings suggest that sex-neutral, restrictive HPV vaccination requirements for school entry are associated with increased vaccination initiation among adolescents aged 13 to 17 years.[41-44] However, it should be noted that initiation does not mean completion of the HPV vaccine series.

Data studying jurisdictions with HPV vaccine requirements have shown that broad opt-out provisions, low enforcement of—and adherence to—HPV vaccine requirements, and no mechanism to ensure completion of the HPV vaccine series have limited the success of requirements.[91] Moreover, without widespread public support, monitoring, sanctions for noncompliance, or changes to the method of vaccine administration, school-entry HPV vaccine requirements are limited in encouraging HPV vaccine initiation and completion alone.[39] Therefore successful efforts have been attributed to limited opt-out provisions, funding efforts to provide HPV vaccines for free, educational campaigns, the route of enacting the HPV requirement, and involvement of a diverse group of interested parties prior to implementation of vaccine requirements.[45,47,61,81] Failed efforts have been attributed to broad opt-out provisions, lack of educational campaigns, and sex-specific requirements.[45,47,61,81] Further, studies have noted that the socio-political differences, barriers and facilitators, including resources and political will, to adopt and implement vaccine requirements are important to consider when evaluating the success of HPV vaccine requirements.[45,47,61,81]

Finally, strong recommendations from health care professionals, parent education, and school and childcare center-based vaccination programs are also effective ways to increase initiation of HPV vaccination and ensure completion of the HPV vaccine series.100 Stronger health care practices such as more in-depth discussions with hesitant parents and establishing vaccination as the default are strategies that could also help improve vaccination coverage rates.[49]

Current AMA policy supports ACIP recommended vaccines and does not single out specific vaccines that should be required for school entry. Rather, AMA policy supports states to have in place an established mechanism, which includes the involvement of qualified public health physicians, of determining which vaccines will be mandatory for admission to school and other identified public venues based upon the recommendations of the ACIP and policies that permit immunization exemptions for medical reasons only.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That our AMA amend policy H-440.872, "HPV-Associated Cancer Prevention" by addition and deletion to read as follows:

HPV-Associated Cancer Prevention, H-440.872
1. Our AMA (a) strongly urges physicians and other health care professionals to educate themselves, appropriate patients, and patients' parents or caregivers when applicable, about HPV and associated diseases, the importance of initiating and completing HPV vaccination, as well as routine HPV related cancer screening; and (b) encourages the development and funding of programs targeted at HPV vaccine introduction and HPV related cancer screening in countries without organized HPV related cancer screening programs.
2. Our AMA will work with interested parties to intensify efforts to improve awareness and understanding about HPV and associated diseases in all individuals, regardless of sex, such as, but not limited to, cervical cancer, head and neck cancer, anal cancer, and genital cancer, the availability and efficacy of HPV vaccinations, and the need for routine HPV related cancer screening in the general public.
3. Our AMA supports legislation and funding for research aimed towards discovering screening methodology and early detection methods for other non-cervical HPV associated cancers.
4. Our AMA:
(a) encourages the integration of HPV vaccination and ~~routine cervical~~ appropriate HPV-related cancer screening into all appropriate health care settings and visits,
(b) supports the availability of the HPV vaccine and routine cervical cancer screening to appropriate patient groups ~~that benefit most from preventive measures~~, including but not limited to low-income and pre-sexually active populations,
(c) recommends HPV vaccination for all groups for whom the federal Advisory Committee on Immunization Practices recommends HPV vaccination.
5. Our AMA supports ~~will encourage~~ efforts by states ~~appropriate stakeholders to investigate means~~ to increase HPV vaccine availability and accessibility, and HPV vaccination rates through a combination of policies such as ~~by~~ facilitating administration of HPV vaccinations in community-based settings ~~including school settings~~ including local health departments and schools, reminder-based interventions, school-entry requirements, and requirements for comprehensive and evidence-based sexual education.
~~6. Our AMA will study requiring HPV vaccination for school attendance.~~
6~~7~~. Our AMA encourages collaboration with interested parties to make available human papillomavirus vaccination, according to ACIP recommendations, to people who are incarcerated for the prevention of HPV-associated cancers.
7. Our AMA advocate that racial, ethnic, socioeconomic, and geographic differences in high-risk HPV subtype prevalence be taken into account during the development, clinical testing, and strategic distribution of next-generation HPV vaccines
8. Our AMA will encourage continued research into (a) interventions that equitably increase initiation of HPV vaccination and completion of the HPV vaccine series; (b) the impact of broad opt-out provisions on HPV vaccine uptake; and (c) the impact of the COVID-19 pandemic and vaccine misinformation on HPV vaccine uptake. (Modify Current HOD Policy)

2. That our AMA adopt the following new HOD policy.

IMMUNIZATON REQUIREMENTS

Our AMA recognizes that immunization requirements, including those for school attendance, serve as a strong motivator for parents and families to immunize their children according to the schedule recommended by the Centers for Disease Control and Prevention. (New HOD Policy)

3. That our AMA reaffirm Policy H-440.970, "Nonmedical Exemptions from Immunizations. (Reaffirm HOD Policy)

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4. REDUCING SODIUM INTAKE TO IMPROVE PUBLIC HEALTH

Reference committee hearing: see report of Reference Committee K.

HOD ACTION: ADOPTED AS FOLLOWS
See Policy H-150.929

INTRODUCTION

At the 2023 Annual Meeting of the American Medical Association (AMA) House of Delegates (HOD), Resolution 423, "Reducing Sodium Intake to Improve Public Health," called for our AMA to work with relevant partners to advocate and advise salt reduction through public outreach, which could include ad campaigns and educational programs. Further, the resolution asked for our AMA to study and report back to the AMA HOD on the effectiveness and feasibility of various salt reduction strategies. This resolution was referred for study. The Reference Committee asked our AMA to review trends in evidence-based strategies that are intended to improve health via sodium reduction in key populations and to report back to HOD.

In 2006, the Council on Science and Public Health (CSAPH) issued a report on reducing sodium intake to decrease the public health burden of cardiovascular disease, providing information on recommended target levels for population sodium intake, and identifying policy approaches to meet these goals. The report summarized the existing evidence on sodium intake and blood pressure, concluding that across populations, increases in blood pressure and the prevalence of hypertension are related to salt intake, with modest but consistent findings showing the effect of salt consumption on blood pressure. The report highlights the potential public health benefits from interventions and policies that could reduce population level sodium intake, but also notes that reduced salt intake "should be only one component of a comprehensive strategy to lower blood pressure. Increasing physical activity, consuming a diet high in fruits and vegetables and low in saturated and total fat, and moderation in alcohol intake," are recommended approaches to preventing and managing hypertension. The report's recommendations, which were adopted, called for a step-wise minimum 50 percent reduction in sodium in processed foods, fast food products, and restaurant meals to be achieved over the next decade. This report provides an update on the current evidence regarding dietary sodium and its impact on blood pressure and cardiovascular disease as well as a summary of the effectiveness and evaluation research on interventions and policies to reduce dietary sodium.

BACKGROUND

Hypertension, otherwise known as high blood pressure, is a condition that develops when blood flows through arteries at higher-than-normal pressures on a consistent basis. Hypertension is an important risk factor contributing to a number of poor health outcomes, including heart disease and stroke, vision impairment, cognitive decline, sexual dysfunction, complications in pregnancy, and kidney disease.[1,2] Hypertension is an epidemic in the U.S. and affects more than an estimated 120 million adults, approximately half the adult population.[3] National Health and Nutrition Examination Survey (NHANES) data over the last 20 years shows an upward trend in hypertension in the last few years after steady declines between 2000 and 2010 (see Figure 1).[4] In 2022, more than 850,000 people died from heart disease and stroke (combined), the first and fifth leading causes of mortality in the U.S., respectively.[5]

Additionally, hypertension and cardiovascular disease disproportionately impact some populations more than others. Non-Hispanic Black Americans are diagnosed with hypertension earlier in life and experience greater hypertension-related morbidity and mortality compared to non-Hispanic White persons.[6,7] While death rates from cardiovascular disease have generally declined since the mid-20th century, mortality rates among Black populations have remained persistently high in comparison with all other racial and ethnic groups.[7,8] Black Americans have a 30 percent higher risk of fatal stroke, 50 percent higher risk of cardiovascular mortality, and more than four times higher risk of end-stage renal disease.[6] However, Black Americans are not the only ones who face inequities in the U.S. Recent data indicate Hispanic and Indigenous populations also have a high prevalence of uncontrolled blood pressure.[9] Many factors contribute to these health disparities, but chief among them are social determinants of health, which include poor access to consistent health care, low health literacy, lower socioeconomic status, neighborhood/environment stability, reduced access to healthy food, as well as the historical context and current state of structural racism.[6,7] One of the most important risk factors for hypertension is poor diet, and high sodium consumption has been described as the leading dietary risk factor for poor cardiovascular outcomes and mortality.[10]

The most common source of sodium in the American diet comes from added salt, or sodium chloride. Sodium is a mineral that plays an important role in our body and is one of the two chemical elements found in salt (40 percent sodium, 60 percent chloride). In terms of the physiological role of sodium, our bodies require a small amount of sodium (estimated to be roughly 500 mg/daily) to conduct nerve impulses, contract and relax muscles, and maintain the proper balance of water and minerals.[11] One teaspoon of salt (about 6g or 6000 mg) is equivalent to 2300 mg of sodium, which is the recommended dietary reference limit developed by the National Academy of Medicine.[12] However, the current average consumption of sodium in the U.S. is about 3400 mg/d, approximately 50 percent more than the recommended limit of 2300 mg/d for adults and children 14 years and older.[13] More than 90 percent of people in the U.S. exceed recommended limits across almost all age groups. For example, more than 95 percent of children aged 2 to 13 years old exceed recommended limits for their age group, the consequences of which could track into adulthood and influence later health outcome (see Figure 2).[13]

The high level of salt in the American diet is primarily a result of packaged and preprepared foods, versus salt added at the point of consumption. More than 70 percent of sodium intake in the U.S. is from packaged food and food prepared away from home, including restaurants and food service operations, while just 11 percent of sodium intake is from sodium added at the table or in cooking at home (see Figure 3).[14] Even though people in the U.S. can reduce their personal use of salt, sodium levels in the U.S. food supply at the time of purchase or consumption make it extremely challenging to reduce overall sodium levels at the population level. The Centers for Diseases Control and Prevention (CDC) has outlined the top foods contributing to high sodium levels in the U.S. diet, which include rice, pasta, and other grain-based dishes; meat, poultry, and seafood dishes; pizza; soups; chips, crackers, and savory snacks; condiments and gravies; cold cuts and cured meats; and breads and tortillas.[15]

To this end, in 2016, the U.S. Food and Drug Administration (FDA) took action on reducing sodium in processed foods by publishing draft guidance on voluntary sodium reduction goals for industry with an aim to reduce U.S. daily intake from 3400 mg to 3000 mg within two years (short-term goal) and to 2300 mg within 10 years (long-term goal). In 2021, the FDA issued the final guidance with voluntary targets for reducing sodium in commercially processed, packaged and prepared food over the next 2 and a half years.[16] Healthy People 2030 data shows that sodium consumption has decreased slightly from the baseline amount of 3,414 mg in 2013-16 to 3,346 mg in 2017-2020 (the most recent years of data), but there is a long way to go to meet the Healthy People 2030 target of 2,731 mg.[17] In August 2024, FDA published new draft guidance with updated, 3-year voluntary sodium reduction targets in foods, referred to as Phase II. The new voluntary targets, if achieved, would help support reducing sodium intake to about 2,750 mg/day in the U.S. general population.[18]

High sodium consumption and hypertension is not only an American challenge; 96 countries around the world are working to reduce sodium intake and 48 have set sodium target levels for one or more processed foods.[13] A study on the health effects of dietary risks in 195 countries across the globe estimated the proportion of disease-specific burden attributable to each dietary risk factor (also referred to as population attributable fraction) among adults aged 25 years or older and found that high sodium intake was the leading dietary risk factor attributable to approximately 3 million deaths and 70 million disability-adjusted life-years (DALYs), whereas the low intake of fruits was associated with 2 million deaths and 65 million DALYs.[19] The World Health Organization (WHO) has prioritized dietary sodium reduction and declared a 30 percent reduction in population sodium intake by 2025 global target for noncommunicable disease prevention.[20] The WHO developed a public health framework to develop a successful salt reduction strategy, called the SHAKE package, with the following key activity areas aligning to the SHAKE acronym: Surveillance, Harness Industry, Adopt standards for labelling and marketing, Knowledge, and Environment.[21] Additionally, the European Food Safety Authority recently proposed that 2000 mg sodium per day is a safe and adequate level of intake for the general population of adults.[22] Further examples of national policies to reduce sodium consumption and their effectiveness are outlined below.

METHODS

English language studies and articles were selected from searches of PubMed and Google Scholar using the search terms “sodium sensitivity”, “sodium and cardiovascular disease and/or hypertension”, “sodium reduction”, sodium chloride/*adverse effects”, and sodium reduction policies”, with a focus on articles published since 2014. Additionally, the Cochrane Database of Systematic Reviews was also searched for relevant studies. Websites managed by government agencies and affinity organizations including but not limited to National Heart Lung and Blood Institute, American Heart Association, U.S. Department of Agriculture, National Academy of Sciences, U.S. F DA, National Salt and Sugar Reduction Initiative, and the Salt Institute were searched for relevant information.

DISCUSSION

Relationship Between Sodium Intake and Health – An update on the evidence

Since the 2006 CSAPH report, there have been numerous studies that have assessed the relationship of dietary sodium intake with several health outcomes, including hypertension, stroke, cardiovascular disease, and mortality, as well as evaluation studies of different policies implemented to decrease dietary sodium. This report highlights the findings from available meta-analyses and systematic reviews as opposed to individual studies given the volume of publications since the previous report.

While there has been extensive research on this topic over the last two decades and consistent governmental calls for population level sodium reduction, there is an ongoing debate on the dose-response relationship between sodium intake and health outcomes. One side argues the relationship is a linear one – as sodium intake increases, so does the risk of poor health outcomes – versus the other side, which argues there is more of a J- or U-shaped relationship – that with sodium intake at either end of the spectrum, either too low or very high, there is an increase in poor health outcomes.[23–26] Proponents of the linear relationship between sodium and poor health outcomes have suggested the controversy on this issue is unfounded and a result of researcher bias resulting from ties with the food and beverage industry, inappropriate research methodology, and a lack of rigor in research.[27,28] Proponents of the non-linear relationship contend that it has not been shown to be feasible to lower sodium intake in entire populations to the recommended low levels, that the evidence linking sodium consumption with cardiovascular disease has been inconsistent, and that current evidence from cohort studies suggests that an average sodium intake between three to five g/day is optimal in that it is associated with the lowest risk of death or cardiovascular disease.[25] Several recent large meta-analyses and systematic reviews generally support the linear dose-response relationship despite some variability in findings. The following research summary focuses on the relationship between sodium and hypertension, followed by a discussion of the research on the association between sodium and other cardiovascular morbidity and mortality outcomes.

Sodium and Hypertension

A 2021 systematic review and dose response meta-analysis of the relationship between sodium intake and hypertension included an analysis of available cohort studies (n = 11) that used dietary intake or urinary sodium excretion to measure sodium intake.[29] The studies included in the analysis were published between 1990 and 2017, with an overall sample size of more than 100,000 participants. The reference category was set at 2 g/day of sodium and study authors demonstrated a relative risk of hypertension equal to 1.04 (95 percent confidence interval of 0.96–1.13) and 1.21 (95 percent confidence interval of 1.06–1.37) at 4 g/day and 6 g/day, respectively. In other words, the risk of having hypertension increased by four percent at 4g/day (although it was not statistically significant) and 21 percent at 6 g/day, as compared to the reference group with an intake of 2 g/day. When the study authors removed studies that had high levels of bias or did not use the more accurate urinary excretion method, the linear relationship was clearer. The authors concluded that inappropriate exposure methodology may have biased previous study results particularly at low sodium intakes, hiding a linear relationship between exposure and blood pressure, indicating that the lower the sodium intake, the lower the risk of hypertension.[29]

In another systematic review by the same authors, they conducted a dose–response meta-analysis using a novel statistical approach, including trials with at least four weeks of follow-up; 24-hour urinary sodium excretion measurements; sodium manipulation through dietary change or supplementation, or both; and measurements of systolic and diastolic BP at the beginning and end of treatment.[30] They identified 85 eligible trials eligible for inclusion in their analysis and demonstrated an approximately linear and significant relationship between sodium intake and mean systolic as well as diastolic blood pressure, with no indication of a J-shaped relationship. Linear regression analyses from this study indicated that every 100 mmol/d reduction in urinary sodium excretion was associated with a lower mean systolic blood pressure of 5.56 mmHg (95 percent confidence interval of -4,52 to -6.59) and a lower mean diastolic blood pressure of 2.33 mmHg (95 percent confidence interval of -1.66 to -3.00). Results were similar for participants with or without hypertension, but the group with hypertension showed a steeper decrease in blood pressure after sodium reduction.[30]

A 2020 Cochrane systematic review on the effects of a low sodium versus high sodium diet assessed 195 randomized controlled trials and 27 population studies. A key takeaway from this review was that a mean salt intake reduction from 11.5 g per day to 3.8 g per day resulted in a reduction of 1.1/0 mmHg (about 0.3 percent)

systolic/diastolic blood pressure in people with normal blood pressure and 5.7/2.9 mmHg (about three percent) in people with hypertension.[31] The finding that sodium reduction had more pronounced impacts on those with hypertension is aligned with the previous mentioned studies. The Cochrane review also evaluated evidence for different populations, finding that for White people with elevated blood pressure, sodium reduction decreases blood pressure by about 3.5 percent, but in Asian and Black individuals the effect of sodium reduction was a little larger. However, the review authors note that there are too few studies to make definitive conclusions.[31]

The Cochrane review findings also highlight the effect of sodium reduction on other hormones and lipids in the body, noting that renin increased 55 percent; aldosterone increased 127 percent; adrenalin increased 14 percent; noradrenalin increased 27 percent; cholesterol increased 2.9 percent; and triglyceride increased 6.3 percent. From these results, the study authors concluded that the potentially harmful increase in hormones and lipids calls into question whether sodium reduction would have overall beneficial effects, particularly in a White population with normal blood pressure which saw only marginal reduction in blood pressure from sodium reduction.[31] Other researchers have called this an erroneous conclusion and called the inclusion of the acute metabolic studies in this Cochrane review irrelevant to the more general public health recommendations of modest reduction in sodium intake over time.[32] Meta-analyses excluding very short-term sodium restriction trials demonstrated that sodium reductions do not have adverse effects on blood lipids while having clinically significant benefits on blood pressure.[33,34] A 2013 Cochrane systematic review and meta-analysis found no significant changes in plasma concentrations of total cholesterol (0.05, $P = 0.18$), low density lipoprotein cholesterol (0.05, $P = 0.11$), high density lipoprotein cholesterol (-0.02, $P = 0.11$), or triglycerides (0.04, $P = 0.22$) but noted statistically significant increases in plasma renin activity (0.26, $P < 0.001$), aldosterone (73.20, $P < 0.001$), and noradrenaline (187, $P = 0.01$).[34]

Sodium and Cardiovascular Morbidity and Mortality

A 2014 update of a Cochrane review done in 2011 assessed the long-term effects of advice and salt substitution, aimed at reducing dietary salt, on mortality and cardiovascular morbidity and whether a reduction in blood pressure is an explanatory factor in the effect of such dietary interventions on mortality and cardiovascular outcomes.[35] Eight studies met inclusion criteria, three for normotensives and five in hypertensives or mixed populations. Risk ratios for all-cause mortality were imprecise and showed no evidence of reduction and there was weak evidence of benefit for cardiovascular mortality. However, small reductions in systolic blood pressure were found in normotensives with greater reductions in hypertensives. The authors concluded there was insufficient power to confirm clinically important effects of dietary advice and salt substitution, which highlights the importance of interventions that focus on removing sodium from the diet at a population level, versus those that focus on individual behavior changes.[35]

A 2018 dose-response meta-analysis of prospective cohort studies on the association of sodium intake with the risk of cardiovascular morbidity and mortality identified 16 relevant studies reporting on over 205,000 individuals.[36] Study authors estimated the effects for 100 mmol-day increases in sodium intake on cardiac death, total mortality, stroke, or mortality and found that an increase in sodium intake had little to no effect on the risk of cardiac death and total mortality, but the risk of stroke incidence and mortality significantly increased. The authors also found that low sodium intake (less than 3 g/day) was associated with an increased risk of cardiac death, while moderate (3-5 g/day) or heavy (greater than 5 g/day) sodium intake was associated with an increased risk of stroke mortality.[36] The findings of this meta-analysis provides some support to the proposition that the dose-response relationship between sodium and some cardiovascular outcomes have a J-shape.
Another 2020 systematic review and meta-analysis evaluated the dose-response relationship between dietary sodium intake and risk of cardiovascular disease.[37] This analysis identified 36 reports, including a total of 616,905 participants, and the study authors found a linear relationship between sodium intake and increased risk of cardiovascular disease, concluding a statistically significant relative risk of 1.06 in cardiovascular disease for every 1 gram of sodium increase.[37] Additionally, a systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ) evaluated the effects of sodium and potassium intake on chronic disease outcomes and risk.[38] Reviewing 171 studies, the AHRQ study identified nearly 50 randomized controlled trial studies supporting a significant lowering effect on blood pressure from sodium reduction in adults, with a stronger effect in those with hypertension. However, the review found only a small number of randomized controlled trial studies assessing the effects of sodium reduction on longer term chronic outcomes, concluding that while sodium levels appear to be associated with all-cause mortality, the shape of the relationship could not be determined. Overall, the AHRQ report concludes that reducing sodium intake, increasing potassium intake, and the use of potassium containing salt substitutes in the diet significantly decreases blood pressure, particularly among those with hypertension. Additionally, they note that limited evidence suggests that sodium intake is associated with risk for all-cause

mortality, and that reducing sodium intake may decrease the risk for cardiovascular disease morbidity and mortality.[38]

Several studies have modeled the reductions in cardiovascular disease outcomes from interventions to reduce dietary salt.[39,40] In one study, the authors used the Coronary Heart Disease Policy Model to quantify the benefits of population-wide reductions in dietary salt of up to 3 gm/day (1200 mg/day of sodium) in the U.S., estimating cardiovascular disease rates and costs in age, sex, and race subgroups.[40] The authors also compared salt reduction with other interventions to reduce cardiovascular risk and determined the cost-effectiveness of salt reduction compared with drug treatment of hypertension. The study estimated a projected 60,000–120,000 fewer new coronary heart disease cases, 32,000–66,000 fewer new strokes, 54,000–99,000 fewer myocardial infarctions, and 44,000–92,000 fewer deaths from any cause annually. Additionally, while all segments of the population were estimated to benefit, blacks would benefit more and women would particularly benefit from stroke reduction, older adults from reductions in coronary heart disease events, and younger adults from lower mortality rates. The authors note the predicted health benefits were on par with benefits achieved from reducing tobacco, obesity or cholesterol and interventions to reduce sodium would be far more cost-effective than treating hypertension with medications.[40]

The overall strength of the evidence indicates a significant and linear relationship between increased sodium intake and hypertension. While there may be lingering concerns or debate on whether low sodium intake is associated with greater cardiovascular disease and mortality risk, a growing body of research demonstrates a linear relationship versus a J- or U-shaped relationship. Interventions to reduce dietary sodium have consistently demonstrated a greater beneficial impact on those with hypertension and may have greater benefit for other subgroups, namely Black populations. Considering the high prevalence of hypertension in the U.S. adult population, and existing health disparities among racial groups, the public health benefit of population-wide sodium reductions would be substantial and could promote greater health equity, as evidenced by model estimates mentioned previously.[40]

Effectiveness Research on Interventions to Reduce Sodium Intake

Many sodium reduction strategies have been proposed and implemented both nationally and internationally. Within the U.S., sodium reduction policies have been enacted and evaluated at the organizational, local, state, and federal level. Additional examples of sodium reduction strategies from other countries include the United Kingdom, South Korea, and Canada (to name a few). A framework has been developed to identify and evaluate the strength of existing sodium strategies, which categorized strategies intro three primary buckets: (1) reducing sodium from packaged goods, (2) reducing sodium from food prepared outside the home, and (3) reducing sodium added in the home (see Table 1 for a replication of the three categories and related examples).[41] Within the framework, a successful strategy has to (1) be scalable and sustainable, with a focus at the population level versus individual, (2) have evidence of effectiveness or innovation, such as a rigorous evaluation, and (3) have a large benefit to be worth the investment. Based on this framework and a review of the evidence, four strategies are recommended that primarily focus on reducing sodium from packaged foods and food prepared outside the home:

1. Setting voluntary or mandatory reformulation targets for sodium in packaged food,
2. Front-of-pack labeling regulations,
3. Regulation of marketing of foods and nonalcoholic beverages to children, and
4. Taxation of high-sodium food[41]

Food procurement policies in public institutions and mass media campaigns have been highlighted as worthwhile interventions, but it is worth noting that, "No single strategy is enough to reach the WHO goal of a 30 percent reduction in sodium intake by 2025, thus a multi-component package is needed."[41] In terms of mass media campaigns, while found to be effective in shaping consumer behavior, their feasibility and sustainability are questionable due to the large and sustained fiscal resources they require.[41]

Similarly, the CDC published an evaluation report on sodium reduction interventions and concluded the policies with the highest degree of evidence of effectiveness at the local and state level included:

1. Daily meal providers serving low sodium items (e.g., daily meal providers could include hospital cafeterias, worksites, nursing homes, home delivered meals, etc.);
2. Sodium limits on items served in workplaces;

3. Item and menu labeling based on sodium content (specifically front of packages – not just under nutritional labeling), and
4. Incentivizing or requiring stores (including chain grocery stores, convenience stores, corner stores, bodegas, gas stations, retailers, and markets) to limit sodium in the foods (i.e., prepared foods, packaged snacks, and/or beverages) they are selling.[42]

Menu Labeling and Sodium Warnings

Further studies of menu labeling in restaurants of high sodium items have been conducted since these two studies were published. Item and menu labeling in restaurants based on sodium content has been implemented in several cities, counties, and states across the U.S. (New York City, NY, Philadelphia, PA, King County, WA, Pierce County, WA, and California). New York City (NYC)'s sodium warning policy went into effect in 2015 with enforcement starting in 2016. This policy required a sodium warning regulation at chain restaurants, which included the placement of an icon next to any menu item containing ≥2,300 mg sodium. One study investigated whether sodium content of menu items changed following enforcement of the sodium warning icon, finding no significant differences in the sodium content of menu items following enforcement efforts, noting the difficulties of reducing sodium levels in restaurants.[43] Another study evaluated changes in sodium and sodium-potassium ratios in NYC adults from 2010 to 2018, following the enforcement of the sodium warning regulation and other local sodium reduction initiatives.[44] The study found that sodium intake did not significantly change from 2010 to 2018 in the overall population. In fact, it increased slightly (3234 mg/d to 3292 mg/d) but it was not a statistically significant increase. However, there was a statistically significant decrease in sodium intake among adults 18-24 years old (3445 mg/d to 2957 mg/d, P = 0.05). The highest sodium-to-potassium ratios were among Black females 18-44 years old (2.0) and 45-64 years old (2.2) and Black (2.1) and Latino (2.1) males between 18 and 44 years old.[44]

Another study of the NYC sodium warning regulation evaluated changes to consumer purchases of high sodium content food (>= 2300 mg) following enforcement of the regulations in 2016.[45] Utilizing a survey and evaluating receipts for verification, consumer purchases were assessed at two full-service and two quick-service chain restaurants in both NYC and a control location that did not implement sodium menu labeling (Yonkers, NY), in 2015 and 2017. The study found mixed evidence of changes in purchasing patterns at NYC full-service restaurants following implementation of the sodium warning icon. Although decreases in purchases of high-sodium items among NYC full-service restaurant respondents were not significant relative to changes in purchases made by Yonkers respondents, both the mean sodium and calorie content of purchases made at NYC full-service restaurants declined significantly compared to Yonkers.[45] Taken together, these studies suggest the sodium warning icon has not been very effective at reducing the sodium content of foods in chain restaurants but may have had an impact on consumer behavior. However, there has been little change in consumer sodium consumption or reducing health disparities among NYC racial and ethnic minority populations.

Reducing sodium in packaged and processed foods

Limiting the level of sodium within the commercial food supply, at both the micro and macro level, is another promising and priority strategy. In the U.S., NYC has been a national leader on this front. The NYC Department of Health and Mental Hygiene initiated the National Salt Reduction Initiative (NSRI) in 2009, a partnership of about 100 health organizations and authorities, aiming to work with the food industry to set voluntary targets to reduce sodium in restaurant and processed foods.[46] The goal of NSRI was to decrease average sodium intake by 20 percent over five years (2009 through 2014) by developing stepwise reductions from 2009 base levels. More than 25 companies, including packaged food corporations and restaurants, responded to NSRI by committing to reductions in the sodium content of some of their products.[47] According to their monitoring efforts, between 2009 and 2019, there was an 8.5 percent reduction in sodium levels among NSRI categories.[46]

At the federal level, several U.S. agencies have taken recent regulatory action on reducing sodium within the food supply. Partially informed by the NSRI, in 2021, the FDA issued final guidance on voluntary targets for reducing sodium in commercially processed, packaged and prepared food over the following 2.5 years.[16] The voluntary targets cover 16 overarching categories of food with 163 subcategories, recognizing that a one-size fits all approach does not work well. The goal of the voluntary guidance is to decrease average daily intake by about 12 percent – from about 3,400 mg to 3,000 mg.[16] The second edition of this guidance, Phase II, was released for public comment in August 2024 and sets new voluntary targets to be achieved over the next three years.[18] Based on recent remarks by FDA's deputy commissioner, preliminary assessment data on the voluntary sodium targets demonstrates

encouraging success at meeting sodium reduction targets in foods among many of the food categories.[48] The preliminary assessment, which compared baseline data in 2010 to the most recent available data in 2022, indicates that 40 percent of food categories had achieved the Phase I sodium targets or were within 10 percent of meeting the targets.[18]

Additionally, in 2024, the U.S. Department of Agriculture, which establishes nutritional guidelines for school meals, issued a final rule, effective as of July 1, 2024, with one gradual sodium reduction target to be achieved over time.[49] For the next three school years, schools will maintain current sodium limits for breakfast and lunch foods (which is dependent on age/grade group), with the aim to implement an approximate 15 percent reduction for lunch and an approximate 10 percent reduction for breakfast by school year 2027-28. The final rule represents a sodium reduction target in between the first and second sodium reduction targets from the proposed rule, as this was believed to be achievable, based on stakeholder comments.[49]

The FDA voluntary sodium reduction targets are very similar to the salt reduction approach that has been implemented in the United Kingdom (UK). In 2003, the UK developed a voluntary salt reduction program, in collaboration with the food industry, which had eight steps but essentially enabled progressively lower voluntary salt targets for 80 different categories of food over time. The program developed a clear time frame for industry to achieve the desired results and was developed in tandem with a product labeling and consumer awareness campaign. Based on program evaluation, there has been a steady decrease in salt intake at a rate of approximately two percent per year since the introduction of the UK salt reduction strategy (as of 2014).[41] Over four years, this strategy successfully lowered salt intake by 15 percent, based on 24-h urinary sodium testing. Population health outcomes also improved; from 2003 to 2011, mean blood pressure was reduced by 3.0/1.4 mmHg and mortality from stroke decreased by 42 percent and ischemic heart disease by 40 percent.[50] Based on the lower blood pressure outcomes achieved by the voluntary salt reduction program, a modeling study was conducted to assess impacts on premature CVD, quality-adjusted survival, and health care and social care costs in England.[39] In comparison to a non-intervention (business as usual) scenario and assuming intake levels are maintained at 2018 levels, the study authors estimated that by 2050 the program is projected to avoid 83,140 premature ischemic heart disease cases, 110,730 premature strokes, and save 1,640 million pounds in health care costs.[39]

Despite these early successes in the UK, there are continued challenges and new targets are needed to further sodium reduction. A strong relationship and cooperation with the food industry is required to make voluntary targets successful, as well as independent and transparent monitoring. While the voluntary program has been successful, it was underpinned by sustained media pressure, and direct pressure on public health ministries and government to maintain a strong stance with the food industry. In terms of best practices, regulatory or legislative approaches may be more effective versus voluntary guidelines but the legislative approach may be complicated depending on the country.[50]

South Korea also implemented a comprehensive salt reduction program, starting in 2012, which included a consumer awareness campaign, increased availability of low-sodium foods at school and worksite meal services, increased availability of low sodium meals in restaurants, voluntary reformulation of processed foods to lower the sodium content, and development of low-sodium recipes for food prepared at home.[41] South Korea has one of the highest rates of sodium intake in the world and is much higher compared to the U.S. In 2010, the average sodium intake was 4831 mg/day. [51] The goal of this program was to reduce population sodium consumption by 20 percent, to 3900 mg/day by 2020. This multi-pronged approach in South Korea has been found to be successful. Sodium intake decreased by 19.5 percent from 2010 and 2014, which was achieved largely by reducing the sodium content in processed food. There were also concomitant reductions in population hypertension prevalence within the same time period, for both men (from 33.5 percent to 26.0 percent) and women (from 25.2 percent to 21.7 percent) aged 30 years and older that were statistically significant. From 2010 to 2014, the rate of death from cerebrovascular diseases also decreased from 53.2 to 48.2 per 100,000 population, but these changes were not statistically significant.[51]

Canada also has a similar voluntary sodium reduction strategy, implemented in 2012, which set voluntary sodium reduction targets for 94 categories of processed foods.[52] In 2018, Health Canada published an evaluation report indicating the sodium reductions in most categories of processed foods were only modest and did not meet targets. Additionally, the report notes that the voluntary efforts only resulted in an eight percent decrease in average sodium intake since 2010, with the average sodium intake of Canadians being about 2760 mg (which is lower than the

current U.S. sodium intake). Health Canada has since published revised voluntary targets for processed foods and continues to work with the food industry to gradually and safely reduce sodium in their food supply.[52]

Taxes on Sodium

One of the other priority strategies identified above to lower sodium intake is taxation on high sodium foods. However, there are limited studies evaluating the effectiveness of fiscal policies to reduce salt consumption.[53] A systematic review of the available literature identified 18 relevant studies, but nearly half of them reported the effects of salt taxes through modeling, not real world implementation, and real world implementation evaluation studies were primarily found in the grey literature.[53] Despite the lack of evidence on the effectiveness of salt taxes, sugar-sweetened beverage (SSB) taxes have been more widely studied.

SSB taxes are tangentially related to proposed sodium taxes to reduce the burden of chronic diseases and improve the typical American diet. Multiple public health initiatives have called for a reduction of both dietary sodium and sugar;[54,55] however, many physicians find that patient adherence to dietary recommendations remains challenging within the clinical context.[56] There are many recognized challenges in adhering to dietary recommendations, including (but not limited to) lack of knowledge or support to make changes, confusing and misleading information provided by the media, difficulties in changing ways of cooking and in translating healthy eating messages into balanced food choices, the cost associated with healthier food options, lack of confidence in cooking skills, cultural acceptability, speed of preparation, family acceptability, and lack of access to supermarkets with fresh and whole food options (i.e., food deserts).[56,57] As such, policymakers in the U.S. and other parts of the world increasingly turn to SSB taxes to improve public health outcomes and prevent chronic disease development. SSBs are non-alcoholic beverages that contain added sweeteners such as sucrose (sugar) or high-fructose corn syrup. In the U.S., SSB taxes are levied locally and currently exist in the following jurisdictions: Boulder, Colorado; the District of Columbia; Philadelphia, Pennsylvania; Seattle, Washington; and four California cities (Albany, Berkeley, Oakland, and San Francisco).[58] No state currently has an excise tax on sugar-sweetened beverages.

Multiple studies have concluded that SSB taxes effectively change consumer shopping habits and there is strong evidence that SSB taxes can be effective in reducing the sales and intake of SSB when taxes are substantial (e.g., at least one U.S. cent per ounce).[41] A 2024 article found that SSB taxes in five U.S. jurisdictions were associated with a 33.1 percent price increase and a corresponding 33 percent reduction in purchase volume.[59] In the U.K., soft drink levies were associated with a 23 percent decrease in sugar consumption from soft drinks in children; in adults, sugar consumption from soft drinks declined by 40 percent.[60] In Mexico, SSB taxes led to similar decreases in soft drink purchases and increased water purchases.[61] Unfortunately, most SSB taxes are too new to demonstrate changes in population health outcomes such as CVD or obesity; however, modeling data suggest that SSB taxes will reduce premature mortality, increase government revenue, and reduce expenditures over time.[62] Additionally, in seven U.S. cities with SSB excise taxes, all tax revenue has been used to support community health initiatives and community capital investments, demonstrating the potential of these policies to yield additional benefits outside of SSB consumption and to support broader community health initiatives.[63]

Feasibility of salt reduction in foods and available alternatives

Salt has played an important role in food, health, and commerce for thousands of years.[25,64] As human societies shifted towards agriculture versus hunting and gathering, salt was needed to supplement the diet and salt became one of the most important commodities across the globe.[64] In ancient Roman times, salt was used not only to supplement flavor and preserve food, but also as an antiseptic. Its overall importance at the time is exemplified by the fact that part of a Roman soldier's pay was in salt, otherwise known as solarium argentum, which formed the basis of our modern word for salary.[64] Salt's osmotic impact (the passage of a liquid through a membrane from a less concentrated solution to a more concentrated one) is responsible for its ability to help preserve foods. Salt allows water to flow through the semipermeable membrane of bacteria which leads to bacterial cell death or injury, and thus reducing bacterial growth.[65] In our modern food system, other preservative methods along with refrigeration obviates the reliance on salt as a primary preservative and the levels of sodium found in processed and prepared foods are well beyond those needed for food safety or physiological reasons.[32,50]

However, salt also affects color, texture and taste properties of food and salt has differential impacts on various food categories.[13,65] Although reducing sodium content in foods is possible, reductions must be considered with respect to the other important properties salt confers from a food technology perspective, including flavor, development of

texture, fermentation, color development, and antimicrobial properties. Reformulation to reduce sodium content in foods can be a complex process, in many cases is not as straightforward as simply adding less sodium to foods and should not be achieved through the addition of increased sugar content or artificial additives, as these also have negative health impacts.[66,67] Further, when salt is reduced quickly, palatability and consumer acceptance of a product generally tends to decrease.[65] On the other hand, consumer acceptance of low sodium products can increase over time. It has been demonstrated that as sodium intake decreases, taste receptors in the mouth adapt and become more sensitive to lower concentrations, often times within a few months.[27]

One potential concern of reduced salt consumption is an increase in iodine deficiency, as salt iodization and fortification of foods with iodine have been primary intervention strategies to prevent iodine deficiency globally (although never mandated in the U.S.).[68] Iodine is required for thyroid hormone synthesis and inadequate iodine intake can result in several health concerns, including goiter and hypothyroidism.[68] However, commercially processed foods generally contain non-iodized salt and since the vast majority of salt consumed in the U.S. is via processed foods, overall reductions in the salt content of processed foods would most likely not have any appreciable effect on the prevalence of iodine deficiency within the U.S.[68]

When assessing alternatives to a high sodium diet, it is important to consider the outsized role of prepackaged and processed foods within the American diet. High sodium consumption is inextricably linked to the overconsumption of ultra-processed foods, which makes up more than half of the calories consumed in the U.S. diet.[69] While many foods go through some amount of processing, ultra-processed foods are defined as those with "formulations of ingredients, mostly of exclusive industrial use, that result from a series of industrial processes."[69] Examples of ultra-processed foods include packaged snacks, mass-produced baked goods, breakfast 'cereals,' hot dogs, sausages, pre-prepared pasta and pizza dishes. A recent study found the consumption of ultra-processed foods has grown from 53.5 percent of calories since 2001-2002 to 57 percent in 2017-2018, while the consumption of whole foods has decreased by a similar percentage over the same period.[70]

The modern Western diet with a focus on ultra-processed foods has also led to a decrease in other physiologically important nutrients, such as potassium. Potassium is a physiologically essential nutrient, whose function is closely intertwined and related to that of sodium in our body.[12] While too much sodium has been found to raise blood pressure, too little potassium has been found to have the same effect.[71] Unlike sodium, Americans tend to not eat enough potassium in their diet, which is found naturally in vegetables, fruit, seafood, and dairy products. The National Academies of Sciences, Engineering, and Medicine concluded there is a moderate strength of evidence that potassium supplementation significantly reduces systolic and diastolic blood pressure, and the effect is even stronger among adults with hypertension.[12] Recently, one study concluded that increasing potassium intake might represent a more advantageous dietary strategy for preventing cardiovascular disease.[72] Traditional dietary cultures from across the globe, many of which are known to be associated with longer and healthier lives, are based on consumption of foods that are unprocessed or minimally processed.[69] Thus, programs and policies to increase the availability, accessibility, and affordability of whole or minimally processed foods that are culturally appropriate should be an important component of a salt reduction strategy and could also have the added benefit of increased potassium intake.

Considering the current U.S. food system context coupled with public health calls for reduced sodium consumption, there have been increasing efforts to establish salt replacement strategies that will meet consumer tastes and demands. Potassium chloride may be the most promising, however, this substitute can be problematic for populations who are required to limit their potassium intake due to health reasons, for example those with kidney disease. A study examining the effects of potassium-enriched salt on cardiovascular disease mortality among elderly veterans found a significant reduction (age-adjusted hazard ratio of 0.59) in mortality among the experimental group that was given potassium-enriched salt.[73] Other salt replacement strategies, particularly from a consumer perspective, is to include other herbs and spices that can provide an alternative method of flavoring in the absence or reduction of salt.[56,65]

Beyond potassium chloride, other viable alternatives exist for replacing sodium. For example, glutamate, a nonessential amino acid, has been used to enhance the taste and palatability of food. Food monosodium glutamate (MSG) is the most common glutamate salt and flavor enhancer used, to lower the overall sodium level in certain foods while maintaining palatability.[56] MSG contains about 12 percent sodium, which is less than one-third of that contained in table salt.[74] MSG safety concerns, namely what was once referred to as "Chinese restaurant syndrome," have been proven to be unfounded and largely driven by a history of prejudice and discriminatory rhetoric and

action against Asian cultures, specifically Chinese culture.[75] A review of the evidence on MSG's alleged health concerns have detected serious methodological flaws with research that indicated safety issues and many of the reported negative health effects of MSG have little relevance considering the average human exposure.[76] Although MSG is the most widely used flavor enhancer in food, other effective glutamate salts, such as calcium di-glutamate, exist but do not provide as pronounced of an effect. A considerable number of studies have demonstrated that various forms of glutamate can help reduce the amount of sodium in specific foods, including soups, prepared dishes, processed meat, and dairy products, by enhancing palatability.[65,77]

Priority Strategies for Reducing Blood Pressure

Sodium reduction is just one of many strategies to prevent and manage hypertension. Priority strategies for controlling blood pressure exist across individual, organization, community and policy levels. Lifestyle change modifications, including the promotion of increased physical activity, weight loss, moderate alcohol consumption, and a healthier diet overall (greater consumption of fruits and vegetables and lower sodium intake), as one study put it, "are the cornerstone of prevention and treatment of hypertension."[10] In 2023, the AMA and the American Heart Association published a joint scientific statement on implementation strategies to improve blood pressure control in the U.S.[9] This joint statement recommends lifestyle modification strategies as the recommended first-line therapy to control blood pressure.[9]

The Dietary Approaches to Stop Hypertension (DASH) has been highlighted in the literature and among federal agencies as a priority diet strategy to reduce blood pressure.[78–80] DASH is a dietary plan or framework that emphasizes eating vegetables, fruits and whole grains; including fat-free or low-fat dairy products, fish, poultry, beans, nuts, and vegetable oils; limiting foods that are high in saturated fat, such as fatty meats, full-fat dairy products, and tropical oils; and limiting sugar-sweetened beverages and sweets. A systematic review of the evidence on DASH to reduce blood pressure found that, compared to a control diet, the DASH diet significantly reduced both systolic blood pressure and diastolic blood pressure, with a greater effect witnessed in those with higher daily sodium intake and of younger age.[81]

Other strategic approaches to improve blood pressure control cut across different levels of interventions and include: antiracism efforts (e.g., policies to dismantle residential segregation and its impacts, policies to eliminate inequities in access to and quality of healthcare), accurate blood pressure measurement and increased use of self-measured blood pressure monitoring, team-based care, standardized treatment protocols, improved medication acceptance and adherence, improving the built environment to facilitate increased walkability and physical activity, continuous quality improvement, financial strategies that sustain the implementation of effective treatment strategies, and large-scale dissemination and implementation.[9,82] However, there are many critical implementation and dissemination gaps and challenges that make it difficult to enact these strategic approaches. A few of these include implementing and evaluating the effect of policy-level changes such as salt reduction in foods and all-payer coverage of self-measured blood pressure monitoring devices on improvement in blood pressure control; exploring and evaluating antiracism, health equity, and social determinants of health implementation strategies focused on improving blood pressure control; assessing the effects of urban planning interventions to improve walkability and increasing green spaces; and implementing culturally sensitive interventions for lifestyle changes.[9] Another challenging area is the implementation of effective lifestyle change counseling and monitoring recommendations at the clinical level, which can help be addressed through the designation of more individuals within practices who are sufficiently knowledgeable in behavior change techniques in order to support effective patient counseling.[82]

Lastly, recent research has strengthened the available evidence on the relationship between air pollution and poor air quality with all-cause cardiovascular mortality and morbidity, stroke, blood pressure, and ischemic heart diseases.[83,84] Therefore, another area of primary prevention for reducing population level hypertension could focus on improving ambient air quality by reducing reliance on fossil fuel combustion for energy generation and transportation, which could also result in numerous other public health benefits.[9,85]

EXISTING AMA POLICY

The AMA already has policy in support of many of the strategies highlighted in the literature and summarized in this report that have been shown to reduce sodium consumption. Following the previous report, Policy H-150.929, "Promotion of Healthy Lifestyles I: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake," aims to reduce sodium in processed foods, fast food products, and restaurant meals by 50 percent.[86]

This policy notes that gradual but steady reductions over several years may be the most effective way to minimize sodium levels. Additionally, this policy states the AMA will work with our federal and organizational partners to educate consumers about the benefits of long-term, moderate reductions in sodium intake and recommends the FDA consider all options to promote reductions in the sodium content of processed foods.

AMA's policy H-150.945, "Nutrition Labeling and Nutritionally Improved Menu Offerings in Fast-Food and Other Chain Restaurants," supports policies at multiple levels to require fast-food and other chain restaurants with 10 or more units to provide consumers with nutrition information on menus and menu boards.[87] Nutrition information provided on menus should include sodium labeling. Further, this policy urges AMA to work with partner organizations to educate people on how to use the nutrition information provided in restaurants to make healthier food choices for themselves and their families and urges restaurants to improve the nutritional quality of their menu offerings, including the use of less sodium. AMA policy H-150.949, "Healthful Food Options in Health Care Facilities," encourages healthful food options in health care facilities, including food offerings with low sodium content, and the publishing of nutrition information with health care facility cafeterias..[88]

AMA's Improving Health Outcomes team has been actively engaged in work to help physicians and care team reduce blood pressure and improve blood pressure control rates across patient populations, with a particular focus on accurate blood pressure measurement and effective treatment of hypertension. For example, the AMA MAP™ Hypertension is a three-part framework and guide for improving hypertension control.[89] AMA's Ed Hub™ also has published educational resources on blood pressure control and management, including a CME Course entitled, "Hypertension: High Blood Pressure Management, Impact and Inequities."[90]

CONCLUSIONS

Reducing dietary sodium is one of several important strategies to reduce hypertension and improve public health. With over 20 years of research on dietary sodium and health outcomes, it is clear that reducing population level sodium intake can have beneficial public health outcomes and save millions of dollars in health care costs. Voluntary targets to reduce sodium in processed foods and other food prepared outside of the home is one of the most promising and well-evaluated large-scale policies to enact population level change in sodium intake and has been successfully implemented across the globe. Preliminary indications from FDA indicate that their voluntary program has been successful at reducing sodium levels in food, enough so that they are preparing to update their guidance, further reducing their targets. Sodium reduction is but one strategy that should be pursued alongside other important lifestyle (i.e., increasing physical activity and preferential consumption of fruits and vegetables), environmental (i.e., reducing air pollution), and community strategies (i.e., reducing structural inequities in access to health care and health promoting resources) to reduce hypertension and promote cardiovascular health.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed.

1. That Policy H-150.929, "Promotion of Healthy Lifestyles I: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake" be amended by addition and deletion to read as follows:

   Our AMA ~~will~~:
   (1) Calls for a step-wise, minimum 50% reduction in sodium in processed foods, fast food products, and restaurant meals to be achieved over the next decade.
   (2) Urges the FDA to publish future editions of their voluntary targets expeditiously to make further progress on sodium reduction.
   (3) Supports federal, state, and local efforts to set robust targets for reducing sodium levels in school meals, meals in health care facilities, and other meals provided by daily meal providers.
   (~~2~~4) Will advocate for federal, state, and local efforts to reduce sodium levels in products from ~~F~~ food manufacturers and restaurants ~~should review their product lines and reduce sodium levels~~ to the greatest extent possible, ~~(~~without increasing levels of other unhealthy ingredients, such as added sugars or artificial ingredients~~)~~. ~~Gradual but steady reductions over several years may be the most effective way to minimize sodium levels.~~

(5) Supports federal, state, and local efforts to require front-of-package warning labels for foods that are high in sodium based on the established recommended daily value.
(~~2~~6) ~~To~~ Will assist in achieving the Healthy People 2030~~2010~~ goal for sodium consumption, by ~~will~~ working with the FDA, the National Heart Lung Blood Institute, the Centers for Disease Control and Prevention, the American Heart Association, Academy of Nutrition and Dietetics, and other interested partners to educate consumers about the benefits of ~~long-term, moderate~~ reductions in sodium intake and other dietary approaches to reduce hypertension.
(7) Supports the continuing education of physicians and other members of the health care team on counseling patients on lifestyle modification strategies to manage blood pressure, advocating for culturally relevant dietary models that reduce sodium intake.
(~~3~~8) Recommends that the FDA consider all options to promote reductions in the sodium content of processed foods.
(9) Supports further study and evaluation of national salt reduction programs to determine the viability, industry engagement, and health and economic benefits of such programs.
(10) Supports federal, state and local efforts to regulate advertising of foods and products high in sodium, especially advertising targeted to children.
(Modify Current HOD Policy)

Fiscal Note: less than $1,000

FIGURES AND TABLES

Figure 1: Prevalence of Hypertension in the U.S. 1999 to 2018, NHANES

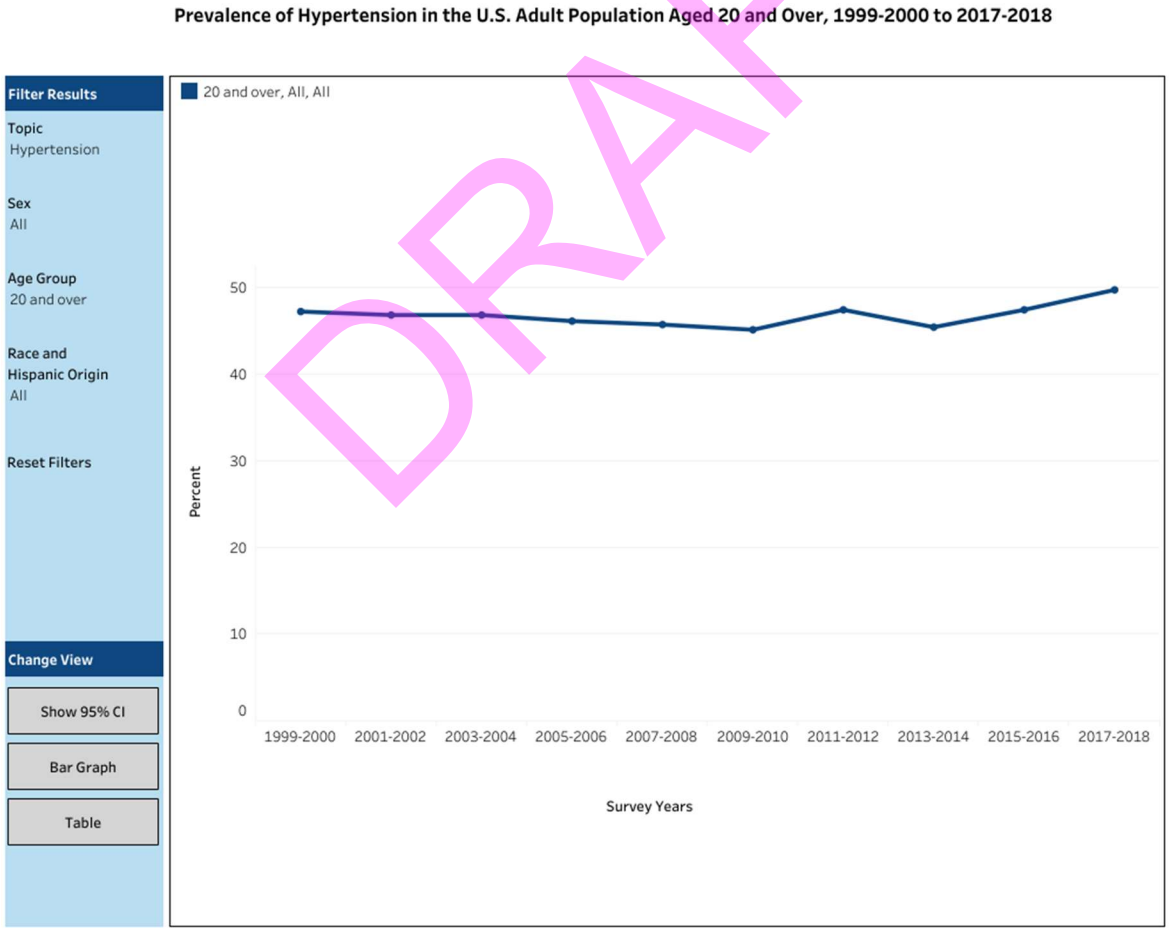


Figure 2: Population Exceeding Recommended Sodium Limit[13]

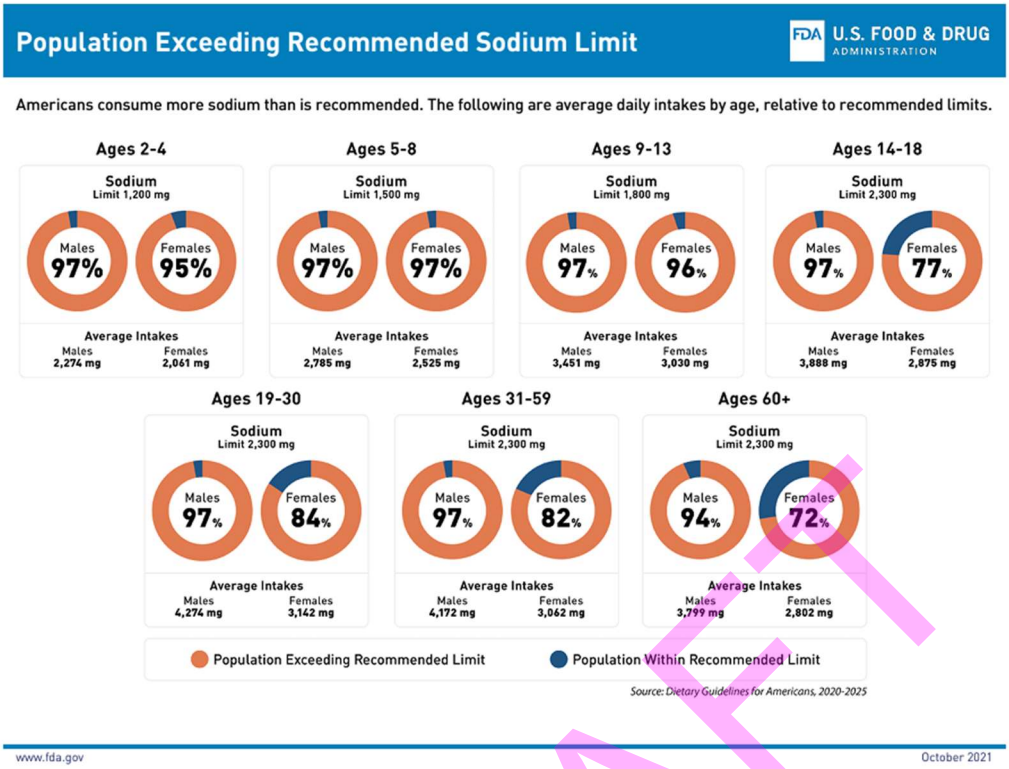


Figure 3: How sodium is consumed in the American diet[14]

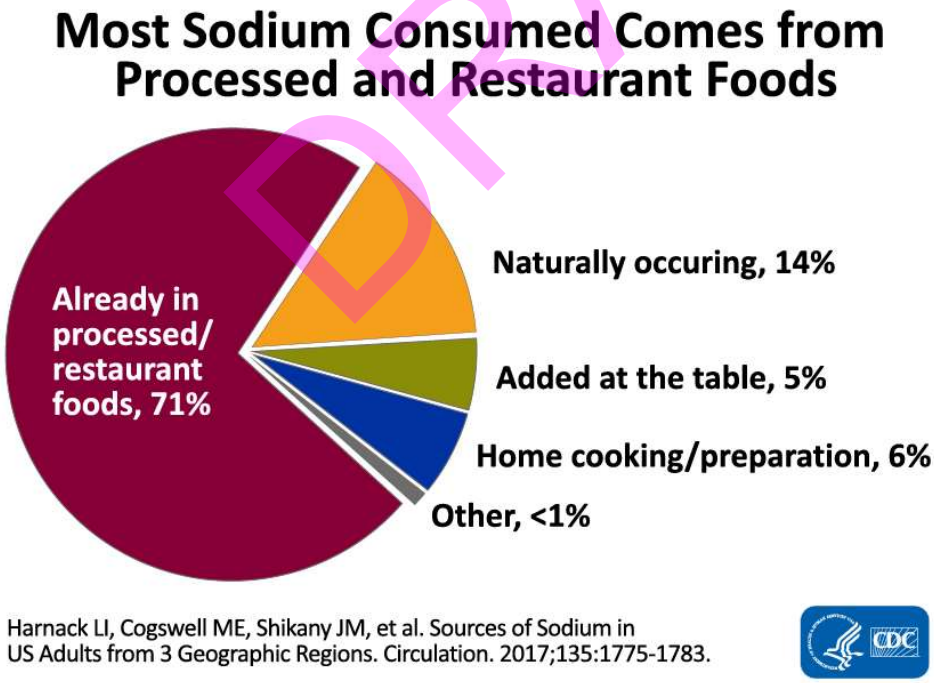
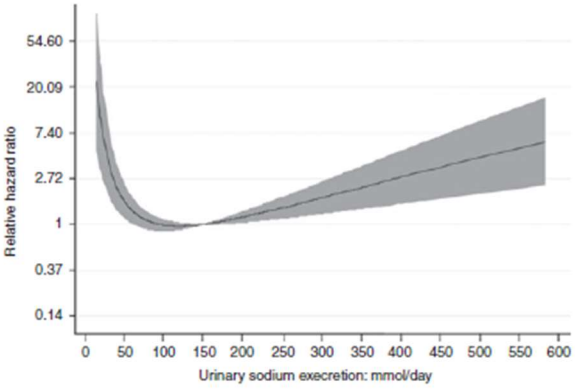


Figure 4 – Examples of J and U-shaped relationship between sodium intake and health outcomes[25]



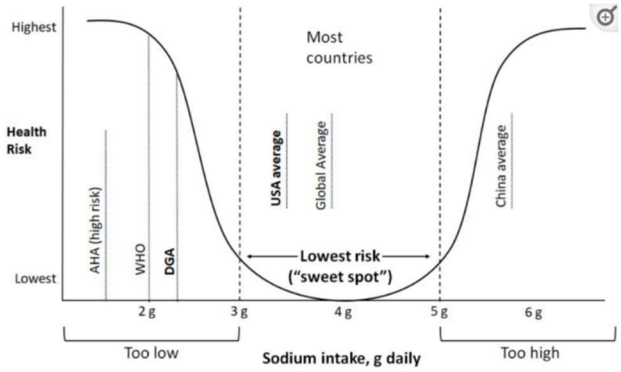


Table 1 – Existing Sodium Reduction Strategies with priority recommended strategies italicized and highlighted with an astericks[41]

Sodium from packaged foods
*Labeling: front-of-pack labeling regulations**
Labeling: mandatory nutrient declaration on labels
Labeling: regulating nutrition/health claims on food packaging
*Food reformulation targets for packaged food (voluntary or mandatory)**
*Regulation of marketing of foods and nonalcoholic beverages to children**
*Fiscal policies: taxation on high sodium foods**
Supermarket interventions using product, placement, price, or promotion strategies
Sodium from food prepared outside the home
*Standards for sodium as part of food procurement policies for public institutions**
Restaurants: menu labeling of high or low sodium items (primarily chain restaurants)
Restaurants: removal of salt shakers and high sodium condiments from tables
Restaurants: chef training on reducing sodium in food
Restaurants: requiring the provision of low sodium or no-sodium added items on menus
Restaurants: food reformulation targets for restaurants (voluntary or mandatory; primarily chain restaurants
Sodium added in the home
*Mass media campaigns**
Community education (e.g., through schools, community groups, workplaces, etc.)
Individual education and counselling (usually through primary health care)
*Increase uptake of low sodium salt (promotion, distribution, subsidies)**

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5. TEENS AND SOCIAL MEDIA

Reference committee hearing: see report of Reference Committee K.

HOD ACTION: **ADOPTED AS FOLLOWS**
See Policies D-478.965 and H-478.976

INTRODUCTION

At the 2023 Annual Meeting of the American Medical Association (AMA) House of Delegates (HOD), Resolution 430, "Teens and Social Media" was adopted. The policy (H-478.976, "Teens and Social Media,") as adopted, asked that our AMA "study and make recommendations for teenage use of social media, including proposing model state and federal legislation as needed, with a report back at the 2024 Annual Meeting."

At the 2023 Interim Meeting of the AMA HOD, Resolution 915, "Social Media Impact on Youth Mental Health," was referred. The resolution asked that our AMA:

(1) work with relevant parties to develop guidelines for age-appropriate content and access and to develop age-appropriate digital literacy training to precede social media engagement among children and adolescents;

(2) amend policy D-478.965 by insertion as follows: (4) advocates for and support media and social networking services addressing and developing safeguards for users, <u>including protections for youth online privacy, effective controls allowing youth and caregivers to manage screentime content and access, and to develop age-appropriate digital literacy training</u>; and

(3) advocate that the federal government requires social media companies to share relevant data for further independent research on social media's effect on youth mental health and fund future federal research on the potential benefits and harms of social media use on youth mental health.

The Council presented the CSAPH 10-A-24, "Teens and Social Media," which addressed both Resolution 430-A-23 and Resolution 915-I-23, for consideration by the HOD. That report was referred back for additional study due to questions regarding content in the body of the report. Having clarified those questions, the Council presents this revised report for consideration.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases using the search terms: "teens" AND "social media" as well as "adolescents" AND "social media." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and applicable professional and advocacy organizations were also reviewed for relevant information.
BACKROUND

The co-occurrence of the growing ubiquity of social media use by adolescents and teens and the increase in poor mental health, among these same age groups, is alarming. These trends have prompted calls for action and research

around adolescents and teens and their use of social media. A common theme in the research is that social media is not inherently beneficial or harmful. Instead, the effects of social media likely depend on what kids see, their pre-existing strengths and weaknesses, and their environment.[1–4] In particular, child-social media interactions may be bidirectional as users shape their experience which in turn shapes them and vice versa.[5,6] Further, many argue that it is important to move away from the false dichotomy of whether social media is hurting or helping adolescents -- instead researchers, parents, and policy makers should consider who is using social media, what are they using it for, when are they using it, and how are they using it.[7–9] The focus of this report will be on adolescents and teens aged 10-17.

Social Media Privacy, Transparency and Accountability

The American Psychological Association (APA) defines social media as, "interactive technologies that facilitate the creation and sharing of information, ideas, interests, and other forms of expression through virtual communities and networks."[10] This can include social networking, gaming, virtual worlds, video sharing sites, and blogs.[3] Social media, internet use, and screentime all fall under the umbrella of digital media - the parent category of all interactive media consumed through screens.[1] These terms are used interchangeably throughout the rest of the report, unless noted otherwise.

The different forms of social media have different possibilities for action and engagement, known as affordances. Affordances, include things like visibility, editability, persistence, replicability, searchability, scalability, and reachability and they manifest as the capacity for public posting, sharing functions, auto-scroll, gamified interaction, push notifications, private messaging, affiliations, and running counts of feedback on posts.[11–13]

Affordances can have meaningful influence on the actions of the user; therefore, many researchers advocate for an affordances approach to understanding and evaluating social media.[14] This is important because affordances are powered by and interact with computational algorithms. These algorithms moderate content by generating recommendations, ranking and removing content, and targeting ads.[3] A challenge with content moderation is that it is intrinsically subjective. The value and appropriateness of content depends on the context – the who, what, why, how, and when of the information being shared may determine if it is elevated, downplayed, or removed.

Most platforms use a mix of artificial intelligence and human editing to enforce content moderation.[3] This can create intentional manipulation of information on the part of individuals. For instance, Facebook allowed advertisers to choose to exclude whole racial, ethnic, and age groups from seeing their ads.[3,15,16] Similarly, TikTok issues separate content moderation approaches for different countries depending on the degree of social conservatism.[3,17] Many platforms can and do selectively reduce or increase the prominence of content from certain users without violating the terms of use.[3,18] There is also unintentional, or at a minimum unexplained, manipulation of information, caused by using machine learning algorithms for content modification. Machine learning algorithms are black box mechanisms that learn without explicitly being programmed. Companies know the inputs, outputs, and training data that go into their algorithms, but the internal processes by which most machine learning algorithms work are less clear. Additionally, algorithms are proprietary, so companies are reluctant to share the details they do have.[3,19,20] Consequently, the intrinsic subjectivity of content moderation is made more opaque by machine learning algorithms as well as the platforms' lack of transparency about them.[3,21]

Relying on machine learning for content modification is not inherently harmful, but it can create recursive feedback loops that exacerbate problems with harmful content and misinformation. The algorithms send users more of the content that they engage with, thereby creating the impression that theories and behaviors they are seeing are potentially more prominent than they are. Moreover, many users do not realize that social media platforms are designed to show them content that is most likely to keep them engaged and on the platform rather than providing a comprehensive view of the content of friends and family.[3,22] There is some evidence that recursive feedback loops and echo chambers exacerbate vaccine hesitancy.[3,23–25] Similarly, content modification, and the echo chambers it creates had a significant impact on behavior during the 2016 Election.[3,26–28]

Ultimately, the current processes for content moderation introduce bias on both the front end (e.g., the training data that informs the algorithms and intentional modification of information) and on the back end (e.g., recursive feedback loops and echo chambers). Content moderation also leverages user data, often in ways the user is unaware of, which raises ethical and privacy concerns.

Furthermore, there is concern among users that companies like Facebook (now Meta) both overlook the risks posed by their product and misrepresent their internal findings when necessary to benefit the company.[3,29,30] It is for these reasons that many criticize platforms and call for evaluation of algorithm bias, transparency, justice, and accountability.[3,20]

Adolescence as a sensitive period

One of the reasons parents, clinicians, researchers, and policy makers have raised alarm about social media use among adolescents is that adolescence is a developmentally sensitive period. There are three key features of adolescent brain development that may impact how youth engage with social media: (1) heightened sensitivity to rewards and dynamic changes in the dopaminergic system;[3,31–33] (2) protracted maturation of brain networks that support cognitive function;[34] and (3) neural sensitivity to specific types of social information.[3,35] As a result, adolescence is a time of tremendous cognitive, social, emotional, and physical change that involves both opportunity for maturation and vulnerability to environmental stressors.[3,36] Evidence from developmental neuroscience illustrates that adolescence is a time of heightened risk taking, impulsivity, and sensitivity to social stimuli.[4,37] Consequently, adolescents are particularly susceptible to environmental influences like drugs, social stress, cognitive training, and likely social media.[3,4,38–41] There is some concern that constant engagement in social media in early adolescence may alter neural sensitivity to rewards and punishment.[3,42] Furthermore, changes in the reward circuit may be a factor in excessive and problematic internet and social media use.[3,43]

At the same time, self-presentation and identity exploration is an important part of adolescence that social media can support.[3,14,44,45] It is a critical time for building relationships and developing a social support system.[3] Adolescents demonstrate an increased ability to consider other perspectives, which drives empathetic and prosocial behaviors on the one hand, as well as increased social comparison on the other.[3,46] The strong desire for social connectedness demonstrated by adolescents suggests that they may be relaxed regarding privacy settings and connecting with strangers.[35,47] Online environments and social media interactions may also lower inhibitions and accelerate intimacy.[48] In this way, online environments create both benefits and risks to development of identity and social connectedness.[48] Adolescence is also a time of increased flexibility and plasticity so researchers and public health practitioners advocate leveraging the plasticity of adolescent brain for health promotion.[37]
Ultimately, the power of social media to influence well-being likely depends on developmental stage.[49] There are ethical reasons to limit marketing to children and teens as they may struggle to resist advertising.[50] At the same time, there is some evidence that the concept of adolescence should be expanded to include individuals aged 10 to 24.[40] An expanded definition of adolescence is essential for developmentally appropriate framing of laws, social policies, and service systems.

YOUTH PREVALENCE, MOTIVATIONS, AND EXPERIENCES ON SOCIAL MEDIA

According to a 2022 Pew survey, 95 percent of teens in the U.S. have a smartphone and 97 percent use the internet daily, which represents a 22 percent increase over the last eight years.[51] The omnipresence of both internet and mobile devices in how youth engage in relationships, learn, and experience milestones reflects a massive cultural shift since the early 2000s.[52] Smartphone use starts in early adolescence, with 40 percent of children ages 8 to 12 owning a smartphone and 18 percent reporting social media use every day.[53]

The 2022 Pew survey also found that 35 percent of teens report using YouTube, Instagram, TikTok, Snapchat, and Facebook almost constantly.[51] Fifty-five percent of teens thought they used social media the right amount, 36 percent thought they use social media too much, and eight percent thought they used it too little.[51] Additionally, 54 percent thought it would be somewhat hard to give up social media.[51] Findings from the Pew study mirror older studies reporting that 50 percent of teens describe themselves as constantly connected and feel that they are addicted.[1,2] There are slight demographic differences as well. Black and Hispanic teens may use online media more than their White peers.[51] Girls use social media more than boys and also report that they would have a harder time giving up social media.[51] Finally, teens over 15 use social media more than teens under 15.[51]

The most popular platform is YouTube, used every day by 95 percent of teens.[51] YouTube is followed by TikTok at 67 percent, Instagram and Snapchat at 60 percent, Facebook at 32 percent, and then Twitter, Twitch, WhatsApp, Reddit, and Tumbler.[51]

Despite widespread use among children and adolescents, robust independent safety analyses on the impact of social media on youth have not yet been conducted.[4] Currently, we do not yet have enough evidence to determine if social media is sufficiently safe for children and adolescents. Yet, the body of research about potential harm evidences the importance of understanding the possible risks and proactively creating digital environments that safeguard children's and adolescents' mental health and well-being during critical stages of development.[4]

MOTIVATIONS FOR USE

Motivations for social media use among teens include social interaction, connection, curiosity-driven learning, information sharing, entertainment, relaxation, stress relief, escapism, novelty seeking, social capital, and appearance feedback.[3,54–56] Moreover, there is evidence that the ways in which youth engage with social media can improve and enrich their lives through social support, connection, community building, identity development, civic engagement, and exposure to new ideas.[57]

Friendship, social support, and connection

Social media plays a vital role in the development and maintenance of friendships and social connectedness.[54,57,58] Communication with friends and family is often reported as the most important function of social media,[59,60] particularly when family and friends are far away.[61] Fifty-seven percent of teens have met a new friend online.[60,62] There appear to be some gender differences in how boys and girls interact with friends on social media. Sixty-one percent of boys and 52 percent of girls made friends online, and video games play a critical role in boys' friendship development.[62] In contrast, one study found that on average, teen girls spend over two hours a day on TikTok, Snapchat, and YouTube and over 90 minutes a day on Instagram and messaging apps.[63] Roughly, 69 percent of teens feel better connected to their friends' feelings, 83 percent better connected to their friends' lives, and 68 percent receive social support during tough times from friends through social media.[62] In this way, social media may be helpful in combating social isolation and building social capital.[3,64]

There is some evidence that social media can both reduce stigma and be a venue for sharing coping strategies.[3] Social media provides a way for youth to connect with people in the same position, which can be particularly valuable to adolescents who feel excluded or otherwise lack offline support, including patients with rare diseases, individuals with disabilities, those who struggle with mental illness and/or obesity, and marginalized groups (e.g., LGTBQ+ youth).[1,4] For instance, through social media, teens who are neurodivergent can connect socially with others in a way that is manageable for them, thereby reducing loneliness.[3,65] Social media may also help teens and youth coping with grief,[66] navigating foster care,[67] dealing with cancer, diabetes, rare diseases,[68,69] and mental illness.[3,70] Sharing on social media about losses and stressors can provide a sense of connection, support, and understanding.[71] Similarly, social media can provide support and connection for young people who live in communities where sexual and gender diversity are not accepted, which may buffer them from stigma and loneliness.[3,72–74] This is particularly true for LGTBQ+ teens in rural areas that are able to find support they do not have offline by connecting with other queer youth.[3,72,75–77]

It is not clear if online and in-person relationships are equivalent; however, friendship and social connection facilitate a sense of belonging.[3,78] Moreover, friendship can reduce anxiety and improve life satisfaction in its own right.[3,79] Cross-sectional studies among undergrads provide some evidence that people who use social media to connect with a diverse friend group tend to have higher social self-efficacy.[3,80] Yet, the relative support provided by online social connection may be influenced by the individual and how they engage with social media.[3,81]

Self-expression, Identity exploration, and Independence

There is some evidence that social media can support self-expression, identity exploration, and independence.[3,14,44,45,57,60,82,83] Adolescents who communicated more with friends online had a greater self-concept clarity.[60] One systematic review found that LGBTQ+ youth negotiated and explored identity using social media to manage identities though anonymity, censoring locations and content, restricting audiences, and using multiple accounts.[72] This suggests social media may support the mental health and well-being of LGTBQ+ youth through identity management.[72] In particular, the online environment of social media creates a space to revel and express differences.[84] Similarly, many cis girls are meticulous about which platforms and accounts they use for specific tasks, because it allows them to experiment with different forms of expression and ways of presenting themselves to

their peers.[3,85] Self-disclosure, a key process in asserting personal agency, may be facilitated through digital platforms.[3,81]

Self-directed learning, Creative expression, and Civic engagement

Social media can also facilitate exposure to new ideas, raise awareness about current events, increase community participation and civic engagement, and allow collaboration on schoolwork.[2] A study of teens in western countries found that social media use predicts greater ability for both reading and navigating information online.[3,86] There is also some evidence that when social media is used for classroom writing exercises, students demonstrate less writing anxiety and increased agency.[87] Similarly, online fanfiction communities facilitate informal learning by creating a space for youth to build literary skills and support the same skills in others.[87] The same can be said for other hobbies, interests, and activities that have a social media component and roughly 70 percent of teens use social media to express their creative side.[54] The informal learning environment of social media facilitates empowerment and agency among some young people.[3,88] It has also been associated with increases in self-motivation among adolescents.[3,88]

About two-thirds of teens ages 13-18 reported using social media to learn about different points of view or show support,[54] and 64 percent of teens look for news online.[3,89] Furthermore, evidence suggests youth who engage in online political discussions also engage in offline political discussions.[3,89,90] Therefore, social media may be a vehicle to engage and utilize the social and political power of young people through civic engagement.[3,90–92] Social media can facilitate political democracy, cultural democracy, and spread of knowledge.[93] Finally, there is some evidence that adolescents both seek out and share health information on social media.[53,54] Therefore, it may be an effective tool for health interventions and health promotion.[1,94,95] On the other hand, health misinformation can exacerbate adoption of harmful behaviors.[96]

ONLINE HARASSMENT AND EXPOSURE TO INAPPROPRIATE CONTENT

Cyberbullying and online harassment

There is evidence that social media increases risk of cyberbullying among youth.[1–3,60,83,97] According to a recent Pew survey, 46 percent of U.S. teens ages 13 to 17 report ever experiencing at least one of six cyberbullying behaviors.[51] Name-calling was most common, with 32 percent of teens reporting they have been called an offensive name online or on their cellphone.[51] False rumors (22 percent), receipt of explicit images (17 percent), pervasive questions about location (15 percent), physical threats (10 percent), and the sharing of explicit images of them without their consent (seven percent) were also reported.[51] There appear to be slight demographic differences in who experiences cyberbullying. Specifically, studies have shown that black teens experience more cyberbullying that their white peers,[51,98] LGBTQ+ youth experience more cyberbullying than their cisgender and heterosexual peers,[51,98] and adolescent girls experience more cyberbullying than adolescent boys.[51,63,99,100] Evidence also suggests that relationship issues (e.g., feeling left out and interpersonal drama) were the most common reason for cyberbullying among adolescent girls.[63,100]

Studies suggest that the size and type of the network as well as anonymity of those on the network impact the likelihood of harassment, but it is not easily predicted.[3,101,102] For instance, online harassment occurs often among video game users, particularly female gamers who commonly report sexual harassment.[3,103,104] One study found that indiscreet posting, time spent on social media, and personality traits were all predictors of cyberbullying.[105] There is some evidence of a relationship across studies between cyberbullying and depression among children and adolescents; however, the evidence of the effect of cyberbullying on other mental health conditions is inconsistent.[100] Adolescents' self-view and interpersonal relationships may be affected through social comparison and negative interactions, like cyberbullying and exposure to inappropriate content.[97]

Responses to cyberbullying are most often passive, with a pervasive lack of awareness or confidence that anything can be done.[100] Despite the prevalence of cyberbullying, some evidence suggests that in-person bullying is more common.[3,106]

Exposure to inappropriate content and misinformation

One major concern of parents, clinicians, researchers, and policy makers is that poorly regulated and moderated social media can result in youth exposure to inappropriate content (e.g., alcohol, tobacco, risky sexual behaviors, cyberflashing, porn, and self-harm).[1–3,107] A survey of more than 1,300 teens aged 13 to 17 found nearly three-fourths had seen pornography online, with social media being the point of access for about 18 percent.[3,108] Moreover, average first exposure was at 12 years old and accidental exposure accounted for 40 percent of cases.[3,108] Cyberflashing – the electronic transmission of sexually explicit photos without the recipients' consent – is a particularly troubling form of online harassment.[3,109] One survey found that 37 percent of girls and 20 percent of boys aged 12 to 18 had received sexual photos online, often from strangers,[3,110] and another study found more than 6 percent reporting the first flashing incident occurred between the ages of 12 and 14.[3,111] It is difficult to evaluate brief and limited exposures; however, there is evidence that repeated exposure to inappropriate content in childhood was associated with risky sexual behavior later in life.[107] Similarly, exposure to alcohol, tobacco, or risky sexual behaviors may be associated with initiation of those behaviors.[1]

Teens and adolescents may also be uniquely vulnerable to misinformation and disinformation because their maturity and cognitive capacities are still evolving.[3,112] Misinformation and disinformation can take a variety of forms including clickbait, hoax, rumor, satire, propaganda, and conspiracy theories.[113,114] Examples include things like foreign interference, political deceit, and claims for ineffective and unproven natural remedies and medical advice.[112] Concerningly, many people lack the ability to identify misinformation and disinformation as evidenced by one study which found that the percentage of people who share fake news without the intention to mislead is five times higher than intentional spreaders.[115] A 2018–2019 survey of 3,446 U.S. high-school students demonstrated that 52 percent believed that a grainy video claiming to show ballot-stuffing in the 2016 Democratic primaries constituted 'strong evidence' of voter fraud in the U.S., and only 0.1 percent were able to track down the original video even though a quick search showed that it was actually shot in Russia.[112,116] Similarly, two-thirds could not tell the difference between news stories and 'sponsored content' (i.e. adverts) on a website.[112,116] Although teens and adolescents may be particularly vulnerable to misinformation and disinformation, there is currently very little data available to provide a clear picture of how misinformation and disinformation may affect their development, well-being, and rights.[112]

IMPACTS OF SOCIAL MEDIA ON ADOLESCENT HEALTH

To understand the impacts of social media on adolescent health, the conflicting and often reciprocal mechanisms through which online experience and health (physical and mental) influence each other must be disentangled.[3] However, there are several factors that make this extremely challenging, including:

(1) the direction of the relationship between social media and health is difficult to determine - social media use influences health and health influences social media use;
(2) the research lacks uniform, consistent, and comparable methodologies;
(3) social media is so ubiquitous it is difficult to separate the impact of exposure;
(4) different levels of analysis may reveal different dynamics – with large scale studies showing population level trends and psychological studies showing mixed, small, or no associations;
(5) social media is not a monolith, the affordances of different platforms and types of social media engender a wide variety of interactions, behaviors, and health impacts; and
(6) the heterogeneity of the literature and the primary reliance on cross-sectional studies (or meta-analysis of cross-sectional studies) make definitive conclusions and causal relationships limited. Most of the associations are qualified or limited to certain populations.[3]

Social Media and Physical Health: Sleep, Physical Activity, and Obesity.

There is evidence that social media use can disrupt sleep.[1–3,97,107,117,118] Specifically, increased duration of computer, internet, and social media exposure,[3,118] and the presence of a tv, computer, or mobile device in the bedroom in childhood were associated with fewer minutes of sleep, greater risk of sleep disturbances, longer sleep latency, worse sleep quality, and daytime dysfunction.[1,119] Gaming predicted delayed bedtimes and reduced attention the following day.[3,120] One study found that screen-based digital media use is closely associated with sleep duration and sleep quality in teens; however, they cautioned that more research was needed to determine the direction of the effect.[3,121] Another study found that smartphone use at night can delay sleep among adolescents.[3,122] In a nationally

representative sample, one-third of parents of teens 12-17 had rules about smartphone use at bedtime and those kids had less daytime sleepiness.[3,123]

However, it is not clear if social media or devices more broadly are driving the relationship. There are three likely ways in which digital media use may disrupt sleep.[3,124] First, social media displaces sleep thereby delaying bedtime, disrupting sleep, and reducing sleep duration.[3,121,124] Second, devices can disrupt circadian rhythms though light emissions which heighten arousal and decrease sleepiness.[3,122,124] Third, social media may be psychologically stimulating in such a way that makes sleep difficult.[3,124,125] Determining which mechanism(s) are driving the association between digital media and poor sleep is necessary given that the cascading impacts of poor sleep and the potential harms of social media overlap significantly.

Observational studies suggest a significant association between poor sleep quality and excess social media use and negative mental health outcomes.[3,126] Therefore, the interplay between social media and sleep quality may impact mental health outcomes. Sleep loss is a risk factor for depression, mood disturbances, injuries, attention problems, and excessive weight gain.[3,127–129] Additionally, teens with restricted sleep have more problems with emotion regulation, anxiety, hostility, and fatigue.[3,130] One study also found that sleep-deprived participants showed worse mood, more social media use, and problems with concentration.[3,131] Moreover, findings from the Youth Risk Behavior Survey illustrated that teens who sleep four or fewer hours a night have 5.9 times higher odds of having a serious suicide attempt.[3,132] Some studies showed sleep quality mediating the relationship between social media use and negative mental health outcomes in youth.[126] In particular, if social media displaces sleep and hobbies, it can be predictive of anxiety and depression.[3,133] Similarly, when screen time displaces sleep and exercise it is predictive of problematic use.[3,134,135] However, the current body of evidence on the directionality and relationships between social media use, mental health, and sleep is inconclusive.[3,126]

There is some evidence that social media use may correlate to non-adequate nutrition, non-physiologic postures, weight gain, and obesity.[1,2,107,117] Excessive TV viewing in early childhood is associated with an increased risk of obesity.[1] Social media could be displacing physical activity, sleep, studying, and other hobbies, resulting in a more sedentary lifestyle and an increased risk of obesity.[3,107,136] In support of this, another study found that increased digital media use was associated with a sedentary lifestyle.[3,137] Social media use is also associated with consumption of fast food, sugary drinks, snacks, and mindless eating.[3,138] One study theorizes that this may be occurring because social media is displacing regular meals.[3,138]

Social Media and Mental Health: Anxiety, Depression, and Loneliness

The findings on the association between social media and adolescent mental health are small, inconsistent, or non-existent. Moreover, the differences in findings appear to be explained by bidirectional interactions, methodological weaknesses and differences, and/or individual rather than population differences.

Several meta-analyses, systematic reviews, and other studies have found small negative associations between social media use and depression, anxiety, psychological distress,[139] loneliness, internalizing problems, and low offline social support.[3,139–147] At the same time, numerous other studies found the relationship between social media and adolescent mental health is non-existent, mixed, or inconsistent.[148–151] Specifically, there was no significant association between social media use and depression, anxiety, and life satisfaction.[148,150,152] Additionally, there is inconsistent evidence that social media makes social comparison, envy, and well-being worse.[149] Importantly, many of these studies note that predictive relationships between social media use and well-being are reciprocal, as well as present only in certain populations, developmental windows, or among certain patterns of use.[49,141–143,151–155]

For instance, one review found that early studies show comparison and envy are common on social media and linked to ill-being, whereas recent studies find positive, person-specific, conditional, and reciprocal effects.[149] Similarly, one study found that social media use in and of itself is not a predictor of life satisfaction; rather the relationship between self-reported estimates of social media use and life satisfaction is more nuanced, reciprocal over time, gender specific, and likely dependent on analytic methods.[152] Another study found that life satisfaction is most negatively associated with social media use in younger adolescents, but also noted possible developmental windows of sensitivity -- at ages 14-15 and 19 for boys and at ages 11-13 and 19 for girls.[49] A longitudinal study that characterized subgroups based on type of social media use found that the high social media use subgroup predicted higher depressive symptoms, panic disorder, delinquent behaviors, family conflict, and lower family and friend support than the high Instagram/Snapchat and low social media subgroup.[154] Similarly, in a study of U.S.

undergrads, social media use was not predictive of impaired mental health; however, “vaguebooking” -- the practice of making a post on social media that is intentionally vague but highly personal and emotional -- was predictive of suicidal ideation.[151] This suggests how individuals use social media is more important than the amount of time they spend on social media, particularly considering that perceived parent-child conflict was a stronger predictor of mental health issues than social media use.[151]

There is also some evidence that young people who report symptoms of depression are using digital tools to learn about and help their mental health problems.[155] One study found that girls and LGBTQ+ teens were more likely to seek out online resources for mental health and showed interest in stories of others with similar experiences.[155] Those who benefit most from social media appear to be those who are marginalized as well as those with chaotic home lives, suggesting the benefits of online social support are most salient when offline social support is lacking.[51,54] These findings highlight the importance of researching patterns, quality, and type of use in addition to amount of use.

Additionally, there are methodological issues that further complicate definitive conclusions. Several studies note that wide variation in methods and rigor make it difficult to synthesize findings.[139,143,154,156,157] For instance, one systematic review found a small association between self-reported social media use and depressive symptoms, but noted that the studies had high heterogeneity, which suggests that other factors are likely moderating the relationship.[143] Another systematic review argued that small associations and inconsistent results may be influenced by choice of mental health indication (e.g., presence of well-being is not necessarily the absence of ill-being and vice versa).[149] Furthermore, the research on social media and adolescent well-being primarily comes from cross-sectional studies, therefore causal associations may be unwarranted.[49,140,152,156–158] Finally, this research should consider a person-specific approach as individual differences may explain the mixed and inconsistent results.[156]

Ultimately, the presence of small associations as well as inconsistent and conflicting results highlights that the evidence is still too weak to promote a uniform interpretation or to support the conclusion that social media causes changes in adolescent mental health at the population level.[3,159] Moreover, the fact that social media use is linked in complex and ubiquitous ways with other aspects of life means it is unclear what such a small effect demonstrates.[159] More research is needed along with improved transparency and greater appreciation for individual differences and to elucidate which features of or use patterns of social media may be beneficial and which may be harmful to mental and physical health.[4,159]

Problematic Internet Use and Internet Gaming Disorder

Internet gaming disorder is defined as persistent and recurrent use of the internet to engage in games, leading to clinically significant impairment or distress.[41] Problematic internet use is defined as internet use that creates psychological, social, school and/or work difficulties in a person's life.[160] This can include video gaming, social media use, web-streaming, and buying; however, those activities are characterized as excessive or poorly controlled preoccupations, urges, or behaviors regarding computer use and internet access that lead to impairment or distress. The key factor is that internet use becomes problematic when it causes dysfunction in daily life activities (e.g., school, sleep, exercise).[3,26,161] There appears to be significant overlap in internet gaming disorder, problematic social media use, and problematic internet use.[3,162,163] At this point it is unclear whether problematic social media use and gaming disorder are distinct or different manifestations of disordered tech use.[3]

There is some evidence that internet gaming disorder predicts depression, anxiety, social phobia, poor school performance, sleep disruption, and poor relationships with parents and peers.[3,164–167] There is also some evidence that problematic internet use is associated with depression, disturbances in sleep and mood, upward social comparisons, cybervictimization, and poor academic performance.[3,4,58,72,168–172] Problematic social media use is most common among older age groups and may be associated with irritability, nervousness, loneliness, and morning tiredness.[169] There are gender differences in internet gaming disorder, as it affects males five times more than females.[173] Moreover, there is some evidence that boys are more addicted to games whereas girls are more addicted to social media.[3,174]

Some researchers suggest that problematic internet use could explain the small negative associations between social media and youth mental health. For instance, problematic social media use mediated the association between depressive symptoms and cyberbullying.[142] Additionally, one study found that teens with problematic internet use reported more difficulty identifying and describing emotions, and there is some evidence that emotion regulation is a

significant mediator in quality of parent-adolescent relationship.[175] Some researchers theorize that problematic internet use might be a coping strategy to compensate for emotion regulation deficits, which might explain why a good relationship with parents reduces problematic internet use.[175] However, problematic use is more complex than simply the amount of time spent on social media. It includes enduring preoccupation with social media, inability to stop, neglect of one's health and other areas of one's life.[156] Therefore, more research is needed to better understand the relationships between problematic internet use, social media, and adolescent mental health.

Attention and Learning

There is limited evidence that social media use negatively impacts attention and learning. One study found that time spent on social media predicts concentration problems in adolescent girls.[3,176] Additionally, there are small associations between both frequency of social media use and number of platforms and attention deficit hyperactivity disorder (ADHD).[3,177–179] However, it is not clear what is driving the association between social media use and decreased attention.[1]

There is some evidence that reading on screens is fundamentally distracting.[3,180] Others have suggested that multitasking is the root of the problem. High proportions of youth engage in heavy smartphone use and media multitasking.[97] Moreover, a recent meta-analysis found associations between multitasking and problems with attention, behavior regulation, impulsiveness, and memory.[3,181] Specifically, media multitasking is associated with negative effects on cognitive control, academic performance, and socioeconomic functioning.[3,97,181,182] One study found that in three hours of studying, adolescents experienced an average of 35 social media distractions that diverted attention.[3,183] Additionally, another study found that the number of social media accounts correlated with parent reports of symptoms of inattention, hyperactivity, impulsivity, oppositional defiant disorder , anxiety, and depressive symptoms, and adolescent reports of fear of missing out and loneliness.[179] Therefore, it has been suggested that the amount of time spent online can have bidirectional effects on depressive symptoms and ADHD; this risk is particularly heightened in those with pre-existing poor mental health.[126]

Body Image and Eating Disorders

Significant research exists on the association between social media use and body image, but the findings are limited, and causal factors are difficult to differentiate. There is some evidence that social media use and consequent exposure to appearance-focused content may be weakly associated with poorer body image.[3,4,184,185] A cross-sectional study found that greater levels of self-objectifying social media use predicted greater body shame among youth, and the association was mediated by an associated increase in body surveillance.[3,186] Specifically, the role of body surveillance was stronger among girls and adolescents who are particularly focused on others for approval.[186] Body image concerns may be a key mechanism underlying the associations between adolescent girls' social media use and mental health.[187]

A scoping review found that social media use may have a variety of impacts on diet, exercise, and body image.[107] Similarly, another study found that the same platform that helped some patients find recovery support was also a source of body shaming and rumination for others.[3,188] Another review found that peer influences on social media span from healthy eating and exercise to disordered eating, and that dietary information shared on social media often misaligns with national dietary standards.[189] Similarly, one study found youth had an increased ability to recall unhealthy food, beverages, and brands particularly when celebrities and influencers are promoting them.[190]

PRIVACY

Researchers have found that the growing use of social networks has led to the emergence of ethical and privacy concerns regarding the management of user data and how social networks train algorithms for economic purposes to organize the content shown to users.[1,191] The new privacy paradox is that these sites have become so ubiquitous that users feel they must disclose information on them even though these sites do not provide adequate privacy controls.[3,192] Specifically, the privacy policies used by platforms either require or allow users to review and consent to their data collection and data use practices; however, most respondents agreed to the terms without reviewing them.[3,193,194] This could be because the policies themselves are long and technical, they do not provide consumers with meaningful choices, and people are skeptical of whether policies achieve their goals.[194] Concern over what platforms do with user data coupled with a sense of futility over having the agency to change anything may explain

why a recent Pew survey found overall strong bipartisan support for more regulation of what companies can do with people's data, with 72 percent of Americans reporting that there should be more regulation than there is now.[194]

These issues may be even more salient for children. A recent Pew study found that Americans worry about kids' online privacy, with 89 percent of respondents reporting that they are very or somewhat concerned about social media platforms knowing personal information about kids.[194] Similar concern arises over how advertisers, online games, and gaming aps collect and use children's data.[194] However, respondent expectations regarding responsibility for protecting kids is placed primarily on parents at 85 percent, followed by technology companies at 59 percent and the government at 46 percent.[194]

The Children's Online Privacy Protection Act (COPPA), which was enacted in 1998, recognizes that young children cannot consent to the terms of use for data collection, and thus prohibits enticing personal disclosures through games and restricts advertising to children. TikTok was recently sued by the U.S. government for allegedly violating COPPA by failing to notify and obtain parental consent before collecting and using personal information from children under the age of 13.[195,196] Yet, COPPA only applies to kids under 13. Consequently, recent legislation has focused on age-appropriate design and proposed additional protections for adolescents.

There is mixed evidence on how adolescents and adults feel about online privacy. There is some evidence that older users are more concerned about privacy than youth.[197] Additionally, a strong desire among adolescents for social connectedness suggests that youth may be more inclined to have relaxed privacy settings and a show a greater willingness to connect with strangers.[3,35,198] However, a different study found a negative relationship between age and privacy; noting that young people are more likely to have taken action to protect their privacy than older people.[192] Therefore, it is possible that the studies finding that young people are not concerned about their privacy may be because they are taking more precautions.

POTENTIAL APPROACHES TO PROTECT CHILDREN ON SOCIAL MEDIA

Despite widespread use among children and adolescents, the evidence on the potential harms and benefits is too weak to promote a uniform interpretation of the impact of social media on adolescent health at the population level. Nonetheless, the current body of research highlights the importance of understanding the risks and benefits and utilizing developmentally appropriate design to proactively create digital environments that protect and enrich children's and adolescents' health and well-being during critical stages of development.[1–4,41]

Developmentally appropriate design focuses on: (1) centering the rights and developmental needs of children and (2) improving privacy protections and transparency by addressing and modifying what data is collected from minors, how it is collected, and how it is used. In practice this might include collecting the minimum information necessary and prohibiting the use of that information in commerce or discouraging persuasive design features (e.g., push notifications, like buttons, tones for new content, and endless scrolling).[41] Although developmentally appropriate design does not require it, involving youth in both the discussions about and solutions for social media and youth mental health is important, and it can be accomplished with youth advisory panels.[199]

Recommendations for Industry

The most common recommendations for the social media industry, which focus on developmentally appropriate design (e.g., implementation of improved privacy protections, increased transparency, and a better system of reporting inappropriate content and ill-actors), come from researchers, medical societies, policy makers, and the surgeon general.[1–4,41,200] However, the mechanisms needed to facilitate these changes are more nuanced as there has been limited success of voluntary self-governance on the part of industry and regulatory approaches face legal and logistical implementation challenges.[201]

Highlighting the success of the Global Internet Forum to Counterterrorism, the National Academy of Science, Engineering, and Medicine (NASEM) argues that the International Organization for Standardization (ISO) should convene an ongoing technical working group comprised of industry, academic, and civil stakeholders to develop standards for social media platform design, transparency, and data use.[3,202] Other researchers, professional organizations, and policy makers also advocate for development of industry standards that improve privacy, transparency, and accountability.[4,201]

The goals of the NASEM proposed work group would be to develop standards that: (1) limit the personal information companies collect, the types of content available, and the prompts to extend time on a platform; and (2) develop easy to use, universal, transparent systems for reporting, follow-up, and adjudication for cases of online harassment and abuse.[3,4,201] Specifically, efforts should be made to move to a functional privacy system that emphasizes transparency of and access to inputs and outputs. On the front-end inputs would include: (1) a clear process for content moderation and use; (2) contents of privacy agreements; and (3) mandatory disclosures to users and the ability to opt out.[3] On the back-end, standard outputs might include: (1) platform health measures (e.g., content moderation and take down policies and data at the community, group level to evaluate platform toxicity); (2) algorithmic transparency standards and summaries at the user level; and (3) reports on efforts to remediate youth mental health problems on the platform.[3,4] This would improve privacy protections and transparency by making it clear what data is collected from minors, how it is collected and used, and what the consequences of use are. Furthermore, this would give companies and researchers more straightforward guidelines for measuring data collection risks that children encounter online, as well as technical standards to benchmark platform operations, transparency, and data use.[3] Arguably social media platforms would benefit from a standard guide of assessment to evaluate how their products influence youth well-being.

Yet developing standards is insufficient unless social media companies adopt the standards both as their policy and as provisions in their terms of service.[3] There is a precedent of self-regulation in media (e.g., tv, movies, videogames, music) using industry standards, as well as early efforts at self-regulation evidenced by Facebook's Oversight Board.[3,201,203–205] However, given that the success of social media is contingent on engaging as many people for as long as possible, implementing standards aimed to reduce controversial, emotional, and inflammatory content might not be in their best interest.[206,207] Moreover, enacting a regulatory framework across jurisdictions on global companies is not always legally or logistically viable; however, voluntarily adopting standards now could reduce the likelihood of more sweeping regulatory action later.[3,201,208,209] Furthermore, evidence from political science literature on transnational governance shows that multistakeholder regulatory standards setting schemes can be a vital part of the corporate regulatory toolbox.[201] However, more research is needed to see how and if they can be implemented to protect adolescent social media users.[201]

A public statement of compliance with standards and a commitment to uphold those standards in the terms of service would be a meaningful step towards an enforceable legal structure.[3] Specifically, the Federal Trade Commission (FTC) can penalize firms that engage in unfair or deceptive business practices and has used this authority against companies that have failed to honor commitments made in their privacy policies and similar agreements.[210–212] Audit and systemic risk reports of compliance with the standards should be available to the FTC, researchers, and the public. Social media companies should make a good faith effort to ensure access to data that facilitates research on the effects of social media on child and adolescent health possibly including removal of the prohibition on researchers' use of publicly available data.[3] More transparency would allow for comparisons across platforms and over time, which would provide a better insight for the companies, the public, and the FTC. Creation of a standard would also support and inform the FTC's use of consent decrees as a regulatory tool.[3,213] Once a company agrees to a consent decree, terms of the decree determine obligations to remediate regardless of whether the terms are within the FTC's authority.[3,214] Creation of an industry standard could support the FTC's governance by consent decree, even for providers who do not explicitly adopt the standard.[3]

Once standards have been created and adopted, it would be much easier to assess and remedy harms posed by social media. For instance, standards could be used to evaluate whether the platform has age-verification processes, data encryption, and privacy policies.[3] Similarly, they could be used to determine whether a platform's content is suitable for children by evaluating the likelihood of exposure to illegal and maladaptive behavior.[41] The first step towards benchmarking is transparency and more fair competition in an opaque market.[3] For instance, ethical artificial intelligence (AI) tool kits could help facilitate more open communication among technology developers, researchers, policy makers, and civil society.[3,215] Additionally, public documentation of the provenance of the dataset used to calibrate machine learning models is gaining traction as way to mitigate harms from biased models.[3,216]

NASEM makes a persuasive case that an ongoing technical workgroup to develop industry standards, ideally facilitated by ISO, as well as near uniform industry adoption of the standards in their policies and terms of service would improve privacy protections, improve algorithmic and other transparency, and facilitate a better system of reporting inappropriate content and ill-actors. However, this is new territory and despite the ISO's strong track record of developing complex technical international standards (e.g., information security management and data protection), it is difficult to fully assess if something similar would be an effective tool to regulate social media.[3,202]

Aside from the NASEM report proposing such a workgroup, there has been very little tangible movement toward such action.

Recommendations for the Federal Government

Developing and adopting social media industry standards through an ISO facilitated workgroup may be the best way to include social media companies in decisions around developmentally appropriate design particularly given that voluntarily self-regulation in the industry is very limited. A more heavy-handed approach is to improve transparency, privacy protections, and developmentally appropriate social media design through federal legislation. This is further supported by the Surgeon General's Advisory on the effects of social media on youth mental health, which urges federal legislative action to ensure social media environments are healthy and safe, and is also reiterated in his recent call for a warning label on social media platforms.[4,217]

This approach is gaining traction, as evidenced by the numerous federal child online safety bills introduced in 2023 and 2024, including the Kids Online Safety Act, Kids Off Social Media Act, and Protecting Kids on Social Media Act.[218–220] Yet, despite public outcry on the need to regulate social media companies and relatively strong bipartisan support, none of the proposed legislation has passed. Additionally, critics of the bills raise serious concerns around privacy, surveillance, age-verification, and expansion of control over young people's rights and autonomy, as well as possible First Amendment challenges.[221,222]

An alternate federal legislative approach could be expansion of COPPA. COPPA already imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age. Specifically, COPPA recognizes that young children cannot consent to the terms of use for data collection, and thus prohibits enticing personal disclosures through games and restricts advertising to children.[223] When companies violate COPPA by collecting data for children under the age of 13, the FTC can and has issued fines. In 2019, the FTC required Google to pay $170 million for data collection in violation of COPPA.[224] In 2021 and 2023, legislation was introduced to extend COPPA protections to kids through age 16 and also expand the scope (e.g., banning targeted advertising to children, shifting the "actual knowledge" standard to a " reasonably likely to be used by children" standard, establishing a digital marketing bill of rights, and providing tools for parents and children to delete or remove the children's personal information when feasible).[225,226] However, there has been no action on either of the bills as of July 2024.

The FTC also has authority over unfair and deceptive practices in commerce. Therefore, in response to concerns about the erosion of consumer privacy, in particular with data collection and use practices, the FTC has issued guidance documents on internet advertising.[3,227–229] Moreover, there is proposed rulemaking on commercial surveillance and data security.[3,230] Additional guidance and/or revisions from the FTC regarding how to make systems for reporting cases of online harassment and abuse that comply with COPPA would be benefical.[3]

In addition to improving children's privacy and better regulating social media providers through the FTC and COPPA, future children's online safety legislative efforts should focus on: (1) centering young people with developmentally appropriate design; (2) increasing access to mental health resources; (3) improving digital literacy and outreach; (4) improving digital tools tailored to youth users to manage content and access (e.g., turning off autoplay, removing recommended content); (5) reducing the scope of advertising on social media; (6) strong data protections and expanded federal privacy legislation; (7) improved algorithmic, data, and process transparency (e.g., impact audits); and (8) developing support programs for children and adolescents who experience digital abuse and evaluate the effectiveness of such programs.[3,221] Finally, assuming industry leaders do not voluntarily remove the prohibitions in their terms of service on the use of publicly available data for research, Congress could pass legislation to ensure researchers can access data to examine the effects of social media on child and adolescent health.[3]

Recommendations for State and Local Agencies

Increasing concerns about social media use and adolescent health coupled with limited progress on federal legislation to protect children while using the internet and social media has prompted state legislators to propose age- and developmentally-appropriate design measures.[231,232]

As of July 2024, 45 states and Puerto Rico introduced legislation around social media and youth, and 20 states enacted bills or adopted resolutions. Among the recently introduced legislation, the following aspects are the most common: (1) creating study commissions and task forces to evaluate the relationship between social media and adolescent health; (2) establishing age-appropriate design code and requiring impact assessments; (3) requiring age verification and/or parental consent to open social media accounts; and (4) adding digital and media literacy to K-12 curriculums.[231,233] Time limits, increased data protections (e.g., limitations on what information can be collected, geolocation/biometrics, and dark patterns), advertising restrictions, restrictions on addictive features, parental consent and access, and modification to the default privacy settings are also being included in state level legislation. However, state level legislative attempts also face serious legal challenges. For instance, Utah enacted the Utah Social Media Regulation Act, which requires age verification of state residents and parental consent for those under the age of 18 to open an account.[234] It also limits the hours of access for certain users, subject to parental or guardian direction, and provides for a private right of action. Similarly, Arkansas created the Social Media Safety Act which requires age verification and parental consent for use of social media. It also establishes a mechanism for liability for failure to perform age verification for use of social media and for illegal retention of data.[235] Finally, in 2022, California passed the Age-Appropriate Design Code Act (AADC).[206] Notable obligations under California's AADC include requiring online providers to: (1) configure a high level of default privacy settings; (2) assess whether algorithms, data collection, or targeted advertising systems could harm children; and (3) use clear, age-appropriate language for user-facing information and documents.[232,236] Yet, as is becoming increasingly more common with state legislation that addresses age verification and content moderation, Utah, Arkansas, and California have faced First Amendment challenges from NetChoice, a coalition representing the country's tech companies.[207] Ultimately, Utah repealed and replaced the Utah Social Media Regulation Act with SB 194 and HB 464. SB 194 implements age assurances and is designed to prohibit harmful and addictive product features on social media, protect minors' privacy, and give parents the tools to keep their children safe. Whereas HB 464 holds social media companies accountable by creating a private right of action for harm to minors for an adverse mental health outcome arising from a minor's excessive use of a social media company's algorithmically curated social media service. Similarly, both the Arkansas and California laws are currently enjoined pending decisions by the U.S. District Court in Fayetteville, Arkansas and Ninth Circuit Court of Appeals, respectively.[206,207,237,238]

Developmentally appropriate design legislation is relatively new at the state level, so the overall impacts are unclear. Some aspects like improved data protections, digital media literacy, and continued research are rationally grounded, appear beneficial, and are likely less subject to First Amendment challenges. However, other aspects like age verification and content moderation raise concerns around privacy, surveillance, First Amendment rights, federal preemption, and expansion of control over young people's rights and autonomy.[221,222,239]

Recommendations for Parents and Kids

Parents and children are encouraged to use social media functions that facilitate social support, online companionship, emotional intimacy, and healthy socialization; particularly during periods of isolation, during stress, mental health crisis, and for marginalized groups.[41] To achieve this, it is recommended that families should collectively develop, review, and follow a family media use plan, which should outline developmentally appropriate types, times, methods, places for, and amounts of acceptable media us.[1,2,4,41] For instance, there is evidence of the impact of excessive digital technology use (e.g., screentime, tv, and social media) by adolescents on negative health impacts.[1,2,240] However, there has been a push among researchers to move away from focusing on screentime and instead to consider how, why, when, and with whom youth are engaging online. Despite this, the American Academy of Pediatrics (AAP), APA, and many other organizations and policy makers advocate for screen time limits and media-free time.[1,2] Specifically, it is recommended that adolescents abstain from using screens 1 hour before bed and that adolescents should not sleep with digital devices in their bedrooms.[7,52] Additionally, there is some evidence supporting open, non-judgmental communication between caregivers and children and some degree of parental monitoring of social media use.[1,2,41,97] Recent surveys suggest roughly 63 percent of adolescents and 70.8 percent of parents reported parental monitoring, and 74.3 percent of adolescents reporting being friends with their parents online.[179] Open communication is helpful for teaching digital literacy, which is necessary for children to understand the limits of "free digital products" that process access in exchange for data on user demographics, politics, mental health, and sexuality generated through engagement and viewing behavior.[50]

Recommendations for Clinicians

It is recommended that clinicians be aware of and talk with children and families about the risks and benefits of social media use.[1–3,107,241] Specifically, communication with adolescents is the most effective in the context of a therapeutic alliance that is open and non-judgmental.[97] Physicians should encourage: (1) setting boundaries for screentime and social media use; (2) discuss the risks and benefits of social media, including impact of smartphones on learning and the importance of digital media literacy; and (3) encourage communication between caregivers and children and advocate use of the Family Media Toolkit and Family Media Use Plan.[1,2,58,60,97]

Recommendations for Training and Education

One way to reduce potential harm to adolescents using social media is through improved digital media literacy. Specifically, it is important to train adolescents and those teaching and advising them skills for assessing and validating information on social media and the internet more broadly.[41,50,60,97,241] Moreover, the approach to digital media literacy needs to be multi-tiered and tailored to children, parents, educators, and clinicians. Specifically, comprehensive digital media literacy should be integrated into the standards set by state boards of education. Moreover, the U.S. Department of Education should draw national attention to the importance of comprehensive digital media literacy.[3] This is necessary to create both an online environment that protects youth and social media consumers who are empowered to protect themselves. Furthermore, educators and clinicians need to be trained in digital media literacy so they can adequately teach and advise adolescents on the risks and benefits of social media.[1–4] This could include incorporation of digital media literacy requirements for licensure as well as ongoing professional development training and resources for both educators and clinicians.[3] In addition to incorporating digital media literacy into training and licensure, additional efforts to improve dissemination of health-related digital media literacy is suggested.[241]

Recommendations for Research

Currently, the research on social media and adolescent health is limited.[3,4] Therefore, federal and non-profit research funders should support a research agenda that prioritizes: (1) the health consequences of social media use and the mechanisms of harm, (2) the epidemiology of problematic use, (3) interventions and other efforts to reduce and remediate harms arising from social media, (4) the role of parents and other adults in influencing positive use, and (5) algorithmic audits.[3,4] There is a need for validated tools to measure exposure to social media affordances, data sharing, and the establishment of long-term cohort studies. Special emphasis should be given to interdisciplinary approaches and study designs that attempt to understand causal directions.

RELEVANT AMA POLICY

The AMA has existing policy that addresses social media and mental health, gun violence, internet pornography, online streaming of sexual encounters, the effects of video game and internet overuse, disinformation, cannabis marketing, and online human subjects' research. In general, these policies advocate the use of education and legislation to: (1) increase awareness about potential risks associated with social media and internet use; and (2) reduce exposure to harmful content (e.g., gun violence, pornography, disinformation, etc.) particularly for children, adolescents, and young adults. Current policy also supports development and implementation of clinical tools for identification and treatment of harms that arise from exposure as well as continued research into potential harms and the effectiveness of screening and treatment. Detailed information on the current AMA policies can be found in the appendix.

CONCLUSION

Digital media, smartphones, and social media have a pervasive presence in nearly all aspects of youth and adolescent life. Despite substantial research efforts, the evidence is too weak to promote a uniform interpretation of the impact of social media on adolescent health at the population level. There are several factors contributing to the weak evidence including: (1) the reciprocal associations between social media use and health; (2) the lack of consistent and comparable methodologies; (3) entanglement of impact and exposure as a byproduct of social media's ubiquity; (4) different dynamics and trends depending on level of analysis; (5) the wide variety of interactions, behaviors, and health impacts engendered by social media; and (6) reliance on cross-sectional studies with high heterogeneity.

Although the evidence is too weak to provide a uniform interpretation, there are clear positive and negative trends. There is some evidence of potential benefit in the form of improved social support, identity development, civic engagement, and self-directed learning. There is also some evidence of potential harm including negative impacts on sleep, physical activity, and mental health, as well as exposure to inappropriate content, and data privacy issues. Furthermore, it is apparent that the relative risks and benefits of social media likely depend on individual differences in: (1) engagement with social media (e.g., what kids see and do online, who they talk to, when they use social media, and how they use social media); (2) pre-exiting strengths and weaknesses; and (3) the cultural, social, and physical environment.

Even though the evidence of harm is limited there is an urgent need for action for two reasons. First, the lack of algorithmic transparency, privacy protections, and accountability and redress for online harassment on most platforms is concerning given the power, reach, and ubiquity of social media. Second, the potential harms are serious, particularly during sensitive developmental periods; therefore, proactively creating digital environments that protect and enrich children's and adolescents' health and well-being is beneficial regardless of the evidence of harm. There are two key approaches that would likely facilitate the creation of safer, developmentally appropriate environments. First, federal and state legislative action (e.g., expansion of COPPA, implementation of age-appropriate design, and mechanisms to address online harassment), and second, development and widespread adoption of industry standards to benchmark platform operations, transparency, and data use. In addition to improving the digital environment, it is imperative that there are simultaneous efforts to address harms that still arise including: (1) education and training on digital media literacy and the potential harms posed by social media; (2) improved screening and support for those who experience harms (e.g., problematic internet use and online harassment); and (3) continued research of the health impacts of social media.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted, and the remainder of the report be filed:

1. That our AMA:

   (1) urges physicians to: (a) educate themselves about social media; (b) be prepared to counsel patients and/or their guardians about the potential risks and harms of social media; and (c) consider expanding clinical interviews to inquire about social media use;
   (2) encourages further clinical, epidemiological, and interdisciplinary research on the impact of social media on health;
   (3) supports education of clinicians, educators, and the public on digital media literacy and the health effects of social media;
   (4) recognizes that the relative risks and benefits of social media may depend on individual differences (e.g., social media engagement, pre-existing traits, and environment);
   (5) supports legislative, regulatory, and associated initiatives that, at a minimum, provide youth with strong data privacy protections, require platforms to be designed to align with child development, and provide transparency into the potential harms posed by platforms to young people and any steps taken to mitigate those harms; and
   (6) will collaborate with professional societies, industry, and other stakeholders to improve social media platform privacy protections, transparency (e.g., algorithmic, data, and process), data sharing processes, and systems for accountability and redress in response to online harassment. (New HOD Policy)

2. That current AMA policy D-478.965, "Addressing Social Media and Social Networking Usage and its Impacts on Mental Health" be amended by addition and deletion to read as follows:

   Our AMA: (1) will collaborate with relevant professional organizations to: (a) support the development of continuing education programs to enhance physicians' knowledge of the health impacts of social media and social networking usage; and (b) support the development of effective clinical tools and protocols for the identification, treatment, and referral of children, adolescents, and adults at risk for and experiencing health sequelae of social media and social networking usage; (2) advocates for schools to provide safe and effective, evidence-based educational programs ~~by which~~ so that (a) all students can learn to identify and

mitigate the onset of mental health sequelae of social media and social networking usage, and (b) all students develop skills in digital literacy to serve as an individual protective foundation for interaction with various types of digital media (including social media); (3) affirms that use of social media and social networking has the potential to positively or negatively impact the physical and mental health of individuals, especially adolescents and those with preexisting psychosocial conditions; (4) advocates for and support media and social networking services addressing and developing safeguards tailored to youth users, including ensuring robust protections for youth online privacy, providing effective tools to manage screentime content and access, considering special circumstances for certain youth populations (such as LGBTQ+ youth and youth with disabilities), and promoting the development and dissemination of age-appropriate digital literacy training; and (5) advocates for the study of the positive and negative biological, psychological, and social effects of social media and social networking services use. (Modify Current HOD Policy)

Fiscal Note: $5,000 - $10,000

APPENDIX: Relevant AMA Policy

Addressing Social Media and Social Networking Usage and its Impacts on Mental Health D-478.965
Our AMA: (1) will collaborate with relevant professional organizations to: (a) support the development of continuing education programs to enhance physicians' knowledge of the health impacts of social media and social networking usage; and (b) support the development of effective clinical tools and protocols for the identification, treatment, and referral of children, adolescents, and adults at risk for and experiencing health sequelae of social media and social networking usage; (2) advocates for schools to provide safe and effective educational programs by which students can learn to identify and mitigate the onset of mental health sequelae of social media and social networking usage; (3) affirms that use of social media and social networking has the potential to positively or negatively impact the physical and mental health of individuals, especially adolescents and those with preexisting psychosocial conditions; (4) advocates for and support media and social networking services addressing and developing safeguards for users; and (5) advocates for the study of the positive and negative biological, psychological, and social effects of social media and social networking services use.

Minimizing the Influence of Social Media on Gun Violence H-478.977
1. Our American Medical Association calls upon all social media sites that allow posting of videos, photographs, and written online comments encouraging and glorifying the use of guns and gun violence to vigorously and aggressively remove such postings.
2. Our AMA strongly recommends social media sites continuously update and monitor their algorithms in order to detect and eliminate any information that discusses and displays guns and gun violence in a way that encourages viewers to act violently.
3. Our AMA will work with social media sites to provide educational content on the use of guns, inherent dangers, and gun safety in an effort to end the ongoing and devastating effects of gun violence in our communities.

Internet Pornography: Protecting Children and Youth Who Use the Internet and Social Media H-60.934
Our AMA:
(1) Recognizes the positive role of the Internet in providing health information to children and youth.
(2) Recognizes the negative role of the Internet in connecting children and youth to predators and exposing them to pornography.
(3) Supports federal legislation that restricts Internet access to pornographic materials in designated public institutions where children and youth may use the Internet.
(4) Encourages physicians to continue efforts to raise parent/guardian awareness about the importance of educating their children about safe Internet and social media use.
(5) Supports school-based media literacy programs that teach effective thinking, learning, and safety skills related to Internet and social media use.
(6) Actively support legislation that would strengthen child-centric content protection by internet service providers and/or search engines in order to limit the access of pornography to minors on the internet and mobile applications.

Addressing Public Health Disinformation Disseminated by Health Professionals D-440.914
Our AMA will collaborate with relevant health professional societies and other stakeholders:

(a) on efforts to combat public health disinformation disseminated by health professionals in all forms of media,
(b) address disinformation that undermines public health initiatives, and
(c) implement a comprehensive strategy to address health-related disinformation disseminated by health professionals that includes:
(1) Maintaining AMA as a trusted source of evidence-based information for physicians and patients.
(2) Ensuring that evidence-based medical and public health information is accessible by engaging with publishers, research institutions and media organizations to develop best practices around paywalls and preprints to improve access to evidence-based information and analysis.
(3) Addressing disinformation disseminated by health professionals via social media platforms and addressing the monetization of spreading disinformation on social media platforms.
(4) Educating health professionals and the public on how to recognize disinformation as well as how it spreads.
(5) Considering the role of health professional societies in serving as appropriate fact-checking entities for health-related information disseminated by various media platforms.
(6) Encouraging continuing education to be available for health professionals who serve as fact-checker to help prevent the dissemination of health-related disinformation.
(7) Ensuring licensing boards have the authority to take disciplinary action against health professionals for spreading health-related disinformation and affirms that all speech in which a health professional is utilizing their credentials is professional conduct and can be scrutinized by their licensing entity.
(8) Ensuring specialty boards have the authority to take action against board certification for health professionals spreading health-related disinformation.
(9) Encouraging state and local medical societies to engage in dispelling disinformation in their jurisdictions.

Television Broadcast and Online Streaming of Sexual Encounters and Public Health Awareness on Social Media Platforms H-485.994
Our AMA urges television broadcasters and online streaming services, producers, sponsors, and any associated social media outlets to encourage education about inclusive safe sexual practices, including but not limited to condom use and abstinence, in television or online programming of sexual encounters, and to accurately represent the consequences of unsafe sex.
Medical and Public Health Misinformation Online D-440.915
Our AMA:
(1) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to further strengthen their content moderation policies related to medical and public health misinformation, including, but not limited to enhanced content monitoring, augmentation of recommendation engines focused on false information, and stronger integration of verified health information;
(2) encourages social media companies and organizations, search engine companies, online retail companies, online healthcare companies, and other entities owning websites to recognize the spread of medical and public health misinformation over dissemination networks and collaborate with relevant stakeholders to address this problem as appropriate, including but not limited to altering underlying network dynamics or redesigning platform algorithms;
(3) will continue to support the dissemination of accurate medical and public health information by public health organizations and health policy experts; and
(4) will work with public health agencies in an effort to establish relationships with journalists and news agencies to enhance the public reach in disseminating accurate medical and public health information.

Marketing Guardrails for the "Over-Medicalization" of Cannabis Use D-95.958
Our AMA will: (1) send a formal letter to the Food and Drug Administration and Federal Trade Commission requesting more direct oversight of the marketing of cannabis for medical use; (2) generate a formal letter for use by state medical societies requesting more direct oversight by state government of the marketing of cannabis; (3) support and encourage federal, state, and private sector research on the effects of cannabis marketing to identify best practices in protecting vulnerable populations, as well as the benefits of safety campaigns such as preventing impaired driving or dangerous use; (4) encourage state regulatory bodies to enforce cannabis-related marketing laws and to publicize and make publicly available the results of such enforcement activities; (5) encourage social media platforms to set a threshold age of 21 years for exposure to cannabis advertising and marketing and improve age verification practices on social media platforms; (6) encourage regulatory agencies to research how marketing best practices learned from tobacco and alcohol policies can be adopted or applied to cannabis marketing; and (7) support using existing AMA channels to educate physicians and the public on the health risks of cannabis to children and potential health risks of cannabis to people who are pregnant or lactating.

Principles of Human Subjects Research Shall Apply to Online Medical Research Projects H-460.898
Our American Medical Association declares social media sites' terms of service as an insufficient proxy for informed consent prior to being enrolled in any medical experiment and recommends that online social networks provide users with specific informed consent outlining the aims, risks and possible benefits of any medical experimental study prior to study enrollment.

Emotional and Behavioral Effects of Video Game and Internet Overuse H-60.915
Our AMA supports increased awareness of the need for parents to monitor and restrict use of video games and the Internet and encourage increased vigilance in monitoring the content of games purchased and played for children 17 years old and younger.

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