December 28, 2015

Via online submission at http://www.uspreventiveservicestaskforce.org/Comment/Collect/QuestionPage

United States Preventative Services Task Force
540 Gaither Road
Rockville, Maryland 20850

Dear Task Force Members,

On behalf of the 13,500 U.S. based members of the American Academy of Dermatology Association (Academy), I am writing to provide comments regarding the Screening for Skin Cancer: U.S. Preventive Services Task Force Draft Recommendation Statement published on November 30, 2015. The Academy appreciates the opportunity to provide comments in response to the questions the U.S. Preventative Services Task Force (USPSTF or Task Force) posed online at http://www.uspreventiveservicestaskforce.org/Comment/Collect/QuestionPage. We hope the USPSTF will consider our responses to these questions as follows:

1. How could the USPSTF make this draft Recommendation Statement clearer?

As the USPSTF is aware, skin cancer is the most common form of cancer in the United States\(^1\), and the incidences of skin cancer continue to rise. It is estimated that 137,310 Americans will be diagnosed with melanoma in 2015.\(^2\) There are 5.4 million cases of nonmelanoma skin cancer diagnosed each year in the United States.\(^3\) The Centers for Disease Control estimates that it costs \$8.1\) billion per year to treat melanoma and nonmelanoma skin cancers combined.\(^4\) The Academy is committed to educating the public on skin cancer prevention to reduce these alarming statistics. Because early detection is a vital in the fight against skin cancer, the Academy encourages all members of the public to serve as their own health advocates by regularly conducting skin self-exams. Individuals, who notice any unusual spots on their skin, including those that are changing, itching or bleeding, should make an appointment with a board-certified dermatologist. Additionally, people with an increased risk of skin cancer or a history of skin cancer should talk to a dermatologist to determine how often they should receive a skin exam from a doctor.

As the scope of the Draft Recommendation Statement is limited to screenings that primary care physicians perform, we recommend that this fact is made clear in the

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summary statement. It is important to highlight to the public that the USPSTF considered patient skin self-examinations and dermatologist-performed skin examinations outside the scope of the recommendation. While the full draft Recommendation Statement makes this distinction, we encourage the Task Force to include it in the summary statement to ensure this important point it is not missed.

We encourage the USPSTF to include language in its Recommendation Statement that recognizes that all skin cancers can lead to significant morbidity as well as be potentially lethal. While it narrowed the focus of its research to melanoma because its mortality rates are higher than those of other skin cancers, the Task Force should address that there is significant value added to skin cancer screenings in detecting other skin cancers—consistent with the broader implications of the title of this recommendation statement. Melanoma and Merkel cell carcinoma (MCC) are the two most lethal skin cancer malignancies, yet the risk of disease-specific death from metastatic squamous cell carcinoma (SCC) is approximately 2%. In addition, both BCC and SCC can be locally destructive, leading to the potential for disfigurement if left untreated.

We further recognize that the USPSTF frames the harms and benefits analysis from a public health perspective rather than a cancer control or dermatologic perspective. As we consider the statement from the perspective of specialists engaged in patient-centered care, we suggest that the Task Force rephrase the sentence, “Potential harms of skin cancer screening include misdiagnosis and overdiagnosis and the resulting cosmetic and — more rarely — functional adverse effects resulting from biopsy and overtreatment.” We recommend that it instead read as follows, “Potential harms from the perspective of patient-centered care are misdiagnosis and overdiagnosis and overtreatment with resulting cosmetic — and more rarely — functional adverse effect.”

2. What information, if any, did you expect to find in this draft Recommendation Statement that was not included?

We encourage the USPSTF to acknowledge in the Recommendation Statement the fact that early detection and surgical treatment offer the best treatment option for all skin cancers. Left untreated, MCC, SCC, BCC, dermatofibrosarcoma protuberans (DFSP), and other skin

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tumors can become locally invasive and potentially metastasize. Dermatologists often see patients whose skin cancers were not detected early and required substantial surgeries, often on the face. Had the skin cancers been detected early, the health system would have been spared higher costs for treatment, and patients and their employers could have been spared the economic impact of missing time from work and productivity.

3. Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions? Please provide additional evidence or viewpoints that you think should have been considered.

In the Recommendation Statement, the USPSTF acknowledges the challenges that conducting a definitive randomized, controlled trial (RCT) on visual skin cancer screenings performed by primary care physicians. We are encouraged by the Task Force position that it would consider well-designed case/control studies in addition to RCT. This acknowledgement raises possibilities for the research community to conduct the type of studies mentioned in the report.

We suggest that the USPSTF reconsider whether there is sufficient evidence to support the role of early detection of skin cancer in reducing morbidity. The Evidence Synthesis includes recognition that thinner melanomas are associated with improved case-based survival (citing increased mortality in association with thicker tumors and more advanced stage disease).

Further, we encourage the USPSTF to consider adding to the evidence synthesis a workplace time study. Namely, the Lawrence Livermore National Laboratories long-term (approximately 20-year) program involved a pre-awareness, education and skin screening program in the workplace, which resulted in a reduction in crude incidence of thicker melanoma and lower than expected death rate compared to CA Cancer Registry statistics over the time period assessed. It is not clear why this study was rejected by the AHRQ epidemiologists who selected the studies the Task Force considered.

The USPSTF may wish to reconsider its statement on cosmetic adverse effects. The single study supporting the cosmetic harm from skin biopsy examines the "scoop" biopsy and does not compare the outcome with other methods of biopsy. The level of evidence of this case series of 77 lesions among 45 outpatients with follow-up at six months for 56 lesions in 35 patients (77% retention) is an insufficient basis for any recommendation. The outcome was assessed by one unblinded physician. The sample size should be the number of subjects completing the study (35 subjects) and not the number of lesions. Furthermore, evaluation of cosmetic results at six months is premature to report the eventual softening of the wound which is relevant to the hypertrophic scar in 7%, and pigmentation with hypopigmentation, which was the primary cosmetic concern (52%), and 'marginal' hyperpigmentation (32%). Cosmetic results should be evaluated at least one year after a skin procedure.

The Recommendation Statement includes the line “A program of public education and disease awareness coupled with visual skin cancer screening by a clinician may reduce the risk of dying

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from melanoma.” We appreciate that the USPSTF recognizes that insufficient evidence to assess the net benefit does not mean that screening isn’t beneficial.

Finally, we question whether the studies in the Evidence Synthesis substantiate harms resulting from skin biopsies. We respectfully suggest that the Task Force revisits whether the inclusion of the article by Gambichler suggests harms from skin biopsies.13 We also question whether the USPSTF should consider the studies which refer to biopsies for nonmelanoma skin cancers when the scope of its recommendation specifically excluded these cancers.

4. What resources or tools could the USPSTF provide that would make this Recommendation Statement more useful to you in its final form?

The AADA appreciates the USPSTF seeking input on tools and resources it should provide with the Recommendation Statement. At this time, we have no suggestions.

5. The USPSTF is committed to understanding the needs and perspectives of the public it serves. Please share any experiences that you think could further inform the USPSTF on this draft Recommendation Statement.

We respectfully suggest that the USPSTF consider whether the standard of evidence it requires to demonstrate the risks associated with visual skin screenings is too high compared to other cancer screenings. Skin cancer screenings are not invasive and do not require surgical or radiological intervention. Therefore, the types of harms that could result from skin screenings are associated with a smaller impact on patients’ lives than is typical for screening for other types of cancer, such as breast, prostate or colon cancer.

Furthermore, we respectfully suggest that the USPSTF’s analysis and AHRQ’s Evidence Synthesis would benefit from the expertise of a dermatologist. For example, dermatologists can help inform clinical distinctions between partial and excisional biopsies for suspicious pigmented lesions, particularly relative to assessing the weight of the evidence. We welcome the opportunity to provide expertise in dermatology to the Task Force as it finalizes its recommendations.

6. Do you have other comments on this draft Recommendation Statement?

Although they are not yet published, it is important to note that there are two relevant studies underway which the USPSTF should consider in the future. The University of Pittsburgh Medical Center is assessing the value, feasibility and outcomes of primary care physician (PCP) based skin screenings in Western Pennsylvania. In that study, PCPs have screened over 54,000 adults over the age of 35. In addition, the Veterans Affairs Palo Alto Health Care System is assessing the feasibility of primary care based screenings in a high-risk population with a longitudinal outcomes study.

Recognizing the limited scope of the USPSTF’s evidence synthesis, we suggest that in the future the USPSTF may want to consider smaller studies related to screening targeted segments of the population based on age or other risk factors present in the general population, to examine and consider whether a separate recommendation is warranted. For example, the USPSTF may want to examine skin cancer screening for older men14, individuals with large

numbers of moles, or individuals that have engaged in intentional UV tanning from the sun or indoor tanning devices. Other high-risk groups for which a targeted screening recommendation would be helpful include patients with a low level of health literacy.

The Academy commends the USPSTF for its continued commitment to ensuring and encouraging wellness for the American people. We would like to be a resource to the Task Force as it finalizes its recommendations regarding this important topic. Please contact Leslie Stein Lloyd, JD, Director of Regulatory and Payment Policy, at lsteinlloyd@aad.org or 202-847-3555 should you have any additional questions.

Sincerely,

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