REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

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The following reports were presented by Noel Deep, MD, Chair:

1. DRUG SHORTAGES: 2022 UPDATE

Reference committee hearing: see report of Reference Committee K.

HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED See Policy TBD

INTRODUCTION

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, 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 (HOD) on progress made in addressing drug shortages in the United States. 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.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2019 to August 2022, using the text term "drug shortages." 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 (NASEM), U.S. Department of Health and Human Services (HHS), American Society of Health-System Pharmacists (ASHP), and Duke Margolis Center for Health Policy.

BACKGROUND

CSAPH has issued twelve reports on drug shortages, with the most recent published at the November 2021 Special Meeting.¹ The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, "National Drug Shortages: Update." The remainder of this report will provide an update on drug shortages since the 2021 report was developed, including specific comment on issues associated with the role of pharmacy benefit managers (PBMs).

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States and the AMA continues to monitor the situation and take action when appropriate. Overall, new drug shortages are decreasing; however, a large number of shortages are still ongoing and pose continued problems for patient care. Additionally, new shortages may occur as manufacturing capacity in the pharmaceutical industry is prioritized during the continuing COVID-19 and monkeypox public health emergencies, specifically for the production of vaccines and treatments.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service (see Box 1 for links to these resources).^{2,3} It should be noted that FDA resources also include guidance on drugs which have had their use dates extended while a known shortage is ongoing.

According to current ASHP statistics (see Appendix 1), the downward trend in new drug shortages over the last few years has continued. At its peak in 2011, there were 267 new drug shortages reported; in 2021, there were 114. For the first 6 months of 2022, there have been 81 newly reported shortages. However, while the number of new shortages may be decreasing each year, the number of active drug shortages has stayed relatively steady (282 active shortages in Q2 2019, 264 shortages in Q2 2022), indicating that individual shortages are taking longer to resolve. For the first two quarters of 2022, the five classes of drugs with the most ongoing shortages include: central nervous system drugs

(40 total), fluids and electrolytes (36), antimicrobials (30), cardiovascular (27), and hormones (19). Fluids and electrolytes were not present in last year's top five classes of drug shortages, indicating a surge in products currently facing shortage.

In addition, the number of manufacturers reporting the underlying cause of the drug shortage as "unknown" has continued to decrease, from 82 percent in 2019 to 42 percent in 2021. Compared to 2020, "business decision" has decreased as well from 14 percent to 4 percent in 2021. Behind "unknown," "supply/demand" was listed as the second most common reason (27 percent) for drug shortages by manufacturers in 2021. Beyond issues with manufacturing, ASHP has also reported that hospitals are having difficulty staffing their pharmacies with experienced staff to proactively identify, prevent and alleviate gaps in supply.⁴

The Food and Drug Administration

The FDA continues to utilize a mobile app to provide up-to-date access to information about drugs in shortage as well as notifications about new and resolved drug shortages. This mobile app also gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, a link to the mobile app, and additional information (Box 1).

The ninth annual report on drug shortages from the FDA to Congress published in early 2022 summarizes the major actions the FDA took in calendar year 2021 related to drug shortages.⁵ During the COVID-19 public health emergency, the FDA continued to closely monitor the medical product supply chain and as expected, the supply chain was impacted by the pandemic, leading to supply disruptions or shortages of drug products in the United States. Appendix 2 includes a breakdown of the FDA's calendar year 2021 metrics, including the number of expedited reviews (274) and expedited inspections (29).

The Essential Medicines Report

In May 2022, HHS and the Assistant Secretary for Preparedness and Response (ASPR) released the first Essential Medicines Supply Chain and Manufacturing Resilience Assessment.⁶ A critical function of this report was to prioritize drugs for increased scrutiny from a previously developed list of essential medicines.⁷ In their report, a group of stakeholders identified 86 medications as critical or important for minimum acute patient care with no other alternative available. Of the drugs identified, 56 drugs (65 percent) at the time of publication were in shortage as described by the ASHP database. Within their report, the group outlines six challenges for addressing drug shortages: market structure, global competition, labor/workforce, manufacturing processes, supply chain/distribution, and regulatory barriers.

The Drug Enforcement Administration

Outside of the FDA, HHS and ASPR, the Drug Enforcement Administration (DEA) is another critical federal agency that impacts drug shortages. As part of its regulatory authority under the Controlled Substances Act, the DEA maintains a closed system around the manufacturing of Schedule I and II drugs, as well as List I chemicals (ephedrine, pseudoephedrine and phenylpropanolamine). This closed system means that the DEA requires the registration and continuous oversight of any entity involved in the manufacturing and distribution supply chain of these drugs, including a strict quota on the volume and quantity of a controlled substance that can be manufactured at a given time. Per the DEA, this quota is intended "prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."⁸ The FDA and DEA have an ongoing memorandum of understanding to share information regarding information that may impact drug shortages.⁹

However, there have been several instances where DEA quotas have either directly or indirectly caused a drug shortage of a critically necessary medication. For example, in 2019 the DEA proposed a 53 percent decrease to the overall quota of Schedule II opioids that could be manufactured in 2020.¹⁰ However, by the spring of 2020, there was a surge in demand for injectable opioids to help patients on ventilators fighting COVID-19.

In response to a 2020 joint letter from AMA, ASHP and other stakeholders,¹¹ the DEA increased the manufacturing quota by 15 percent, yet injectable fentanyl, hydromorphone, and morphine are all still classified as active shortages

by ASHP in 2022.¹² Other drugs, such as mixed amphetamine salts for the treatment of attention deficit hyperactivity disorder, are similarly facing decreases in DEA manufacturing quotas while under an active drug shortage.

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In light of the opioid crisis, in which medications that help prevent overdose are underprescribed nationwide, supply restrictions may have significant unintended consequences. The potential benefit of supply reduction is that it may discourage the diversion of controlled substances. The potential harm of supply reduction is that patients may suffer serious harm when needed medications are unavailable for any reason. Your Council on Science and Public Health is currently unaware of any evidence that the overall benefits of supply reductions outweigh the overall harms.

Pharmacy Benefit Managers

At the AMA 2022 Annual Meeting, the topic of PBMs and their role in driving drug shortages was specifically raised. PBMs, which serve as an intermediary between health insurers and pharmaceutical companies, have long been a source of scrutiny by our AMA, with a multitude of policies directly calling for oversight or reform of PBM activities.

Concern around PBMs and drug shortages is the potential for manipulating price and access to medications. However, these claims cannot be tested as PBM pricing information has historically been opaque, but that may be changing. On June 7, 2022, the Federal Trade Commission (FTC) announced that it has launched an investigation into vertically integrated PBMs and has specifically cited issues around PBM-owned pharmacies and prior authorizations.¹³ In April 2022, prior to the FTC's decision, the AMA sent a letter urging the FTC to take action and increase PBM transparency.¹⁴ Additional bipartisan legislation, the Pharmacy Benefit Manager Transparency Act of 2022, was introduced on May 24, 2022, and at the time of writing is pending review by the Senate Commerce, Science and Transportation committee. In its current form, the PBM Transparency Act would require, among other things, for PBMs to file annual reports with the FTC on many of their practices.¹⁵

Beyond possible manipulations of cost and access, other PBM practices may exacerbate drug shortages or otherwise impact the ability of a practice to mitigate shortages. For example, PBMs may utilize techniques known as "brown bagging," in which a health plan requires a patient to obtain a medication from a PBM-owned specialty pharmacy and then bring it to the clinic for the practitioner to administer. Previously, the Council on Medical Service has investigated the issue of brown bagging medications in the context of patient care.¹⁶ In the context of drug shortages, brown bagging decreases visibility of the supply chain for hospitals and practices; they are unable to predict which medications are to be needed when, and as such may be unable to procure or adequately plan for future demand.

Monkeypox Vaccines

Amidst the monkeypox public health emergency, there is currently a shortage of vaccinations available in the United States. Two vaccines may be used for the prevention of monkeypox disease.¹⁷ The JYNNEOS vaccine, a third-generation vaccine produced by a small European biotech company, Bavarian Nordic, is approved for the prevention of monkeypox and smallpox disease and the ACAM2000 vaccine, produced by Baxter, is approved for immunization against smallpox disease and made available for use against monkeypox under an Expanded Access Investigational New Drug (EA-IND) protocol. In the United States, there is a large supply of ACAM2000, but this vaccine has more known side effects and contraindications.¹⁸ JYNNEOS is the primary vaccine being used in the U.S monkeypox outbreak.

After its FDA approval in 2019, the Strategic National Stockpile (SNS) was reportedly supposed to procure 120 million doses of JYNNEOS, enough to immunize sixty million people as one element of the U.S. government's smallpox preparedness efforts.¹⁹ However, as with other supplies in the national stockpile, JYNNEOS inventory was not maintained to an appropriate level due to chronic underfunding as well as the redirection of funds to other purposes, such as shelter for 20 thousand unhoused migrant children at the southern border.^{20,21} With a shelf-life of 3 years, millions of doses of JYNNEOS in the SNS had expired.²² Only 2,400 doses of the JYNNEOS vaccine were available in the immediate holdings of the SNS at the onset of the current monkeypox outbreak.²³ More than 1.1 million doses of the vaccine purchased by the U.S. government were at Bavarian Nordic's facility in Denmark and required authorization from an on-site FDA inspection before they could be shipped to the U.S.²⁴

To help alleviate the shortage, the FDA granted emergency use authorization for intradermal administration of JYNNEOS, which utilizes approximately one-fifth of the total volume of vaccine compared to currently approved subcutaneous administration.²⁵ In addition, the administration has increased efforts to boost domestic manufacturing,

including partnerships with Michigan-based facilities to perform filling and finishing to expedite the distribution of previously ordered vaccines.²⁶

CURRENT AMA DRUG SHORTAGE ACTIVITIES

AMA staff continue to remain engaged in drug shortage activities. Staff are involved in a multi-stakeholder effort to remain current on policies, drug shortage and supply chain issues, and to develop group recommendations on the topics. The effort includes our AMA, the ASHP, the American Hospital Association (AHA), the United States Pharmacopeia (USP), the American Society of Anesthesiologists (ASA), and the American Society of Clinical Oncology (ASCO).

Earlier this year, our AMA additionally sent a letter to leadership of the Senate Committee on Health, Education, Labor and Pensions to advocate for legislation modernizing the medical supply chain.²⁷ In the letter, the AMA called upon Congress to, among other things:

- Incentivize advanced manufacturing technology and develop new continuous manufacturing technology for critical drugs and active pharmaceutical ingredients;
- Improve the function and composition of the Strategic National Stockpile;
- Improve multinational cooperation on supply chain resilience;
- Incentivize quality and resilience; and
- Replicate asks for critical drug manufacturing transparency and oversight for medical devices and ancillary supplies (e.g., PPE).

CONCLUSION

The rate of new medical product shortages is decreasing, but individual shortages are lasting longer. Due to the ongoing COVID-19 and monkeypox public health emergencies, the medical supply chain has been under intense, increased scrutiny. The AMA's drug shortage policy is timely and already addresses a variety of issues that are under consideration by the White House, FDA, and other stakeholders. Additional policy modifications have been recommended to reflect ongoing efforts by other organizations interacting with the drug manufacturing space, such as the DEA and FTC.

RECOMMENDATIONS

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

- 1. Policy H-100.956, "National Drug Shortages" be amended by addition to read as follows:
 - 1. Our AMA 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 US 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 to oversee and regulate such forces.
- 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 Federal Trade Commission 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 to provide greater transparency regarding the pharmaceutical product supply chain, including production locations of drugs, 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.
- 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 (EHR) 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 (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

- 19. <u>Our AMA urges the Drug Enforcement Administration and other federal agencies to regularly communicate</u> and consult with the FDA regarding regulatory actions which may impact the manufacturing, sourcing, and distribution of drugs and their ingredients.
- 2. That Policy H-440.847, "Pandemic Preparedness," which addresses the adequacy of the Strategic National Stockpile, be reaffirmed.

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

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

REFERENCES

- 1. Council on Science and Public Health. Drug Shortages: 2021 Update. American Medical Association; Nov 2021.
- 2. American Society of Health-System Pharmacists. *Shortage Resources*. <u>https://www.ashp.org/Drug-Shortages/Shortage-Resources</u>. Accessed August 1, 2022.
- 3. U.S. Food and Drug Administration. *Drug Shortages*. <u>https://www.fda.gov/DrugSafety/DrugShortages/default.htm</u>. Accessed August 1, 2022.
- 4. Kate Traynor. *Drug Shortages Worsening, Pharmacists Say*. American Society of Health-System Pharmacists. <u>https://www.ashp.org/News/2022/03/16/drug-shortages-worsening-pharmacists-say</u>. March 16, 2022.
- U.S. Food and Drug Administration. Drug Shortages for Calendar Year 2021. <u>https://www.fda.gov/media/159302/download</u>. Accessed August 1, 2022.
- 6. Department of Health and Human Services. *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*. <u>https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf</u>. Accessed August 1, 2022.
- U.S. Food and Drug Administration. Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944. <u>https://www.fda.gov/media/143406/download</u>. Accessed August 1, 2022.
- 8. U.S. Department of Justice. *Diversion Control Division*. <u>https://www.deadiversion.usdoj.gov/prog_dscrpt/</u>. Accessed August 1, 2022.
- 9. U.S. Food and Drug Administration. *MOU 225-15-11*. <u>https://www.fda.gov/about-fda/domestic-mous/mou-225-15-11</u>. Accessed August 1, 2022.
- Drug Enforcement Agency. DEA proposes to reduce the amount of five opioids manufactured in 2020, marijuana quota for research increases by almost a third. <u>https://www.dea.gov/press-releases/2019/09/11/dea-proposes-reduce-amount-five-opioids-manufactured-2020-marijuana-quota</u>. Accessed August 1, 2022.
- 11. American Medical Association. *AMA praises DEA allowing increase in controlled substance production*. <u>https://www.ama-assn.org/press-center/press-releases/ama-praises-dea-allowing-increase-controlled-substance-production</u>. Accessed August 1, 2022.
- 12. Ed Silverman. *DEA moves to fight shortages of medicines needed for Covid-19 patients*. STAT News. https://www.statnews.com/pharmalot/2020/04/07/dea-covid19-coronavirus-ventilators-shortages/. Accessed August 1, 2022.
- 13. Federal Trade Commission. *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*. <u>https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry</u>. Accessed August 1, 2022.
- American Medical Association. Letter to FTC re: Solicitation for Public Comment on the Business Practices of Pharmacy Benefit Manager. <u>https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-4-26-Letter-to-Khan-re-FTC-PBM-RFI-v2.zip%2F2022-4-26-Letter-to-Khan-re-FTC-PBM-RFI-v2.zdf.</u>
- 15. 117th Congress of the United States. *S.4293 Pharmacy Benefit Manager Transparency Act of 2022*. https://www.congress.gov/bill/117th-congress/senate-bill/4293/text. Accessed August 1, 2022.
- Council on Medical Service. *Medication "Brown Bagging"*. American Medical Association; June 2016.
 Centers for Disease Control and Prevention. Monkeypox, Vaccine Considerations.
- https://www.cdc.gov/poxvirus/monkeypox/health-departments/vaccine-considerations.html. September 28, 2022.
- 18. Centers for Disease Control and Prevention. *ACAM2000 Vaccine*. <u>https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/acam2000-vaccine.html</u>. August 9, 2022.
- Erin Banco and Helen Collis. Before monkeypox outbreak, U.S. officials knew for years they didn't have enough of key shot. Politico. <u>https://www.politico.com/news/2022/08/18/u-s-officials-knew-for-years-they-did-not-have-enough-jynneos-vaccine-00052694</u>. August 18, 2022.

- Erin Banco and Helen Collis. Before monkeypox outbreak, U.S. officials knew for years they didn't have enough of key shot. <u>https://www.politico.com/news/2022/08/18/u-s-officials-knew-for-years-they-did-not-have-enough-jynneos-vaccine-00052694</u>. September 28,2022.
- 21. Adam Cancryn. Biden admin reroutes billions in emergency stockpile, Covid funds to border crunch. Politico. https://www.politico.com/news/2021/05/15/hhs-covid-stockpile-money-border-migrants-488427. May 15, 2021.
- 22. Adam Cancryn. Biden admin reroutes billions in emergency stockpile, Covid funds to border crunch. Politico. https://www.politico.com/news/2021/05/15/hhs-covid-stockpile-money-border-migrants-488427. May 15, 2021.
- U.S. Department of Health and Human Services. Fact Sheet: U.S. Department of Health and Human Services Response to the Monkeypox Outbreak. <u>https://www.hhs.gov/about/news/2022/07/21/fact-sheet-us-department-of-health-and-humanservices-response-to-the-monkeypox-outbreak.html</u>. September 28, 2022.
- Bavarian Nordic Receives U.S. and EU Approvals of its Fill and Finish Vaccine Manufacturing Facility <u>https://www.globenewswire.com/en/news-release/2022/07/27/2487043/0/en/Bavarian-Nordic-Receives-U-S-and-EU-Approvals-of-its-Fill-and-Finish-Vaccine-Manufacturing-Facility.html</u>. September 28, 2022.
- Food and Drug Administration. Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply. <u>https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-authorizes-emergency-usejynneos-vaccine-increase-vaccine-supply</u>. August 9, 2022.
- Lia DeGroot. HHS Doles Out \$11 Million For U.S.-Based Monkeypox Vax Production. Inside Health Policy. <u>https://insidehealthpolicy.com/daily-news/hhs-doles-out-11-million-us-based-monkeypox-vax-production</u>. August 29, 2022.
- American Medical Association. Comment Letter to U.S. Senate. <u>https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2022-2-4-Letter-to-Senate-HELP-re-PREVENT-Act-v3.pdf</u>. February 4, 2022.

APPENDIX 1 - ASHP/University of Utah Drug Information Service Drug Shortage Data



Figure 1. National Drug Shortages: New Shortages by Year: January 2001 to June 30, 2022

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 June 30, 2022, % Injectable

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.





Note: Each point represents the number of active shortages at the end of each quarter. University of Utah Drug Information Service Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

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Figure 4. National Drug Shortages: Active Shortages Top 5 Drug Classes

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

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.

Active Shortages June 30, 2022

Figure 6. National Drug Shortages: Reasons for Shortages as Reported by Manufacturers During UUDIS Investigation - 2021





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

APPENDIX 2

Breakdown of CDER's and CBER's Shortage Numbers, CY 2021

	CDER	CBFR
	CDER	CDER
New Shortages	38	3
Prevented Shortages	303	14
Ongoing Shortages	79	4
Notifications	744	33
No. of Manufacturers Notifying	98	23
ACTIONS TAKEN TO MITIGATE SHORTAGES		
Regulatory Flexibility and Discretion	97	0
Expedited Reviews	260	14*
Expedited Inspections	29	0

* This number includes expedited reviews for eight biologics license application (BLA)/BLA supplements and six lot-release submissions for CBER-regulated products.

2. CLIMATE CHANGE AND HUMAN HEALTH

Reference committee hearing: see report of Reference Committee K.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED See Policy TBD

The Council on Science and Public Health initiated this report due to the significant public health threat that climate change represents and the impact on the health of patients, with marginalized populations expected to be disproportionately impacted. The Council's last update on climate change was CSAPH Report 3-I-08, "Global Climate Change and Human Health."

The Council's 2008 report recognized that ongoing adverse global climate change is widely accepted by the majority of scientists, climatologists, and meteorologists, and human activity is influencing the rate and extent of this process. The report noted that the extent of climate change will depend on many factors, most notably, changes in global greenhouse gas (GHG) emissions. Anthropogenic contributions to global climate change exist, and the International Panel on Climate Change (IPCC), as well as many other reports, make a compelling case for linkage between these events. The report concluded the potential exists for devastating events with serious health implications, including extreme heat and cold events, flooding and droughts, increases in vectors carrying infectious diseases, and greater air pollution. Furthermore, the report noted the health effects from these events should be of concern to the medical community and require action. The report called on the health care community to advocate for public health policies that recognize and mitigate climate risk and strengthen health services, as well as improve communication and coordination at regional and international levels.

While the American Medical Association (AMA) House of Delegates (HOD) has adopted numerous policies on climate changes since 2008, the Council initiated this report with acknowledgement that an update on this topic is long overdue. There is growing recognition of the impacts of climate change on health, with record-breaking heat waves, wildfires, droughts, and devastating floods impacting our patients and our communities and a limited window to act. We acknowledge that additional reports on the topics of climate mitigation and adaptation will be necessary but have decided to focus this report on the health effects of climate change and decarbonization. We also want to recognize that the AMA Board of Trustees (BOT) is working on a strategic plan on climate change, which will be presented to the HOD at the 2023 Annual Meeting. The BOT will also consider Resolution 605-A-22, which called for the AMA to establish a climate crisis campaign, determine high-yield advocacy and leadership opportunities, and centralize our AMA's efforts towards environmental justice and an equitable transition to a net-zero carbon neutral society. We hope that this report informs the strategy being developed by the BOT.

EXISTING AMA POLICY

In June 2022, the AMA declared climate change a public health crisis that threatens the health and well-being of all individuals and called on the AMA to protect patients by advocating for policies that: (a) limit global warming to no more than 1.5 degrees Celsius, (b) reduce US greenhouse gas emissions aimed at carbon neutrality by 2050, and (c) support rapid implementation and incentivization of clean energy solutions and significant investments in climate resilience through a climate justice lens. The policy also called on the AMA to develop a strategic plan for how we will enact our climate change policies including advocacy priorities and strategies to decarbonize physician practices and the health sector with report back to the House of Delegates at the 2023 Annual Meeting. (D-135.966, "Declaring Climate Change a Public Health Crisis")

AMA policy supports scientific findings that the Earth is undergoing adverse climate change which will create conditions that affect public health and will have a disproportionate impact on vulnerable populations, including children, the elderly, and the poor (H-135.938, "Global Climate Change and Human Health"). Accordingly, our AMA supports increased climate change education so physicians may understand the health risks that climate change poses and counsel patients on how to protect themselves from those health risks (H-135.919, "Climate Change Education Across the Medical Education Continuum"). It is the policy of the AMA to encourage physicians to implement programs in their practices that promote environmental sustainability and communicate these practices to their patients and their community (H-135.923, "AMA Advocacy for Environmental Sustainability and Climate"). Additionally,

the AMA will urge physicians to become spokespersons for environmental stewardship (H-135.969, "Environmental Health Programs").

With respect to air pollution and GHG reduction, the AMA urges the enactment of comprehensive legislation to address adverse health effects that are the product of air pollution (H-135.984, "Federal Clean Air Legislation"). The AMA encourages the US EPA to use its authority to regulate GHG emissions and limit carbon dioxide emissions. The AMA believes the coordinated efforts of the government along with industry and the public is the best way to minimize air pollution (H-135.999, "Federal Programs").

METHODS

Sentinel reports on climate, global climate change, and human health were reviewed including the Intergovernmental Panel on Climate Change (IPCC) assessment reports, *Lancet* Countdown on Health and Climate Change reports, reports from the World Health Organization (WHO), the Environmental Protection Agency (EPA), and the National Oceanic and Atmospheric Administration (NOAA).

English language articles were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2012 to June 2022 using the search terms: "climate change and health," "climate crisis and health," "decarbonization and health," and "climate change and equity." Additional articles were also identified by manual review of the reference lists of pertinent publications. Websites managed by federal agencies, applicable professional organizations, and foundations were reviewed for relevant information.

DEFINITIONS

Adaptation is "taking action to prepare for and adjust to both the current and projected impacts of climate change."1

Climate change is "a long-term change in the average weather patterns that have come to define Earth's local, regional and global climates."²

Decarbonization means "switching from the use of fossil fuels such as coal, natural gas or oil to carbon-free and renewable energy sources."

Global warming is "the long-term heating of Earth's surface observed since the pre-industrial period (between 1850 and 1900) due to human activities, primarily fossil fuel burning, which increases heat-trapping greenhouse gas levels in Earth's atmosphere. This term is not interchangeable with the term "climate change."³

Greenhouse gases (GHGs) are gases that trap heat in the atmosphere.⁴ GHGs emitted in the US include carbon dioxide (79 percent), methane (11 percent), nitrous oxide (7 percent), and fluorinated gases (3 percent).⁵

THE INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE (IPCC)

The IPCC is the United Nations body for assessing the science related to climate change. Limiting global warming to no more than 2 degrees Celsius above pre-industrial levels was the *de facto* target for global policymakers at the UN's 2010 climate conference in Cancun, Mexico. In 2015, scientists warned that the 2 degrees Celsius limit was not adequate for avoiding some of the more severe impacts of climate change and reducing the limit to 1.5 degrees Celsius would be preferable.⁶

The Paris Agreement

The Paris Agreement is a legally binding international treaty on climate change. It was adopted by 196 Parties at the UN Climate Change Conference of the Parties (COP) 21, on December 12, 2015, and entered into force on November 4, 2016.⁷ Its goal is to limit global warming to well below 2, preferably to 1.5 degrees Celsius, compared to preindustrial levels. To achieve this goal, countries aim to reach global peaking of greenhouse gas emissions as soon as possible to achieve a climate neutral world by mid-century. The Paris Agreement is important because for the first time, a binding agreement brings all nations into a common cause to undertake ambitious efforts to combat climate change and adapt to its effects.

Special Report on Global Warming of 1.5°C

In 2018, the IPCC issued a special report on the impacts of global warming of 1.5 degrees Celsius above pre-industrial levels and related GHG emission pathways contained in the Paris Agreement.⁸ The report concluded the global climate has changed relative to the pre-industrial period, and there is evidence that these changes have had impacts on organisms and ecosystems, as well as on human systems and well-being.⁹ Human activities are estimated to have caused approximately 1.0 degree Celsius of global warming above pre-industrial levels, with a likely range of 0.8 to 1.2 degrees Celsius.¹⁰ Risks to natural and human systems are expected to be lower at 1.5 degrees Celsius than at 2 degrees Celsius of global warming. This is true for heat-related morbidity and mortality and for ozone-related mortality if emissions needed for ozone formation remain high. Global warming is likely to reach 1.5 degree Celsius between 2030 and 2052 if it continues to increase at the current rate.¹¹ The report finds that limiting global warming to 1.5 degrees Celsius would require "rapid and far-reaching" transitions in land, energy, industry, buildings, transport, and cities.¹² Global net human-caused emissions of carbon dioxide would need to fall by about 45 percent from 2010 levels by 2030, reaching 'net zero' around 2050. The report also recognized that many of the impacts of warming will fall disproportionately on the poor and vulnerable.

The Sixth Assessment Cycle

To date the IPCC has released three reports during this cycle. The Synthesis Report for this cycle is scheduled to be released in late 2022 or early 2023. Below are the high-level findings from the Sixth Assessment reports.

<u>The Physical Science Basis¹³ (2021)</u>. It is unequivocal that human influence has warmed the atmosphere, ocean and land. The scale of recent changes across the climate system as a whole are unprecedented over many centuries to many thousands of years. Human-induced climate change is already affecting many weather and climate extremes in every region across the globe. Evidence of observed changes in extremes such as heatwaves, heavy precipitation, droughts, and tropical cyclones, and their attribution to human influence, has strengthened. Global warming of 1.5 and 2 degrees Celsius will be exceeded during the 21st century unless deep reductions in GHG emissions occur in the coming decades.

<u>Mitigation of Climate Change¹⁴ (2022)</u>. Total net anthropogenic GHG emissions have continued to rise during the period 2010–2019, and average annual GHG emissions during 2010–2019 were higher than in any previous decade, but the rate of growth between 2010 and 2019 was lower than that between 2000 and 2009. Net anthropogenic GHG emissions have increased since 2010 across all major sectors globally. An increasing share of emissions can be attributed to urban areas. The unit costs of several low-emission technologies (solar energy, wind energy, and lithium-ion batteries) have decreased, but innovation has lagged in developing countries due to weaker enabling conditions.

Global GHG emissions are projected to peak between 2020 and 2025 in global modelled pathways that limit warming to 1.5 degrees Celsius with no or limited overshoot and in those that limit warming to 2 degrees Celsius. Global net zero CO2 emissions are reached in the early 2050s in modelled pathways that limit warming to 1.5°C (>50%) with no or limited overshoot, and around the early 2070s in modelled pathways that limit warming to 2°C (>67%). Reaching and sustaining global net zero GHG emissions results in a gradual decline in warming. Reducing GHG emissions across the full energy sector requires major transitions, including a substantial reduction in overall fossil fuel use, the deployment of low-emission energy sources, switching to alternative energy carriers, and energy efficiency and conservation. The deployment of carbon dioxide removal (CDR) to counterbalance hard-to-abate residual emissions is unavoidable if net zero CO2 or GHG emissions are to be achieved.

<u>Impacts</u>, <u>Adaptation</u>, and <u>Vulnerability</u>¹⁵ (2022). Climate change is affecting nature, people's lives and infrastructure and its dangerous and pervasive impacts are increasingly evident in every region of the world. These impacts are hindering efforts to meet basic human needs and they threaten sustainable development. This report found that the extent and magnitude of climate change impacts are larger than estimated in previous assessments. They are causing severe and widespread disruption in nature and in society; reducing our ability to grow nutritious food or provide enough clean drinking water, thus affecting people's health and well-being and damaging livelihoods.

Many species are reaching limits in their ability to adapt to climate change, and those that cannot adjust or move fast enough are at risk of extinction. We see a lengthening wildfire season and increases in the area burned. Roughly half of the world's population experiences severe water shortages at some point during the year, in part due to climate change and extreme events such as flooding and droughts. Drought conditions have become more frequent in many regions, negatively affecting agriculture and energy production from hydroelectric power plants. Globally, climate change is increasingly causing injuries, illness, malnutrition, threats to physical and mental health and well-being, and even deaths. Climate change impacts are expected to intensify with additional warming.

Climate change risks and impacts can be reduced, within limits, if humans and nature adapt to the changing conditions. The scale and scope of actions to reduce climate risks have increased worldwide. However, there are large gaps between ongoing efforts and adaptation needed to cope with current levels of warming. Poverty and inequality present significant adaptation limits, resulting in unavoidable impacts for vulnerable groups, including women, young people, the elderly, ethnic and religious minorities, indigenous people, and refugees.

HEALTH EFFECTS OF CLIMATE CHANGE

Impacts from climate change on extreme weather, air quality, and the transmission of disease increasingly threaten the health and well-being of people in the U.S., particularly populations that at increased risk.¹⁶ The health effects of climate change include increased allergies, asthma, respiratory and cardiovascular disease; injuries and premature deaths related to extreme weather events; heat-related deaths due to continued warming; changes in the prevalence and geographical distribution of food- and water-borne illnesses and other infectious diseases, and threats to mental health.¹ (See Figure 1.) While not discussed in detail in this report, it is important to recognize that climate change can cause or exacerbate resource scarcity, which may result in conflict or migration of populations.¹⁷ Individuals most at risk are typically the least able to relocate.¹⁸ The health effects of climate change are outlined in the Council's 2008 report, but as the IPCC reports indicate, the frequency and intensity of extreme weather events will likely increase.

<u>Allergies and Respiratory Health</u>. The combustion of fossil fuels is a major source of air pollution and cause of climate change. Fossil fuels release airborne fine particulate matter and ground-level ozone. Poor air quality contributes to a range of non-communicable diseases, including cardiovascular and respiratory disease.¹⁹ It is estimated that more than 8 million people died in 2018 from fossil fuel pollution, significantly higher than previous estimates—meaning that air pollution from burning fossil fuels was responsible for about 1 in 5 deaths worldwide.²⁰ Furthermore, hotter temperatures and lack of rainfall increase the risk of drought and wildfires, both of which create particle pollution.²¹ As temperatures rise, plants produce more pollen, increasing ragweed and other allergens. Warmer temperatures allow allergens to thrive in new regions and for allergy seasons to last longer-^{22,23}

<u>Cardiovascular Disease</u>. Air pollution can exacerbate cardiovascular disease and contribute to the development of the disease. The evidence is particularly strong for outdoor particle pollution exposure. Exposure to PM <2.5 μ m in diameter (PM_{2.5}) over a few hours to weeks can trigger cardiovascular disease–related mortality and nonfatal events; longer-term exposure (increases the risk for cardiovascular mortality to an even greater extent and reduces life expectancy within more highly exposed segments of the population by several months to a few years; reductions in PM levels are associated with decreases in cardiovascular mortality within a time frame as short as a few years.²⁴ Short -and long-term exposure to increased concentrations of PM_{2.5} has been shown to increase hospitalizations for serious cardiovascular events such as coronary syndrome, arrhythmia, heart failure, stroke, and sudden cardiac death, particularly in people with established heart disease.²⁵ Numerous studies have shown that exposure to higher concentrations of PM_{2.5} and some gaseous air pollutants (nitrogen oxides, sulfur dioxide, and ozone) can also result in arterial hypertension and increased blood pressure.²⁶ Extreme heat also impacts heart health. A recent study showed 600-700 additional deaths from cardiovascular disease annually over a decade-long period in the U.S.²⁷ The spike in deaths during heat waves was most pronounced in men and non-Hispanic Black adults.²⁸

Agriculture and Food Security. The agriculture sector is responsible for 11 percent of U.S. GHG emissions, which come from livestock, agricultural soils, and rice production.²⁹ GHG emissions from agriculture have increased by 6 percent since 1990, largely driven by a 62 percent growth in combined CH₄ and N₂O emissions from livestock manure management systems.³⁰ Research indicates that shifts towards sustainable diets could lead to co-benefits, such as minimizing GHG emissions and land use, reducing the environmental footprint, aiding in climate change mitigation, and improving population health.³¹ This is possible by reducing reliance on red meat consumption and prioritizing plant-based foods and other healthier alternatives, which can reduce chronic disease risk. Climate change is also expected to threaten food production, food prices, and distribution systems. Crop yields are predicted to decline due to changes in rainfall, severe weather events, and increasing competition from weeds and pests.³² Prices are expected to rise in response to declining food production leading to food insecurity and a reliance on foods of poor nutrient quality.

<u>Vector-borne diseases</u>. Climatic hazards have enhanced specific aspects of pathogens, including improved climate suitability for reproduction, acceleration of the life cycle, increasing seasons/length of likely exposure, enhancing pathogen-vector interactions (for example, by shortening incubations) and increasing virulence. Between 2004 and 2018, the number of reported illnesses from mosquito, tick, and flea bites more than doubled, with more than 760,000 cases reported in the United States^{33,36}Nine new germs spread by mosquitoes and ticks were discovered or introduced into the United States during this period.³⁴ Warming had positive effects on mosquito population development, survival, biting rates and viral replication, increasing the transmission efficiency of West Nile virus.³⁵ Global mobility, urbanization and climate change is also major driver of the increase in the number of dengue virus infections, which have doubled every decade since 1990.^{36,37} Further, the geographic ranges where ticks spread Lyme disease, anaplasmosis, ehrlichiosis, and spotted fever rickettsiosis have expanded, and experts predict that tickborne diseases will continue to increase and perhaps worsen.³⁸

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<u>Fungi</u>. Rising temperatures have allowed certain disease-causing fungi to spread into new areas that previously were too cold for them to survive. For example, Valley fever, caused by a fungus that lives in the soil in hot and dry areas, has already spread into the Pacific Northwest.³⁹

<u>Water-borne diseases</u>. Ocean warming has accelerated the growth of harmful algal blooms and diseases caused by *Pseudo-nitzschia sp.*, blue green cyano-bacteria, and dinoflagellates.⁴⁰ Ocean warming and heavy precipitation, which reduces coastal water salinity, is predicted to also provide fertile conditions for *Vibrio vulnificus* and *Vibrio cholerae*, this being a leading explanation for Vibriosis outbreaks in areas where this disease is rare.^{41,42} Further, floods and storms are associated with wastewater overflow, leading to the direct and foodborne transmission of noroviruses, hantavirus, hepatitis and *Cryptosporidium*.^{43,44,45}

<u>Zoonotic diseases</u>. Patterns of contact between human and wildlife reservoirs have increased as human populations move into previously unoccupied regions. Changing environmental conditions can also alter species range and density, leading to novel interactions between species, and increase the risk of zoonotic emergence.⁴⁶ Further, habitat disruptions caused by warming, drought, heatwaves, wildfires, storms, floods and land cover change were also associated with bringing pathogens closer to people. Spillovers from viruses (Nipah virus and Ebola), for instance, were associated with wildlife (bats, rodents, and primates) moving over larger areas foraging for limited food resources caused by drought or finding new habitats following wildfires.⁴⁷

<u>Mental Health</u>. The connections between climate change and mental health have been mostly discussed in relation to emergency preparedness and disaster response, particularly in the context of extreme weather events. The mental health effects of disasters may include trauma and shock, post-traumatic stress disorder (PTSD), feelings of abandonment, and anxiety and depression that can lead to suicidal ideation and risky behavior.⁴⁸ Rising temperatures can lead to mood and anxiety disorders, schizophrenia and vascular dementia, and can increase emergency department usage and suicide rates.⁴⁹ Concern about climate change coupled with worry about the future can lead to fear, anger, feelings of powerlessness, exhaustion, stress and sadness, which is being referred to as "eco-anxiety" or "climate anxiety." Climate anxiety and dissatisfaction with government responses are widespread in children and young people and can impact their daily functioning.⁵⁰ Distress about climate change in young people is associated with perceiving that they have no future, that humanity is doomed, and that governments are failing to respond adequately, and with feelings of betrayal and abandonment by governments and adults.⁵¹

DECARBONIZATION

In 2021, President Biden announced the U.S. target was to achieve a 50-52 percent reduction from 2005 levels in economy-wide net GHG pollution by 2030.⁵² Since 1990, gross U.S. GHG emissions have decreased by 7 percent.⁵³ In 2020, U.S. GHG emissions decreased 11 percent compared to 2019 levels primarily from CO₂ emissions from fossil fuel combustion largely due to the COVID-19 pandemic and reductions in travel and economic activity.⁵⁴ However, it is estimated that in 2021 U.S. GHG emissions increased by 6 percent above 2020 levels, returning to pre-pandemic levels.⁵⁵

In efforts to reach the U.S. commitments under the Paris Agreement, the administration signed Executive Order (EO) 14057, "Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability", a multi-faceted approach to addressing climate change.⁵⁶ EO 14057's stated goals include:

- 100 percent carbon emission free electricity by 2030,
- 100 percent of government acquired vehicles to be zero emission vehicles by 2035,

- a net-zero emission federal building portfolio by 2032,
- a 65 percent reduction in overall greenhouse gas emissions by 2030

Other goals without explicit time frames include net-zero emissions of federal procurements, climate resilient infrastructure and a climate focused federal workforce.

The Lancet Countdown on Health and Climate Change

Published annually, the Lancet Countdown is an international, multidisciplinary collaboration, dedicated to monitoring the health profile of climate change, and independently assessing the delivery of commitments made by governments under the Paris Agreement. In 2021, the report indicated that the current global decarbonization commitments are "insufficient to meet Paris Agreement ambitions and would lead to a roughly 2.4 degrees Celsius average global temperature increase by the end of the century."57 To meet the Paris Agreement goals and prevent catastrophic levels of global warming, global GHG emissions must reduce by half within a decade. Emissions are declining too slowly or heading in the wrong direction in the highest emitting sectors. This delay in progress is contributing to millions of deaths each year. At the current pace of reduction, it would take more than 150 years for the energy system to fully decarbonize, and the unequal response between countries is resulting in an uneven realization of the health benefits of a low-carbon transition.⁵⁸ The use of public funds to subsidize fossil fuels is partly responsible for the slow decarbonization rate, with 65 out of 84 countries reviewed still providing an overall subsidy to fossil fuels in 2018.59 Despite years of scientific reporting on the impacts of climate change, efforts to build resilience have been slow and unequal, with countries with low levels of human development index being the least prepared to respond to the changing health profile of climate change and funding remaining a consistent challenge. Even with overwhelming evidence on the health impacts of climate change, countries are not delivering an adaptation response proportionate to the rising risks their populations face.⁶⁰

Role of the Health Sector

The U.S. health care sector is responsible for an estimated 8.5 percent of national carbon emissions. These emissions stem from the operations of health care facilities (scope 1), from both purchased sources of energy, heating, and cooling (scope 2) and from the supply chain of health care goods and services (scope 3). The U.S. health sector accounts for 25 percent of global health sector emissions—the highest proportion attributable to any individual country's health sector.⁶¹ In 2021, as part of the United Nations Climate Change Conference (COP26), 60 countries, including the United States, committed to creating climate-resilient, low-carbon, sustainable health systems, with 20 countries committing to net-zero health care system emissions by 2050. However, while more than 90 percent of Standard & Poor's 500 Companies annually publish sustainability reports, as do many private and nongovernmental entities, the same cannot be said of U.S. health care organizations, despite their commitment to improving health.⁶²

HHS Health Sector Climate Pledge

In 2022, the US Department of Health & Human Services announced a pledge initiative, calling upon the private health care sector to publicly commit to reducing and reversing their carbon footprint.⁶³ The voluntary pledge calls upon signees to reduce emissions by 50 percent by 2030, become net-zero emitters by 2050, complete an inventory of supply chain emissions and to develop climate resilience plans for their facilities and communities. The pledge has been signed by more than 60 major hospital groups, pharmaceutical companies, insurers, and medical associations.⁶⁴

National Academy of Medicine: Action Collaborative on Decarbonizing the U.S. Health Sector

NAM has launched an Action Collaborative on Decarbonizing the U.S. Health Sector. This public–private partnership includes leadership from the federal government, the biomedical and pharmaceutical industries, hospital systems, private payers, and health professions, including the AMA, with the aim to develop and implement a shared action plan for decarbonizing the health sector and strengthening its sustainability and resiliency.⁶⁵

The collaborative is focusing its decarbonization efforts in four areas: (1) working with industry to reduce scope 3 emissions, as well as facilitate coordination with the federal government to accelerate and better enable low-carbon innovations; (2) accelerating climate-sensitive health care delivery and practice, including reducing scope 1 and scope 2 emissions and identifying opportunities for linking performance on sustainability metrics to value-based payment and reimbursement; (3) expanding health professionals' curricula and programming on climate change; and (4)

developing sustainability metrics and indicators for industry and health systems, along with shared plans for public reporting.⁶⁶

Resources on Health System Decarbonization

Health Care Without Harm has released a Road Map that provides a plan to get health care toward zero emissions. By implementing this set of seven high-impact actions, health care can put itself firmly on the road to zero emissions, while helping provide leadership for the rest of the world to travel in the same direction.⁶⁷ The Road Map identifies seven high-impact actions as key to health care decarbonization:

- 1. Power health care with 100 percent clean, renewable electricity.
- 2. Invest in zero emissions buildings and infrastructure.
- 3. Transition to zero emissions, sustainable travel, and transport.
- 4. Provide healthy, sustainably grown food and support climate resilient agriculture.
- 5. Incentivize and produce low-carbon pharmaceuticals.
- 6. Implement circular health care and sustainable health care waste management.
- 7. Establish greater health system effectiveness.

The UK's National Health Service (NHS) is the world's first health care system to commit to achieve net-zero carbon emissions. Its Greener NHS plan contains critical lessons for the U.S. health system.⁶⁸ The NHS has taken action in the following areas:

- Developing a framework to evaluate the carbon reduction associated with new models of care under consideration.
- Working with suppliers to ensure they meet or exceed the NHS commitment on net-zero emissions before the end of the decade, with new procurement from April 2022 onward required to consider net zero as part of the purchasing process.
- Shifting to using zero-emission vehicles, including production of the world's first zero-emission ambulance.
- Ensuring that digital transformation of health care aligns with the goal of becoming a net-zero health service, investing in innovations to support that goal, and setting up a scanning mechanism to identify future pipeline innovations.
- Supporting the construction of 40 new net-zero hospitals as part of the government's health infrastructure plan, which includes a new net-zero carbon hospital standard.
- Completing a \$60 million LED lighting replacement program that will improve patient comfort and save money.
- Making health care systems more resilient to enable them to withstand or adapt to the demands of future climate events, such as floods and extreme temperatures.
- Appointing a new chief sustainability officer to lead the national program and report regularly to the national board; ensuring that every NHS organization has a board-level net-zero lead and a green plan; and supporting an update to the NHS constitution to include the response to climate change as a core principle.

To support healthcare organizations in advancing toward their decarbonization commitments, the Agency for Healthcare Research and Quality (AHRQ) contracted with the Institute for Healthcare Improvement to develop a primer that offers guidance on high-priority measures and strategies for health care organizations to reduce their carbon footprint.⁶⁹ The recommendations are intended to inform organizations beginning their journey in measuring and reducing GHG emissions. The primer describes six domains contributing to GHG emissions in health care: building energy, transportation, anesthetic gas, pharmaceuticals and chemicals, medical devices and supplies, and food. To meaningfully track and reduce GHG emissions, the primer recommends health care organizations should use the Greenhouse Gas Protocol (GHGP) framework, a globally recognized standard for quantifying and reporting on emissions.

U.S. Securities and Exchange Commission (SEC) and Decarbonization

The SEC is expected to finalize a rule requiring publicly traded companies to disclose climate-related risks.⁷⁰ The proposed rules also would require a registrant to disclose information about its direct GHG emissions (Scope 1) and indirect emissions from purchased electricity or other forms of energy (Scope 2). In addition, a registrant would be required to disclose GHG emissions from upstream and downstream activities in its value chain (Scope 3), if material or if the registrant has set a GHG emissions target or goal that includes Scope 3 emissions. These proposals for GHG

emissions disclosures would provide investors with decision-useful information to assess a registrant's exposure to, and management of, climate-related risks, and in particular transition risks.

EPA AUTHORITY

The Clean Air Act is the law that defines the EPA's authority and responsibility to regulate air pollutants. In 2015, the Obama Administration's Clean Power Plan (CPP) established guidelines for to cut power-plant emissions and instructed the states to submit their plans by 2018 and then gave them until 2030 to meet their goals. The CPP relied on section 7411 of the Clean Air Act to enforce guidelines on power plants. In 2019, the Trump Administration issued its Affordable Clean Energy (ACE) Rule which eliminated the guidelines set by the Clean Power Plan. However, the ACE rule was vacated by the U.S. Court of Appeals. As a result, petitioners challenged the EPA's authority to broadly regulate GHG emissions. In a recent Supreme Court decision, *West Virginia v. EPA*, the Court held Congress did not grant the EPA, under the Clean Air Act, the authority to devise emissions caps based on the generation shifting approach the agency took in the Clean Power Plan (CPP). This decision limited the EPA's ability to reduce pollution from power plants.

FEDERAL LEGISLATION

In August 2022, Congress passed H.R. 5376, also known as the Inflation Reduction Act of 2022 (IRA). The IRA authorized spending of \$369 billion over the next ten years, with much targeted towards environmental policies. According to the Department of Energy, these policies are anticipated to cut domestic greenhouse gas emissions by up to 40 percent by 2030.⁷¹ Several of the programs contained in the IRA are targeted at reducing or reimbursing the upfront investments required to convert to more environmentally friendly technology. For example, the IRA contains tax credits or reimbursements for electric vehicle purchases, households that install rooftop solar panels or heat pumps, and a new Advanced Industrial Facilities Deployment Program to provide financial assistance for facilities looking to modernize. Other key elements are investments in the domestic manufacturing workforce to promote green technology production within the United States.

In addition to monetary investments, the IRA also contains important policy changes, particularly around the powers conferred to the EPA. While the IRA does not abrogate the holdings of *West Virginia v. EPA*, it does provide direct funding to the EPA for seven programs to reduce GHG, and it explicitly defines GHG as carbon dioxide, hydrofluorocarbons, methane, nitrous oxide, perfluorocarbons, and sulfur hexafluoride.⁷² These changes are expected to strengthen the agency's ability to mount a legal defense against challenges similar to those levied in *West Virginia v. EPA*.

The bill also includes tax credits for carbon capture and sequestration, which could extend the life of coal plants and make it harder to reach critical targets for clean power. The bill requires the federal government to offer parts of the Gulf of Mexico and Alaska's Cook Inlet for oil and gas development. It also requires additional oil and gas leasing for new wind and solar projects to be approved. As a part of the compromise, negotiators are expected to put forth a separate bill on oil and gas "permitting reform" that could weaken environmental protections under the National Environmental Policy Act.

STATE AND LOCAL ACTIONS

At the state level, many of the most impactful state policies are enacted by coalitions of multiple states. For example, California has been allowed to institute stricter tailpipe emission standards since obtaining a Clean Air Act waiver in 1970, and other states are allowed to adopt California's standards. As of 2019, 17 states and the District of Columbia, representing approximately 40 percent of light duty vehicle sales in the United States, utilize California's low-emission vehicle emission regulations.⁷³ As such, this informal coalition of states places significant market pressure on car manufacturers to simply have *all* new vehicles meet California emission standards rather than dealing with the logistical complexity of having two markets with two different sets of regulations in the United States.⁷⁴

Similarly, when the United States initially withdrew from the Paris Agreement, 24 states and 2 territories representing approximately 50 percent of the United States population formed the United States Climate Alliance pledging to meet the US's Paris Agreement goals under the Clean Power Plan. Other important state coalitions include the Regional Greenhouse Gas Initiative, the Western Climate Initiative, Inc., and the Midwestern Greenhouse Gas Reduction Accord which serve as major "cap-and-trade" markets for their respective regions.

Other notable state-level actions in recent years include California's Plastic Pollution Prevention and Packaging Producer Responsibility Act (requiring all packaging in the state to be recyclable or compostable by 2032), Illinois' Climate and Equitable Jobs Act (requiring 100% renewable energy by 2050), and Wisconsin's Office of Sustainability and Clean Energy (100% carbon-free electricity by 2050).

As of writing, 35 of the 50 largest cities in the United States have published local climate action plans.⁷⁵ Similar to states, local governments and cities often tackle climate change through coalitions such as Climate Mayors, a collection of 470 mayors representing approximately 74 million Americans committed to building political will for climate change policy. Many municipal climate plans echo those seen at the federal and state levels aiming to reduce greenhouse gas emissions, but they also provide insight into the unique issues facing different geographies. For example, the city of Miami has invested \$400 million into the Miami Forever bond to fund projects addressing sealevel rise and flood prevention,⁷⁶ and the city of Ann Arbor implemented the 10,000 Trees Initiative to give away free trees and rebuild the city's canopy.⁷⁷

AMA ACTIONS

Medical Society Consortium on Climate and Health (MSCCH)

The AMA is a member of the MSCCH. The Consortium works to facilitate the medical community's awarenessraising efforts, by bringing together associations representing over 600,000 clinical practitioners to carry three simple messages:

- Climate change is harming Americans today and these harms will increase unless we act;
- The way to slow or stop these harms is to decrease the use of fossil fuels and increase energy efficiency and use of clean energy sources; and
- These changes in energy choices will improve the quality of our air and water and bring immediate health benefits.

In 2019, the AMA signed on to the "Climate, Health, and Equity: A Policy Action Agenda," which recognizes climate change is a public health emergency and outlines ten policy recommendations to provide a roadmap to develop coordinated strategies for simultaneously tackling climate change, health, and equity.³ The agenda calls out 10 specific policy priorities, including the following:

- 1. Meeting and strengthening greenhouse gas emission reduction commitments and supporting the Paris Agreement.
- 2. Transitioning rapidly away from the use of coal, oil and natural gas to clean, safe, and renewable energy and energy efficiency.
- 3. Emphasizing active transportation in the transition to zero-carbon transportation systems.
- 4. Promoting healthy, sustainable and resilient farms and food systems, forests, and natural lands.
- 5. Ensuring that all U.S. residents have access to safe and affordable drinking water and a sustainable water supply.
- 6. Investing in policies that support a just transition for workers and communities adversely impacted by climate change and the transition to a low-carbon economy.
- 7. Engaging the health sector voice in the call for climate action.
- 8. Incorporating climate solutions into all health care and public health system.
- 9. Building resilient communities in the face of climate change.
- 10. Investing in climate in a way that benefits health, and health in a way that doesn't harm the climate.

In January of 2020, the AMA joined the MSCCH in calling on President Trump to stop our withdrawal from the Paris Climate Agreement. The letter recognizes that climate change is a public health emergency. Rejoining the Paris Climate Agreement is not just about preventing the worst of the devastating health harms climate change will bring. It is also about seizing this public health crisis and turning it into a major public health opportunity.

NAM Action Collaborative on Decarbonizing the Health Sector

The AMA is also a member of the National Academy of Medicine Action Collaborative on Decarbonizing the Health Sector as a member of the Steering Committee and co-lead of the Health Care Delivery Workgroup, which is working toward the following four goals:

- Goal 1: Make the multi-faceted case for health systems and hospitals to minimize their carbon footprints and operate more sustainably
- Goal 2: Identify a set of policy and regulatory barriers preventing progress on decarbonization and resilience from accelerating, and identify solutions
- Goal 3: Identify a core set of sustainability metrics for hospitals and clinical practice
- Goal 4: Develop decarbonization playbooks and best practices for hospitals and health care delivery institutions, leveraging existing frameworks and success stories

AMA Litigation Center

The AMA has long advocated for upholding the Clean Power Plan through amicus briefs and most recently filed such a brief with the American Thoracic Society and dozens of leading medical organizations and public health leaders in *West Virginia v. EPA*. The AMA brief stated the importance of the EPA's authority to regulate carbon dioxide emissions from power plants in order to mitigate the health effects of climate pollutants and help address climate change as a threat to public health.

CONCLUSION

It is now unequivocal that human influence has warmed the atmosphere, ocean and land. The scale of recent changes across the climate system are unprecedented over many centuries to thousands of years. Human-induced climate change is affecting weather and climate extremes in every region across the globe. The extent and magnitude of climate change impacts are larger than previously estimated and they are causing severe and widespread disruption in nature and in society; reducing our ability to grow nutritious food or provide enough clean drinking water, thus affecting people's health and well-being and damaging livelihoods. Limiting global warming to 1.5 degrees Celsius would require "rapid and far-reaching" transitions in land, energy, industry, buildings, transport, and cities.⁷⁸

Impacts from climate change on extreme weather, air quality, and the transmission of disease increasingly threaten the health and well-being of people in the U.S., and it is widely recognized that many of the impacts of warming will disproportionately impact the most vulnerable. The health effects of climate change include increased allergies, asthma, respiratory and cardiovascular disease; injuries and premature deaths related to extreme weather events; heatrelated deaths due to continued warming; changes in the prevalence and geographical distribution of food- and waterborne illnesses and other infectious diseases, and threats to mental health.

To meet the Paris Agreement goals and prevent catastrophic levels of global warming, global GHG emissions must be reduced by half within a decade. Emissions are declining too slowly or heading in the wrong direction in the highest emitting sectors. This delay in progress is contributing to millions of deaths each year. The U.S. health care sector is responsible for an estimated 8.5 percent of national carbon emissions. These emissions stem from the operations of health care facilities (scope 1), from both purchased sources of energy, heating, and cooling (scope 2) and from the supply chain of health care goods and services (scope 3). The U.S. health sector accounts for 25 percent of global health sector emissions, the highest proportion attributable to any individual country's health sector. Physicians pledge to do no harm; it is time for the health sector to do the same by addressing the climate crisis and protecting public 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 D-135.966, "Declaring Climate Change a Public Health Crisis" be amended by addition to read as follows:
 - 1. Our AMA declares climate change a public health crisis that threatens the health and well-being of all individuals.
 - Our AMA will protect patients by advocating for policies that: (a) limit global warming to no more than 1.5 degrees Celsius, (b) reduce US greenhouse gas emissions aimed at <u>a 50 percent reduction in emissions by 2030 and carbon neutrality by 2050, and (c) support rapid implementation and incentivization of clean energy solutions and significant investments in climate resilience through a climate justice lens. 3. <u>Our AMA</u>
 </u>

consider signing on to the Department of Health and Human Services Health Care Pledge or making a similar commitment to lower its own greenhouse gas emissions. 4. Our AMA encourages the health sector to lead by example in committing to carbon neutrality by 2050. 5. Our AMA will develop a strategic plan for how we will enact our climate change policies including advocacy priorities and strategies to decarbonize physician practices and the health sector with report back to the House of Delegates at the 2023 Annual Meeting.

2. That Policy H-135.938, "Global Climate Change and Human Health" be amended by addition and deletion to read as follows:

Our AMA: 1. Supports the findings of the Intergovernmental Panel on Climate Change's fourth assessment report and concurs with the scientific consensus that the Earth is undergoing adverse global climate change and that anthropogenic contributions are significant. These climate changes <u>have adversely affected the physical and mental health of people. will create conditions that affect public health, with We recognize that minoritized and marginalized populations, children, pregnant people, the elderly, rural communities, and those who are economically disadvantaged will suffer disproportionate impacts harm from climate change populations, including children, the elderly, and the poor.</u>

2. Supports educating the medical community on the potential-adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.

3. (a) Recognizes the importance of physician involvement in policymaking at the state, national, and global level and supports efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and (b) recognizes that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.

4. Encourages physicians to assist in educating patients and the public <u>on the physical and mental health effects</u> <u>of climate change and</u> on environmentally sustainable practices, and to serve as role models for promoting environmental sustainability.

5. Encourages physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently, and that adaptation interventions are equitable and prioritize the needs of the populations most at risk, and that the AMA's Center for Public Health Preparedness and Disaster Response assist in this effort.

6. Supports epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment.

7. Encourages physicians to assess for environmental determinants of health in patient history-taking and encourages the incorporation of assessment for environmental determinants of health in patient history-taking into physician training.

3. That Policy D-150.978, "Sustainable Food" be amended by addition and deletion to read as follows.

Our AMA: (1) supports practices and policies in medical schools, hospitals, and other health care facilities that support and model a healthy and ecologically sustainable food system, which provides food and beverages of naturally high nutritional quality; (2) encourages the development of a healthier food system through supports sustained funding for evidence-based policies and programs to eliminate disparities in healthy food access, particularly for populations vulnerable to food insecurity, through measures such as tax incentive programs, community-level initiatives and federal legislation; and (3) will consider working with other health care and public health organizations to educate the health care community and the public about the importance of healthy and ecologically sustainable food systems.

4. That Policy H-135.977, "Global Climate Change - The "Greenhouse Effect"" be rescinded.

Our AMA: (1) endorses the need for additional research on atmospheric monitoring and climate simulation models as a means of reducing some of the present uncertainties in climate forecasting;

(2) urges Congress to adopt a comprehensive, integrated natural resource and energy utilization policy that will promote more efficient fuel use and energy production;

(3) endorses increased recognition of the importance of nuclear energy's role in the production of electricity;

(4) encourages research and development programs for improving the utilization efficiency and reducing the pollution of fossil fuels; and

(5) encourages humanitarian measures to limit the burgeoning increase in world population.

Figure 1



Source: Centers for Disease Control and Prevention

REFERENCES

- 1. Environmental Protection Agency. Climate Adaptation and EPA's Role. Available at: https://www.epa.gov/climate-adaptation/climate-adaptation-and-epas-
- role#:~:text=Climate%20change%20adaptation%20or%20climate,projected%20impacts%20of%20climate%20change. 2. National Aeronautics and Space Administration. Global Warming vs. Climate Change. Available at:
- https://climate.nasa.gov/global-warming-vs-climate-change/.
- 3. Id.
- 4. Environmental Protection Agency, Overview of Greenhouse Gases. Available at
- https://www.epa.gov/ghgemissions/overview-greenhouse-gases.
- 5. Id.
- 6. United Nations. Report on the structured expert dialogue on the 2013–2015 review. Available at https://unfccc.int/resource/docs/2015/sb/eng/inf01.pdf.
- 7. United Nations. The Paris Agreement. Available at <u>https://unfccc.int/process-and-meetings/the-paris-agreement/the-paris-agreement/the-paris-agreement.</u>
- Intergovernmental Panel on Climate Change (IPCC), 2018: Global Warming of 1.5°C. An IPCC Special Report on the impacts of global warming of 1.5°C above pre-industrial levels and related global greenhouse gas emission pathways, in the context of strengthening the global response to the threat of climate change, sustainable development, and efforts to eradicate poverty. Available at <u>https://www.ipcc.ch/sr15/</u>.
- 9. Id.
- 10. Id.
- 11. Id.
- 12. Id.

13. IPCC. Climate Change 2021: The Physical Science Basis. Contribution of Working Group I to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change. Available at: https://www.ipcc.ch/report/ar6/wg1/.

191

- 14. IPCC. Climate Change 2022: Mitigation of Climate Change. Contribution of Working Group III to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change. Available at https://www.ipcc.ch/report/ar6/wg3/.
- 15. IPCC. Climate Change 2022: Impacts, Adaptation and Vulnerability. Contribution of Working Group II to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change. Available at https://www.ipcc.ch/report/ar6/wg2.
- 16, U.S. Global Climate Change Research Program, 2018: Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II [Reidmiller, D.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, K.L.M. Lewis, T.K. Maycock, and B.C. Stewart (eds.)]. U.S. Global Change Research Program, Washington, DC, USA, 1515 pp. doi: 10.7930/NCA4.2018.
- The White House. Report on the Impact of Climate Change on Migration. October 2021. Available at https://www.whitehouse.gov/wp-content/uploads/2021/10/Report-on-the-Impact-of-Climate-Change-on-Migration.pdf.
- 18. Id.
- 19. Schraufnagel et al., 2019. Air pollution and noncommunicable diseases: a review by the forum of international respiratory societies' environmental committee, part 2: air pollution and organ systems. Chest, 155 (2019), pp. 417-426.
- 20. Vohra K. et al. Global mortality from outdoor fine particle pollution generated by fossil fuel combustion: Results from GEOS-Chem. *Environmental Research*, Volume 195, April 2021, 110754.
- 21. American Lung Association. Climate Change and Air Pollution. Available at <u>https://www.lung.org/clean-air/climate-change/climate-change-air-pollution</u>.
- 22.. American Lung Association. Climate Change and Air Pollution. Available at https://www.lung.org/clean-air/climate-change/climate-change-air-pollution.
- Poole, Jill A. et al. Impact of weather and climate change with indoor and outdoor air quality in asthma: A Work Group Report of the AAAAI Environmental Exposure and Respiratory Health Committee Journal of Allergy and Clinical Immunology, Volume 143, Issue 5, 1702 – 1710.
- Brook RD et al. American Heart Association Council on Epidemiology and Prevention, Council on the Kidney in Cardiovascular Disease, and Council on Nutrition, Physical Activity and Metabolism. Circulation 2010 Jun; 121(21):2331-2378.
- 25. Environmental Protection Agency. Air Pollution and Cardiovascular Disease Basics. Available at: <u>https://www.epa.gov/air-research/air-pollution-and-cardiovascular-disease-basics</u>.
- 26. Konduracka, E., Rostoff, P. Links between chronic exposure to outdoor air pollution and cardiovascular diseases: a review. *Environ Chem Lett* (2022). https://doi.org/10.1007/s10311-022-01450-9.
- American College of Cardoliolgy. As Temperatures Spike, So Do Deaths from Heart Disease. Available at <u>https://www.acc.org/About-ACC/Press-Releases/2022/03/22/20/06/As-Temperatures-Spike-So-Do-Deaths-from-Heart-Disease</u>. May 23, 2022.
- 28. Id.
- 29. Environmental Protection Agency. Sources of Greenhouse Gas Emissions. Available at
- https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions.
- 30. Id.
- 31. Laine J, Huybrechts I, Gunter M, Ferrari P, Weiderpass E, Tsilidis K, Dagfinn A, Schulze M, Bergmann M, Temme E, Boer JMA, Agnoli C, Ericson U, Stubbendorff A, Ibsen DB, Dahm CC, Deschasaux M, Touvier M, Kesse-Guyot E, Sánchez M-J, Barranco MR, Tong TYN, Papier K, Knuppel A, Boutron-Ruault M-C, Mancini F, Severi G, Srour B, Kühn T, Masala G, Agudo A, Skeie G, Rylander C, Sandanger TM, Riboli E, Vineis Pet al., 2021, <u>Co-benefits from sustainable dietary shifts</u> for population and environmental health: an assessment from a large European cohort study, *The Lancet Planetary Health*, Vol: 5, Pages: e786-e796, ISSN: 2542-5196
- 32. Centers for Disease Control and Prevention. Climate and Health: Food Security. Available at https://www.cdc.gov/climateandhealth/effects/food_security.htm
- Rosenberg R, Lindsey et al. (2018). Vital Signs: Trends in Reported Vectorborne Disease Cases United States and Territories, 2004–2016. MMWR Morb Mortal Wkly Rep. 67:496–501. http://dx.doi.org/10.15585/mmwr.mm6717e1
- 34. Centers for Disease Control and Prevention. Vital Signs. Illnesses on the rise from mosquito, tick, and flea bites. https://www.cdc.gov/vitalsigns/vector-borne/index.html. November 28, 2018.
- 35. El-Sayed, A. and Kamel, M. (2020). Climatic changes and their role in emergence and re-emergence of diseases. Environ. Sci. Pollut. Res. 27, 22336–22352. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7187803/
- 36. Iwamura T, Guzman-Holst A, Murray KA. (2020) Accelerating invasion potential of disease vector Aedes aegypti under climate change. Nat Commun. 11: 2130. https://pubmed.ncbi.nlm.nih.gov/32358588/.
- 37. Romanello, Marina., *et al.*(2021). The 2021 report of the Lancet Countdown on health and climate change: code red for a healthy future. Lancet. 398: 1619–62. https://doi.org/10.1016/ S0140-6736(21)01787-6.
- 38. Centers for Disease Control (CDC). 2022. Climate change and infectious diseases. Available at: https://www.cdc.gov/ncezid/what-we-do/climate-change-and-infectious-diseases/index.html.
- 39. Nnadi NE, Carter DA (2021) Climate change and the emergence of fungal pathogens. PLoS Pathog 17(4): e1009503. https://doi.org/10.1371/journal.ppat.1009503.
- 40. Ruszkiewicz, J. A. *et al.* (2019). Brain diseases in changing climate. Environ. Res. 177:108637. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6717544/.
- 41. Burge, C. A. *et al.* (2014). Climate Change influences on marine infectious diseases: implications for management and society. Ann. Rev. Mar. Sci. 6: 249–277. https://doi.org/10.1146/annurev-marine-010213-135029

- Herrador, B. R. G. *et al.* (2015). Analytical studies assessing the association between extreme precipitation or temperature and drinking water-related waterborne infections: a review. Environ. Health 14:29. https://pubmed.ncbi.nlm.nih.gov/25885050/.
 43Patz, J. A., Engelberg, D. and Last, J. (2000). The effects of changing weather on public health. Ann. Rev. Public Health
- 21: 271–307. https://pubmed.ncbi.nlm.nih.gov/10884955/.
 44. Yavarian, J., Shafiei-Jandaghi, N. Z. and Mokhtari-Azad, T. (2019). Possible viral infections in flood disasters: a review
- considering 2019 spring floods in Iran. Iran. J. Microbiol. 11: 85-89. https://doi.org/10.18502/ijm.v11i2.1066. 45. Mora, Camilo., *et al.* (2022). Over half of known human pathogenic diseases can be aggravated by climate change. Nature
- 45. Mora, Camilo., *et al.* (2022). Over half of known human pathogenic diseases can be aggravated by climate change. Nature Climate Change. https://doi.org/10.1038/s41558-022-01426-1.
- 46. Carlson, C. J. et al. (2022). Climate change will drive novel cross- species viral transmission. Nature. 607:555-562. https://www.nature.com/articles/s41586-022-04788.
- Baker E, Rachel *et al.*, (2022). Infectious disease in an era of global change. Nature Reviews. 20: 193-205. https://doi.org/10.1038/s41579-021-00639- z.
- Clayton, S., Manning, C. M., Speiser, M., & Hill, A. N. (2021). Mental Health and Our Changing Climate: Impacts, Inequities, Responses. Washington, D.C.: American Psychological Association, and ecoAmerica.
- 49. Id.
- 50. Hickman C. et al. Climate anxiety in children and young people and their beliefs about government responses to climate change: a global survey. The Lancet: Planetary Health. 2021. Vol. 5(12):E863-E873.
- 51. Id.
- 52. The White House. Fact Sheet: President Biden Sets 2030 Greenhouse Gas Pollution Reduction Target Aimed at Creating Good-Paying Union Jobs and Securing U.S. Leadership on Clean Energy Technologies. Available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/04/22/fact-sheet-president-biden-sets-2030-greenhouse-gas-pollution-reduction-target-aimed-at-creating-good-paying-union-jobs-and-securing-u-s-leadership-on-clean-energy-technologies/.
- 53. Climate Action Tracker. Available at https://climateactiontracker.org/countries/usa/.
- 54. Environmental Protection Agency. Greenhouse Gas Emissions. Available at: https://www.epa.gov/ghgemissions/sources-greenhouse-gas-
- emissions#:~:text=The%20primary%20sources%20of%20greenhouse,share%20of%20greenhouse%20gas%20emissions. 55. Climate Action Tracker. Available at <u>https://climateactiontracker.org/countries/usa/</u>.
- 56. Federal Register. Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability. December 13, 2021. <u>https://www.federalregister.gov/documents/2021/12/13/2021-27114/catalyzing-clean-energy-industries-and-jobs-through-federal-sustainability</u>
- 57. Romanello, Marina et al. The 2021 report of the Lancet Countdown on health and climate change: code red for a healthy future. The Lancet, Volume 398, Issue 10311, 1619 1662.
- 58. Id.
- 59. Id.
- 60. Id.
- 61. Dzau. V. et al. New England Journal of Medicine. 2022. *Decarbonizing the U.S. Health Sector A Call to Action. NEJM.* Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2115675..
- 62. Senay, E., T. Cort, W. Perkison, J. G. Laestadius, and J. D. Sherman. 2022. What can hospitals learn from the Coca-Cola Company? Health Care Sustainability Reporting. NEJM Catalyst. https://doi.org/10.1056/CAT.21.0362.
- 63. U.S. Department of Health and Human Services Press Office. HHS Launches Pledge Initiative to Mobilize Health Care Sector to Reduce Emissions. US Department of Health & Human Services. April 22, 2022. https://www.hhs.gov/about/news/2022/04/22/hhs-launches-pledge-initiative-mobilize-health-care-sector-reduce-emissions.html
- 64. Id.
- 65. Dzau. V. et al. New England Journal of Medicine. 2022. *Decarbonizing the U.S. Health Sector A Call to Action. NEJM.* Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2115675.
- 66. Id.
- 67. Health Care Without Harm. Global Road Map for Health Care Decarbonization. Available at https://healthcareclimateaction.org/roadmap.
- 68. Emily Hough, Evan D. Gumas, and Shanoor Seervai, *Action to Decarbonize the U.S. Health Care System: Lessons from the U.K. 's National Health Service* (Commonwealth Fund, July 2022). <u>https://doi.org/10.26099/aed1-3n95</u>
- 69. Sampath B, Jensen M, Lenoci-Edwards J, Little K, Singh H, Sherman JD. Reducing Healthcare Carbon Emissions: A Primer on Measures and Actions for Healthcare Organizations to Mitigate Climate Change. (Prepared by Institute for Healthcare Improvement under Contract No. 75Q80122P00007.) AHRQ Publication No. 22-M011. Rockville, MD: Agency for Healthcare Research and Quality; September 2022.
- 70. Federal Register. The Enhancement and Standardization of Climate-Related Disclosures for Investors. April 11, 2022. <u>https://www.federalregister.gov/documents/2022/04/11/2022-06342/the-enhancement-and-standardization-of-climate-related-disclosures-for-investors</u>
- 71. Department of Energy. DOE Projects Monumental Emissions Reduction From Inflation Reduction Act. August 18, 2022. https://www.energy.gov/articles/doe-projects-monumental-emissions-reduction-inflation-reduction-act.
- 72. Jennifer Hijazi. Climate Law Gives Clean Air Act a Legal Boost After Court Rebuke. Bloomberg Law. August 22, 2022. https://news.bloomberglaw.com/environment-and-energy/climate-law-gives-clean-air-act-a-legal-boost-after-court-rebuke.

- 73. California Air Resources Board. States that have Adopted California's Vehicle Standards under Section 177 of the Federal Clean Air Act. December 6, 2021. <u>https://ww2.arb.ca.gov/sites/default/files/2022-01/177_states_12062021_nada_sales.pdf</u>
- Evan Symon. Five Car Makers Back Biden Decision To Allow California's Stricter Auto Emissions. California Globe. June 9, 2022. <u>https://californiaglobe.com/articles/five-car-makers-back-biden-decision-to-allow-californias-stricter-autoemissions/</u>
- 75. Ballotpedia. Climate action plans in the 50 largest cities. February 2022. https://ballotpedia.org/Climate_action_plans_in_the_50 largest_cities
- 76. David Smiley. Miami gets \$200 million to spend on sea rise as voters pass Miami Forever bond. Miami Herald. November 08, 2017. <u>https://www.miamiherald.com/news/politics-government/election/article183336291.html</u>
- Ryan Stanton. Washtenaw County residents can get free trees at upcoming giveaway event. MLive Michigan. August 30, 2021. <u>https://www.mlive.com/news/ann-arbor/2021/08/washtenaw-county-residents-can-get-free-trees-at-upcoming-giveaway-event.html</u>
- 78. IPCC, 2018: Global Warming of 1.5°C. An IPCC Special Report on the impacts of global warming of 1.5°C above preindustrial levels and related global greenhouse gas emission pathways, in the context of strengthening the global response to the threat of climate change, sustainable development, and efforts to eradicate poverty. Available at https://www.ipcc.ch/sr15/.