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Robert F. Kennedy, Jr. Secretary Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Dear Secretary Kennedy,

The Society of Gynecologic Oncology (SGO) congratulates you on your confirmation to lead the Department of Health and Human Services (HHS) and looks forward to working with you to advance care for individuals living with gynecologic cancers.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our more than 3,000 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate to increase public awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our primary mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

Background on Gynecologic Cancers

Gynecologic cancers originate in the female reproductive organs including the cervix, ovaries, uterus, fallopian tubes, vagina, and vulva. The American Cancer Society estimated that in 2025 there will be over 118,920 new cases diagnosed and approximately 34,630 deaths from gynecologic cancers in the United States.¹ The five major types of gynecological cancers include: cervical, ovarian, uterine/endometrial, vaginal, and vulvar.

Uterine/Endometrial Cancer

Uterine or endometrial cancer is cancer of the lining of the uterus, also known as the endometrium. Endometrial cancer is the most common form of cancer of the female reproductive organs. In fact, in 2025, it is estimated there will be 69,120 new cases of uterine cancer diagnosed, and about 13,860 women will die from endometrial cancer.² The average age of women diagnosed is 60, as this cancer primarily affects post-menopausal women. Furthermore, endometrial cancer is one of the few cancers with an increasing incidence and is being diagnosed more frequently in younger women. This is particularly concerning since there

¹ <u>https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf</u>

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²<u>https://www.cancer.org/cancer/types/endometrial-cancer/about/key-statistics.html</u>

is currently no routine screening test for uterine cancer; however, many women have symptoms early in the disease process, including abnormal vaginal bleeding.

Ovarian Cancer

Ovarian cancer develops in the ovary(s) and can spread to other parts of the body. Many people use "ovarian cancer" as an umbrella term to include not only ovarian cancer but also fallopian tube cancer and primary peritoneal cancer.³ Ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system.⁴ Specifically, in 2025, it is estimated that approximately 20,890 people will receive a new diagnosis of ovarian cancer, and about 12,730 people will die from the disease.

Ovarian cancer's symptoms are subtle and often mistaken for other health issues, symptoms include bloating, difficulty eating, abdominal/pelvic pain, and urination frequency. There is no effective screening test for this cancer, which most frequently presents at a late stage. A CT scan or an MRI and a blood test for CA 125, a cancer antigen, are important diagnostic tools but a pathology-based tissue exam is required for diagnosis.

Cervical Cancer

Cervical cancer begins in the cervix, the narrow end of the uterus that forms a canal between the uterus and the vagina.⁵ Approximately 13,360 women in the United States are estimated to be diagnosed with cervical cancer and approximately 4,320 to die of cervical cancer in 2025.⁶ Cervical cancer is caused by Human Papillomavirus, or HPV, and is the only vaccine-preventable gynecologic cancer. It is easy to reduce the risk of cervical cancer by using screening tests such as a Pap test and HPV testing. However, despite the availability of effective screening and an efficacious vaccine, cervical cancer continues to be diagnosed regularly.

Innovation Needed in Gynecologic Cancers

Gynecologic cancers, specifically ovarian and endometrial cancers, pose a significant threat to Americans' health, yet there is a lack of innovative research in these cancers. Notably, despite advancements in many other areas of cancer care, endometrial cancer stands out as one of the few malignancies with rising incidence and mortality rates, as mentioned above. Additionally, an alarming trend in endometrial cancer is how it is linked to obesity.⁷ As rates of obesity rise in the United States and globally, gynecologic oncologists see rising rates of endometrial cancer in younger patients, which further poses problems in treatment options and fertility decisions. Your focus on reducing chronic conditions, including obesity, has the potential to significantly improve the current trends related to this cancer. Furthermore, endometrial cancer mortality is

³ <u>https://www.sgo.org/patient-resources/ovarian-cancer/</u>

⁴ <u>https://www.cancer.org/cancer/ovarian-cancer/about/key-statistics.html</u>

⁵ <u>https://www.foundationforwomenscancer.org/gynecologic-cancers/cancer-types/cervical/</u>

⁶ <u>https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf</u>

⁷ https://pmc.ncbi.nlm.nih.gov/articles/PMC5455320/

now neck-and-neck with that of ovarian cancer, and by 2030, endometrial cancer is projected to surpass colon cancer and become the third most common malignancy diagnosed in women.⁸ However, millions of women are at risk because there is no screening test for this cancer. Developing effective screening methods could drastically shift the trajectory of these diseases by enabling early detection, improving outcomes, and reducing the substantial economic and emotional toll on families. As an example, cervical cancer has decreased significantly in the past 40 years due to effective screening tools, with studies showing that regular screening can reduce cervical cancer incidence and mortality by at least 80 percent.⁹

The SGO encourages you to prioritize innovative research that will progress the development of screening tests for ovarian and endometrial cancer, which will have life-saving consequences for American women. To do this, the National Institutes of Health (NIH) still requires robust funding and support. We respectfully request that any changes made to the agency as part of the current Department of Health and Human Services (HHS) reorganization preserve its expertise and experience in endometrial and all other cancers to support intramural and extramural research as well as support programs to train the next generation of physician-scientists.

Women's Health Research

There is a strong correlation between investments in women's health and economic prosperity. Specifically, investing in women's health research (WHR) leads to better outcomes in women's health, which results in overall economic and societal gains. Looking at the numbers, women constitute nearly 50 percent of the workforce, control 60 percent of wealth, are responsible for 85 percent of consumer spending, and make 80 percent of healthcare decisions in the United States.¹⁰ Yet, according to the National Academies of Science, Engineering, and Medicine (NASEM), only 8.8 percent of NIH grant spending from 2013 to 2023 focused on WHR, and this funding decreased as a share of overall NIH funding over that period.¹¹

This lack of research funding is a huge economic loss for the United States—an estimated \$300 million investment into WHR could yield a \$13 billion economic return, reduced healthcare costs, better quality of life, and years of productivity returned to the global workforce.¹² Increased research funding leads to positive patient outcomes, such as reduced age incidence, reduced disease severity, reduced disease-specific mortality, and increases in quality-adjusted life years and productivity. These improved health outcomes result in positive economic and societal outcomes, such as reduced nursing home costs, increased and long-term workforce

⁸ https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.5578

⁹ <u>https://www.cancer.gov/types/cervical/hp/cervical-screening-pdq</u>

¹⁰ <u>https://thewhamreport.org/</u>

¹¹ <u>https://www.nationalacademies.org/news/2024/12/to-advance-womens-health-research-nih-should-form-new-institute-and-congress-should-appropriate-new-funding-says-</u>

report#:~:text=An%20analysis%20by%20the%20committee,increases%20in%20the%20agency's%20budget.

¹² <u>https://www.weforum.org/stories/2023/01/davos2023-womens-health-rethinking-the-cost-as-an-investment-for-societal-</u>

gain/#:~:text=Investment%20in%20women%20is%20unrivalled,a%20%2413%20billion%20economic%20return.

participation, healthier and better-educated families, and economic gains that will impact more generations to come.¹³

Additionally, investments in WHR also benefit our military service members, our veterans, and our national security. Women are the fastest-growing demographic in the military and Veteran Health Administration (VHA) patient populations,¹⁴ and without dedicated research for diseases and conditions that are more common or only exist in women, these communities will face increasing health burdens, affecting troop readiness and familial well-being.

Ultimately, by investing in WHR we are investing in our economy, society, and national defenses. As HHS and NIH review their research portfolios, we urge you to preserve and make additional investments that will improve the health of women by studying conditions that occur differently or disproportionately or are unique to women, like gynecologic cancers. SGO is eager to collaborate with your team to advance research efforts in women's health, particularly in addressing critical gaps in gynecologic cancer prevention, detection, and treatment. Together, we can prioritize innovative solutions that improve health outcomes for women and our country.

Chemotherapy Shortages

In 2023 and 2024, the United States experienced the worst chemotherapy drug shortage in its history, with 15 indispensable chemotherapy drugs in short supply simultaneously. Some of the most prescribed chemotherapies – carboplatin, cisplatin, methotrexate, fluorouracil, paclitaxel docetaxel, leucovorin, vinblastine, and liposomal doxorubicin – were in shortage. Carboplatin and cisplatin are first-line therapies for ovarian, endometrial, and cervical cancers. Carboplatin serves as a backbone drug for most gynecologic cancer therapies. At the onset of the shortage, the SGO estimated that over 500,000 patients were affected by chemotherapy drug shortages. The American Society of Health-System Pharmacists found that 99% of hospital pharmacists reported shortages, causing 85% to ration treatments and 84% to rely on different dosages.¹⁵

The strain on patients, providers, and pharmacies caused by the drug shortages can be avoided. While the causes of these chemotherapy shortages are multiple and complex, your administration and Congress must act to prevent future shortages. Policies should encourage the manufacture of high-quality generic drugs through resilient supply chains and provide the Food and Drug Administration (FDA) with the authority to require manufacturers to report additional information about shortages.

The SGO has made the following recommendations to Congress and encourages your administration to explore what actions it can take unilaterally:

¹³ <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC4814064/</u>

¹⁴ <u>https://www.womenshealth.va.gov/about-us.asp</u>

¹⁵ <u>https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf</u>

- Support the FDA's quality management maturity (QMM) program: QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. According to the FDA, the root cause for many drug shortages is the absence of incentives for manufacturers to strive for more than simply meeting current good manufacturing practice regulations and to develop mature quality management systems. The FDA Drug Shortages Task Force recommended creating this program for which a pilot was recently completed. The QMM rating system will help incent manufacturers to attain higher levels of QMM at their facilities and should be authorized and funded to ensure it works as envisioned.
- Support the inspection of Risk Management Plans (RMPs) for high-priority essential generic medicines, including rating the strength of the RMP: The FDA already has guidance on RMPs, which are designed to proactively identify, prioritize, and implement strategies to mitigate hazards that can cause supply disruptions, yet drug purchasers lack insight regarding manufacturers' QMM and supply chain practices. A robust RMP would provide drug purchasers with meaningful evaluations of manufacturers' practices so they could purchase drugs from companies that invest in their supply chains. Given the shortages stemming from issues with generic manufacturers, an enhanced program should focus on these manufacturers.
- Provide incentives to realign hospital purchasing practices to promote the purchase of high-quality generic drugs: Currently, hospitals purchase drugs from group purchasing organizations (GPOs), pharmacy benefit managers (PBMs), and entities that provide the lowest prices because there are no incentives for purchasing drugs from more reliable manufacturers at higher prices. The information from the RMPs and QMM programs could be used to inform standards and best practices for contracts with GPOs and PBMs and allow the Centers for Medicare & Medicaid Services (CMS) to establish a voluntary reporting system that would include financial rewards for purchasing drugs from manufacturers with more resilient supply chains. This policy is being considered by the Senate Finance Committee as a potential policy solution.
- Include commonly utilized, life-saving chemotherapy drugs on the FDA Essential Medicine List and empower the Administration of Strategic Preparedness and Response (ASPR) to oversee and respond to critical drug shortages.
- Provide the FDA with additional authorities to require manufacturers to report additional data on shortages, including notifying the FDA when circumstances, such as an increase in demand, are likely to leave the manufacturer unable to meet demand for a drug and providing the FDA with information about the manufacturers of the active pharmaceutical ingredients in their drugs.

SGO understands that FDA's workforce will decrease by approximately 3,500 full-time employees and ASPR will move under the Centers for Disease Control and Prevention (CDC) as part of the HHS reorganization. We urge you to ensure that both entities have the resources and expertise necessary to prevent and respond to future drug shortages. We owe it to all Americans, including cancer patients, to provide timely access to first line therapies.

Improving Medicare Physician Payment

Medicare physician reimbursement has stagnated for the last two decades while physician practices must continue to pay market rate for supplies, equipment, and staff wages. According to an American Medical Association (AMA) analysis of Medicare Trustees data, Medicare physician payment has been reduced by 33% when adjusted for inflation from 2001–2025. The Medicare Physician Fee Schedule (MPFS) does not have a consistent mechanism for updating payments, and the results are clear: payment for Medicare physician services have not kept pace with those delivered outside of the physician office, the consumer price index, or practice costs.

While the MPFS lacks an annual payment update, other Medicare providers' payment systems (i.e., inpatient hospitals, outpatient hospital services, skilled nursing facilities, etc.) include automatic annual updates to payment rates consistent with practice costs. The lack of an annual update for Medicare physician services will impede patient access to physician care and undermines the financial stability of physician practices. Further, the discrepancy between Medicare physician payment and practice costs, combined with existing administrative and financial burden of prior authorization, other utilization management requirements, and quality reporting programs, will lead to greater incentives for market consolidation and dissolve physician practices in rural and underserved areas, further exacerbating health inequities.

For these reasons, the SGO urges you to work with Congress and prioritize the implementation of long-term systemic reforms that preserve patient access to medical services and bring predictability and sustainability to the MPFS. Specifically, we hope you will consider (1) Authorizing an inflationary update to the conversion factor that is equal to the Medicare Economic Index (MEI); and (2) Updating the budget neutrality threshold to \$53 million and then indexing it for inflation every five years. These changes will ensure that Medicare physician payment keeps pace with practice costs associated and protect Medicare beneficiaries' access to care provided by gynecologic oncologists and other physicians.

Administrative Burden and Physician Burnout

In recent years, the HHS, through the Centers for Medicare & Medicaid Services (CMS) prioritized reducing administrative burden by creating the Office of Healthcare Experience and Interoperability (OHEI). One of the OHEI goals to reduce administrative burden by "streamlining administrative health care transactions and set standards for transmitting electronic health information." The OHEI was originally created during the first Trump administration and at the time was called the Office of Burden Reduction and Health Informatics. Our Society supported the creation of this department under the Cut the Red Tape executive order of 2017. During the HHS reorganization process, we encourage you to maintain the OHEI to support physicians and healthcare entities in running their practices efficiently while developing policies that alleviate burden and burnout, ensuring a sustainable physician workforce. The country needs an adequate supply of physicians now more than ever to meet the goals of your initiative to Make America Healthy Again.

We note that the SGO supports the electronic exchange of information between providers and payers to speed the process of prior approvals for surgeries, chemotherapies and other interventions associated with the treatment of gynecologic cancers and wish to see policy implemented that streamlines the prior authorization process. The cancers our member physicians treat are often aggressive, and timely access to care is key to positive outcomes. Delays in care caused by the lack of a prior authorization or a delay in receiving a prior authorization causes undo emotional and potentially physical harm to the patient. Worse than delays in treatment are completely abandoning treatment. An annual physician survey conducted by AMA concluded that 78 percent of physician respondents stated that the prior authorization process sometimes leads to treatment abandonment.¹⁶ This can be particularly devastating to anyone, but particularly those with aggressive cancers. We ask that you continue to provide resources and build programs and processes that address the burden of prior authorization, while maintaining a healthy population.

The SGO supports initiatives that allow physicians to focus on their patients and practice of medicine rather than paperwork. Despite these efforts, more work must be done to reduce the administration burden of the practice of medicine and the resulting burnout. Addressing these issues is a priority of the SGO and necessary to ensure that there is a well-trained physician workforce available to meet the health care needs of the growing Medicare population.

Additionally, we encourage the HHS to address the burdensome, time-consuming, and laden with paperwork prior authorization process. Administrative burden can take many forms for physicians, but the prior authorization process appears to be the leading cause of increased administrative burden and frustration with the health care system and a leading cause of physician burnout.¹⁷ The same AMA survey found that the prior authorization process is time consuming, can cause serious patient adverse events, and increases overall spending to the entire health care system.¹⁸ The survey also found that physicians and their staff spend nearly two full workdays each week on the prior authorization process, time that could have been spent delivering vital patient care. Informal interviews with our members track with these findings and we have found that reducing administrative burden, including supporting policy that streamlines the prior authorization process, will again be one of the top priorities of our organization in the coming year.

The SGO welcomes the opportunity to work with you to address the ongoing challenges posed by prior authorization, particularly as they relate to chemotherapies and other drugs, as well as other policies to improve physician satisfaction with the practice of medicine. Thank you for your consideration of these recommendations as your administration develops your priorities. The SGO stands ready to collaborate with you to improve Americans' health.

¹⁶ 2021 AMA prior authorization (PA) physician survey. <u>https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</u>. Accessed February 7, 2023.

¹⁷ Colligan L, Sinsky C, Goeders L, Schmidt-Bowman M, Tutty M. Sources of physician satisfaction and dissatisfaction and review of administrative tasks in ambulatory practice: A qualitative analysis of physician and staff interviews. October 2016. Available at: ama-assn.org/go/psps.

¹⁸ 2023 AMA Prior Authorization (PA) Physician Survey; <u>https://www.ama-assn.org/system/files/prior-authorization-</u> <u>survey.pdf</u>

Please contact Erika Miller at <u>emiller@dc-crd.com</u> should we be able to provide you with any assistance advancing these goals or if you have any questions.

Sincerely,

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Karen H. Lu, MD President