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Summary of key points:

1. Primary care is a specialty, and one of the critical areas where primary care clinicians specialize is in preventing disease before it starts in an otherwise healthy general population. The USPSTF was established in 1984, under the Reagan administration, as an independent, nonpartisan, expert panel that seeks to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. Our panel is made up of 16 volunteer members who each serve four-year terms; most are clinicians in one of the primary care specialties (general medicine, pediatrics, geriatrics, family medicine, nursing, and OB-GYN), and all are experts in evaluating the scientific evidence.
2. Since its inception, the USPSTF has developed recommendations to inform care and to be useful guides for all stakeholders about what the evidence tells us about which preventive services work. We do not make or enforce insurance coverage decision; these are the domain of insurers, regulators, and the state and federal government. Regardless of how healthcare is financed, knowing what the science tells us about which preventive services work is critical. This was true when the USPSTF was created more than thirty years ago and remains true now.
3. Our recommendation statements are more than just the letter grade and contain detailed information about the primary evidence, how one might implement the recommendation, and about populations that are disproportionately burdened by the condition we seek to prevent. All of this is important to clinicians for allowing them to tailor recommendation to their patients and particularly for addressing disparities in health.
4. Transparency is foundational to our recommendation development process. We are devoted to engaging the public in all stages of our process – from the nomination of new topics, to the development of the research plan, to the evidence review and final recommendation

statement. We both invite general comments from the public and solicit specific feedback from professional groups and advocacy groups who have interest in a particular recommendation. We have an active website, other tools to assure broad engagement, and strong partners to help us share our information and assure broad feedback.

5. The input from medical and surgical sub-specialists who treat the conditions that we are trying to prevent is already an essential element of our work. In our current prostate cancer update, for example, in addition to the methodological experts from the Evidence-based Practice Centers and the primary care specialists who are members of the Task Force, we have engaged 15 sub-specialty experts in prostate cancer, including three urologists. Sub-specialists are not voting members of the 16 person USPSTF because
    a. our scope of work is to inform decisions made in the primary care setting by primary care clinicians (over half of medical visits each year in the US are to primary care),
    b. given the broad range of over 100 topics under our purview, the most efficient and effective approach is consultation with sub-specialists for the specific topic in which they have expertise, and
    c. because the livelihoods of sub-specialists are often directly affected by our guidelines (thus giving the appearance of a financial or intellectual conflict), and because many sub-specialists have specific ties to the industries that make screening tests or treatments, per the USPSTF conflict of interest protocols, these conflicts would likely prohibit most sub-specialists from serving on the USPSTF, or at the very least would preclude them from supporting the few topics for which they have expertise.
6. We are committed to making guidelines that are trustworthy and free of bias. We continue to strive to meet or exceed of the standards set by the National Academy of Medicine in its "Clinical Practice Guidelines We Can Trust" report and were called out in this report as a leader in meeting the 8 standards for trustworthy guidelines. We hold our own membership

to extremely high standards for conflicts of interest and have an open and transparent process for disclosure and for mitigating conflicts. These efforts are essential for the credibility of our work and for achieving guidelines free of bias, as envisioned when the USPSTF was created. The creation of guidelines in which bias and conflict have been minimized has been a critical factor in the widespread adoption of our guidance to inform care in many health systems.

Full Testimony

Chairman Pitts, Ranking Member Pallone, and members of the House Energy and Commerce Health Subcommittee, thank you for the opportunity to testify today on behalf of the U.S. Preventive Services Task Force.

I am the current chair of the USPSTF, and the Lee Goldman, MD Endowed Chair in Medicine and professor of medicine and of epidemiology and biostatistics at the University of California, San Francisco. I am also a general internist who provides primary care to adult patients at the public hospital in San Francisco—Zuckerberg San Francisco General Hospital. I have been in practice for more than 15 years.

One third of all physicians are primary care clinicians, and over half of all medical visits made each year in the U.S. are primary care visits. Primary care is a specialty, and one of the critical areas where primary care clinicians specialize is in preventing disease before it starts in an otherwise healthy general population. Since becoming a physician, it is this focus on prevention that has been the most gratifying for me. If we can prevent future suffering from occurring—indeed if we can prolong years of healthy life—the benefits are clearly significant for our patients, their loved ones, and for all of us. And that is what patients ask of us in primary care.

Ruth is a lovely and very active 63-year-old woman I saw in clinic several weeks ago. She is a retired teacher and continues to work as a caregiver. She exercises daily and eats a healthy diet. And when she came to her appointment with her husband, she asked the question many of my patients ask: “What can I do to make sure I live a long and healthy life, to lower my chance of getting sick in the future?”

I take my answers to these questions very seriously. I want to be clear that if I recommend something for Ruth—a particular screening test, a preventive medication, advice about a

behavior—that my recommendation has some chance of preventing disease, of preventing future suffering, of prolonging or improving her life. I also want to make sure that I can give Ruth a complete understanding of potential side effects of these tests and treatments. And I want to have some certainty that on balance, Ruth is more likely to experience benefits from my recommendation than to be harmed. This is particularly important because as Ruth asks me these questions she feels well and is not experiencing any symptoms of disease. In fact, Ruth is doing everything she can to keep herself healthy, and she has put her trust in me that based on my recommendation and our shared discussion and decision-making, together we can arrive at a plan to continue to keep her healthy for many years to come. *This is the domain of prevention in the primary care setting: making recommendations for people without signs or symptoms of disease, about clinical services aimed at preventing future disease and prolonging life. And because of this important responsibility placed on us in primary care, knowing what the science tells us about the likelihood a preventive service will be beneficial is critical.*

Since I began my medical training in 1995, the recommendations of the USPSTF have always been there to help primary care clinicians and patients decipher the evidence behind preventive services. As a medical student and resident, the bound copies of the USPSTF recommendations were easily the most well-worn books in the back room of our clinic. This is because as primary care clinicians, we are not just concerned with preventing one disease or one condition, but rather with the range of health problems for which a patient may be at risk. For Ruth, I want to make sure I've given her the best advice about how we can detect cancers early so that they can be treated. But my focus on prevention is not limited to one type of cancer: I want to help Ruth prevent breast cancer *and* cervical cancer *and* colorectal cancer. I also want to minimize her chances of developing a heart attack or stroke, to help prevent her from suffering a fall, ***and*** to identify underlying depression before it compromises her health. For Ruth and for the many other patients like her, we in primary care look to the Task Force's

guidelines to tell us about the entire range of preventive services that might be applicable and what the evidence tells us about whether these services are likely to be beneficial.

The USPSTF was established in 1984, under the Reagan administration, as an independent, nonpartisan, expert panel that seeks to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. Our panel is made up of 16 volunteer members who each serve four-year terms. Most of us are primary care clinicians in the areas of general medicine, pediatrics, geriatrics, family medicine, nursing, and OB-GYN, and others have specific expertise in areas such as behavior change. In addition to this clinical background, all Task Force members are experts in evaluating the scientific evidence. We work closely with researchers and experts at the Evidence-based Practice Centers located at universities around the country who conduct the evidence reviews that are the scientific basis for our recommendations. We take these systematic reviews of the evidence and use them to formulate a recommendation with a letter grade that signifies what the science tells us about the potential benefits and the potential side effects or harms of a preventive service.

We are known for the grades we give to preventive services. Our A, B, and C grades all indicate that the science gives us moderate to high certainty that this preventive service is likely to yield net health benefits. In other words, the service works, it is beneficial, and we recommend it. A, B, and C grades are all statements in favor of the service; the only difference is how much future health benefit one might anticipate: A signifies substantial, B moderate, and C small.

Sometimes a preventive service might have important potential benefits, but also significant potential harms, so that on balance, when one considers both the benefits and the harms, the evidence tells us that a patient is not likely to benefit overall from the service or may even be

harmed. In this case, we give a D grade and recommend against routinely engaging in this preventive service.

Finally, we are sometimes faced with not enough evidence to make a recommendation, even for important conditions that we would like to prevent. In this case, we offer an I statement for insufficient evidence, and we make a clear call to the scientific community about the need for more research. We know that practicing clinicians need to make decisions even in the face of insufficient evidence, so we include details within the I statements about what we do know that might be helpful for clinical practice. It is important to note that ALL of our recommendations must be based on evidence, and so when this is lacking, we must issue an I statement, rather than substituting our own judgment about what we might do in our own practice.

I would like to make two critical points that are often misunderstood about our grades:

First, since the inception of the Task Force, our grades have been meant to inform care and to be useful guides for all stakeholders about what the evidence tells us about which preventive services work. Decisions about insurance coverage are *not* in our domain; these are the domain of insurers, regulators, and the state and federal government. We do not make or enforce insurance coverage decisions. Our role is to evaluate the science on the benefits and harms of a given preventive service and to inform the public so they can make informed decisions about their healthcare. The USPSTF maintains that the science on effectiveness is foundational, but is only one factor that needs to be considered in developing coverage policy. We also maintain that the linkage between our recommendations and the ACA coverage mandate sets a logical minimum standard for coverage of preventive services. Those that make coverage determinations—insurers, regulators, and state and federal governments—have the discretion to cover more than recommendations that receive A and B grades, and they have

exercised that authority in the past. We also maintain that regardless of how healthcare is financed, knowing what the science tells us about which preventive services work is critical. This was true when the USPSTF was created in 1984, and it remains true now.

Secondly, our recommendation statements are far more than the simple letter grade. They contain detailed information about the primary evidence and about our rationale for arriving at the recommendation. I know from my colleagues that the ability to review the primary evidence and understand the thinking behind our grade is exactly what allows them to tailor a recommendation to the patient that is sitting in front of them. The practice of medicine is complex; it is not amenable to simple cookie-cutter solutions. Our grades are the starting point and an extremely useful way to understand what to recommend across multiple types of preventive services, but important details about the underlying science are critical as well so that the recommendation can be adapted to the individual patient. Our recommendation statements contain useful information about the diversity of the patient populations to which a recommendation may apply because we know that primary care clinicians across the country see many different types of patients in their clinical practices. Understanding which groups may be more or less likely to experience a particular condition or to benefit from a particular service is crucial for primary care clinicians, and particularly vital to addressing the important disparities in health that exist across groups in the U.S. Our recommendation statements also contain information for how one might generally implement a recommendation when faced with decisions in clinical practice and have helped guide health systems seeking to more widespread implementation of evidence-based practice.

A good example of the rich detail contained within our statements is from our 2012 prostate cancer screening recommendation. I know that prostate cancer is an important health issue for many on this committee, as it is for many clinicians and patients across the country, including myself. We are currently in the process of updating our 2012 recommendation statement on

screening for prostate cancer with the PSA test. In 2012, we issued a D grade for prostate cancer screening because while there are benefits of screening for some men, there are also harms for many more men. We recommended against routinely screening all men with PSA tests, but importantly also included this language in the recommendation statement:

> *"The USPSTF recognizes the common use of PSA screening in practice today and understands that some men will continue to request screening and some physicians will continue to offer it. The decision to initiate or continue PSA screening should reflect an explicit understanding of the possible benefits and harms and respect patients' preferences. Physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by patients. Similarly, patients requesting PSA screening should be provided with the opportunity to make informed choices to be screened that reflect their values about specific benefits and harms."*

Simply put, our recommendation statement put the emphasis back on clinicians and patients having the discussion and together making the informed decision about this screening practice in light of what the evidence shows about benefits and harms.

Additionally, the recommendation statement also highlighted the critical need for more research in men at high risk for prostate cancer, including African American men. African Americans make up more than 13 percent of the U.S. population, and African American men are 1.6 times more likely than white men to suffer from prostate cancer. The sad fact is that of the tens of thousands of men included in the U.S. clinical trials for prostate cancer screening that we reviewed in 2012, less than 4 percent were African American. We need to do more to address unacceptably high rates of prostate cancer in African American men, including supporting more high-quality research in those at highest risk for prostate cancer to inform our prevention efforts.

I would like to address some specific issues related to the bill being discussed here today, because many of the issues included in this bill are already part of the robust policies and procedures that guide the USPSTF:

1. Transparency is foundational to our recommendation development process. We are devoted to engaging the public in all stages of our process and have received unwavering support in these efforts from the Agency for Healthcare Research and Quality (or AHRQ), the Health and Human Services (HHS) agency that provides logistical support for our activities. We have a public nomination process for new Task Force members and a public nomination process for new topics. When we take on a new topic or update an existing topic, we post our research plan for public comment and, in addition to soliciting general comments, we also reach out to professional and advocacy groups that might have a particular interest in the topic to give us specific feedback. We incorporate this feedback and then post our final research plan. Our research plans are always comprehensive, and we always include a focus on the specific populations that may be disproportionately affected by a condition because we recognize the important role our recommendations can play in addressing disparities in health.

   As more individuals and groups engage in the public comment period, I now routinely hear that many see that we have incorporated *their* comments in our work. The Prostate Health Education Network (PHEN) is one group that recently acknowledged to me that their comments had been incorporated into the research plan on prostate cancer when I

joined them for the 12th Annual African American Prostate Cancer Disparities Summit on Capitol Hill earlier this fall. In our prostate cancer screening draft research plan, we called out African Americans and men with a history of prostate cancer as a focus of our update because of the higher risk of prostate cancer in these men. The comments from PHEN were among the more than 350 comments we received on our draft research plan, and in response we clarified and expanded the types of evidence we would include when examining differences in men at higher risk for prostate cancer.

We always post a draft version of our recommendation statement, as well as our evidence report, and invite public comment on both. All comments are reviewed by USPSTF members and other scientists. We make explicit decisions about how to address these comments and incorporate them into our final research plans, evidence reports, and recommendation statements. At the end of each final recommendation statement is a summary of how we have addressed the comments we received.

We have many organizations with whom we partner and who help us in assuring that our work is widely shared. The Prostate Health Education Network that I mentioned earlier has become one of our latest dissemination partners and will work with us when our prostate cancer recommendation update is finalized. Effective communication and dissemination is critical for us, and we are constantly working to ensure that this is occurring in an optimal fashion. We have an active website with tens of thousands of page views a month where you can find the more than 100 recommendations in our library, drafts that are available for public comment, and tools that might help busy clinicians implement our recommendations. We have a great app that also aids in the implementation of our recommendations in clinical practice. And we have a strong publication partner in the *Journal of the American Medical Association (JAMA)* and the

JAMA network, which, in addition to providing a broad reach among its readership, has created outstanding short videos and podcasts to share our information with patients and clinicians of all specialties.

2. The input from medical and surgical sub-specialists who treat the conditions that we are trying to prevent is already an essential element of our work. We seek out the input of sub-specialists at every stage in our guideline-making process—from the time we formulate our research plan, through to the evidence report and our final recommendation statement. In our current prostate cancer update, for example, in addition to the methodological experts from the Evidence-based Practice Centers and the primary care specialists who are members of the Task Force, we have engaged 15 sub-specialty experts in prostate cancer, including three urologists. Incorporating input from sub-specialists has long been our standard practice. Another tangible example from our prior prostate cancer recommendation published in 2012 is the paragraph I cited earlier advising healthcare providers to engage in informed decision-making with their patients before they order a PSA test. This paragraph was developed in consultation with Dr. Otis Brawley, a medical oncologist and the Chief Medical Officer of the American Cancer Society.

While we value the input of sub-specialists and have explicit procedures for soliciting input at every stage in the recommendation process, sub-specialists are not voting members of the 16-person Task Force. This is true for several reasons. First, we make recommendations for patients without signs or symptoms of disease who are seen in the primary care setting. That is why our panel consists of clinicians who specialize in primary care, as it is primary care clinicians who, together with their patients, make these decisions about prevention. Second, we make recommendations across a range of

conditions seen in primary care, and within this range, it is just not feasible to construct a panel where the breast surgeons who treat breast cancer are helping us to decide on glaucoma recommendations—or the glaucoma expert helping us decide on the evidence for mammography screening. The most efficient and effective approach is one where we work closely with sub-specialists for each recommendation where they have expertise to offer, like we do today. Finally, one of the important standards articulated by the National Academy of Medicine in its report, "Clinical Practice Guidelines We Can Trust," is the minimization of potential conflicts of interest among guideline-making bodies. Those providers whose livelihoods are affected by the diagnosis and treatment of disease—as is the case with many sub-specialists—often have the appearance of a financial or intellectual conflict in creating prevention guidelines, and many sub-specialists even have specific ties (including as consultants or speakers) to the industries that make screening tests or treatments. Per the USPSTF conflict of interest protocols, these conflicts would likely prohibit most sub-specialists from serving on the Task Force, or at the very least would preclude them from supporting the few topics for which they have expertise.

3. We are committed to making guidelines that are trustworthy and free of bias. We continue to strive to meet or exceed of the standards set by the National Academy of Medicine in its "Clinical Practice Guidelines We Can Trust" report. This report opens with an acknowledgement of the daunting task faced by practicing clinicians:

> *"When treating patients, doctors and other healthcare providers often are faced with difficult decisions and considerable uncertainty. They rely on the scientific literature, in addition to their knowledge, experience, and patient preferences, to inform their decisions… Because of the large number of clinical practice*

guidelines available, practitioners and other guideline users find it challenging to determine which guidelines are of high quality. If guideline users had a mechanism to immediately identify high quality, trustworthy clinical practice guidelines, their health-related decision making would be improved—potentially improving both health care quality and health outcomes."

This landmark report called out the USPSTF as a leader in meeting the eight standards for the development of high-quality, trustworthy guidelines. We have continued to work to meet or exceed each of these standards, including holding our own members to high conflict of interest standards. Both the financial and the non-financial conflicts of our members are examined before they are appointed to the Task Force, as well as in an on-going fashion for each recommendation topic. Important conflicts that require mitigation are published both on our website and with the recommendations, as are the steps that we've taken to mitigate any potential conflicts, including limiting the voting or work of particular members on particular topics. These efforts are essential for the credibility of our work and for achieving guidelines free of bias, as envisioned when the Task Force was created. The creation of guidelines in which bias and conflict have been minimized has been a critical factor in the widespread adoption of our guidance to inform care in many health systems.

One of the joys of being physician who delivers primary care is the relationship that develops between you and your patients over time. I look forward to continuing to get to know Ruth even better, to understanding more about what's important to her, and to working in partnership with her—armed with the science about what preventive services work—to help her continue to achieve her goal of good health. As Ruth ages, we will together face different decisions, and perhaps make different choices, than the ones we made when we met recently. As she gets

older, new conditions may take priority in our preventive efforts, and we may need to reexamine whether taking that daily aspirin to prevent heart attacks and colorectal cancer is still the best option for her. Over time, new science will emerge that will continue to inform these decisions and help us set our priorities. I know that I will continue to look to the USPSTF to keep us up-to-date with the science and to help guide Ruth and I in our decisions. Even after I finish my service as chair next year, I know that the robust, high-quality, and unbiased policies and procedures of the Task Force will continue to make it a trusted source for information about the science of prevention. I know that as our clinic works together as a team of health professionals—including doctors-in-training, nurses, nurse practitioners, and other physicians in our network—our collective trust in the work of the USPSTF will assure that evidence will guide our practice regardless of who is caring for Ruth over time. It is our trust in the high-quality, unbiased work of the USPSTF that has given us confidence in the past and will continue to do so in the future, allowing us to answer Ruth and the many, many patients like her in primary care with assurance when they ask: “What can I do to make sure I live a long and healthy life, to lower my chance of getting sick in the future?”