American Cancer Society and American Cancer Society Action Network Comments on the United States Preventive Services Task Force Draft Colorectal Cancer Screening Recommendation Statement

The American Cancer Society is a nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer through research, education, advocacy and service. The Society, operating through its national office and 11 geographic divisions throughout the United States, is the largest voluntary health organization in the United States.

The American Cancer Society Cancer Action Network (ACS CAN) is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supporting evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. We share a critical interest in cancer prevention. The American Cancer Society and ACS CAN appreciate the opportunity to comment on the Draft Colorectal Cancer Screening Recommendation Statement ("Draft"), and we appreciate the United States Preventive Services Task Force's (USPSTF) effort to solicit comments from the public prior to finalizing a new recommendation.

The Society and ACS CAN agree with many of the Task Force's conclusions. In particular we agree with the finding that a preponderance of evidence demonstrates that screening for colorectal cancer (CRC) with several different methods can accurately detect early-stage colorectal cancer and adenomatous polyps, and that screening for CRC in adults ages 50 and older reduces CRC mortality.

We have a number of questions, concerns and recommendations related to the Draft – as delineated below.

General comments:

Generally the Task Force recommendations need to be clearer. Providers will be looking to these recommendations to make clinical recommendations and importantly, payers, will be looking to these recommendations to make coverage decisions, based on the requirements of the Affordable Care Act. We are concerned that the creation of a new category, "Alternative Tests," will undoubtedly create confusion among provider, payers and the public. The clearer the Task Force can be about which tests should receive an "A" or "B" rating, the better.

Similarly, while we applaud emphasizing that screening is a "cascade of events," there are still numerous ways to interpret that statement. While the Departments of Labor and Health and Human Services has

clarified that certain events should be considered part of screening colonoscopy (pre-colonoscopy exam consultation, anesthesia, pathology, and polyp removal, for instance)(1,2,3), it remains unclear if a follow up colonoscopy after a positive stool test is still considered part of the screening continuum. We believe that it is and that the public health would benefit from the Task Force defining it as such.

Additionally, we are concerned that the Task Force based its recommendations on 100 percent compliance of each test, given the emerging importance of patient choice in the decision to get screened. Since the last update of both USPSTF and ACS guidelines, there has been a growing literature on levels of acceptance of the various CRC screening options. While there have been complaints that the number of testing options make referral to CRC screening too complex, it also appears to be the case that non-adherence to the recommendation to be screened often is due to patients not being presented with options. Thus, while we understand the logic for head to head comparisons of screening tests using 100 percent compliance, 100 percent compliance with any given test is not realistic, and at this time, each test likely has a dissimilar maximum level of acceptance in the adult population. We know that gFOBT has a lower adherence rate than FIT. We also know that adherence rates to the recommendation to be screened are higher when the option of colonoscopy and FIT is presented to the patient vs. just one or the other. Given our concerns that two tests with performance very similar to the recommended tests are included in the alternative test category (with unclear implications for coverage under the ACA), and whose exclusion seems questionable based on modeling decisions noted below, we recommend that prior to finalizing these recommendations modeling also be conducted to examine outcomes with lesser and greater adherence to screening recommendations based on current data on test acceptability.

1) *Centers for Medicare & Medicaid Services. Affordable Care Act Implementation FAQs - Set 12. 2015. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html (accessed August 25, 2015).*

2) *United States Department of Labor. FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation. October 23, 2015. http://www.dol.gov/ebsa/faqs/faq-aca29.html (accessed October 26, 2015).*

3) *Centers for Medicare & Medicaid Services. FAQs About Affordable Care Act Implementation (Part XXVI). May 11, 2015. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf (accessed August 25, 2015).*

Comments on Specific Sections:

Recommendation Summary

We applaud the new language clarifying the importance of individualized decision making for adults ages 76 to 85, “taking into account the patient’s overall health and prior screening history”. It is

important for the Recommendation Summary to be clear and comprehensive about the recommendation and the populations to which it applies. Many clinicians and payers will rely on the Recommendation Summary only, and will not refer to the full Recommendation Statement in making recommendations to their patients about CRC screening. The 2008 Task Force recommendation statement read "USPSTF recommends against routine screening for colorectal cancer in adults age 76 to 85 years. There may be considerations that support colorectal cancer screening in an individual patient." Experience suggests that, in the absence of the additional context included in the current statement, not recommending an intervention above a specified age cut-off may lead clinicians to discontinue the intervention, even for the healthiest older patients who would be most likely to benefit (4,5).

Further, many payers, including Medicare, will look to the Task Force to understand whether or not an exam should be covered free of cost sharing for a given population. The clearer the Task Force can be in regard to what scenarios and tests receive an "A" or "B" rating, the better.

As such, the Task Group should consider reframing the recommendation summary, so that "Screening would be most appropriate among adults age 76 to 85 who: 1) have never been screened OR who have been screened, but: 1) are healthy enough to undergo treatment if colorectal cancer is detected, and 2) do not have comorbid conditions that would significantly limit life expectancy" is its own population category with its own grade (presumably, an "A" or "B" for adults in these categories).

Similarly, the recommendations would benefit from clearer rules about which specific tests receive which ratings. It is not clear if CTC or stool DNA and the new "alternative test" category are recommended by the Task Force or not. Without specific letter grades given to both the recommended and alternative tests we believe that patients, providers, and insurers will be left with more confusion around CRC screening strategies.

Finally, we believe the summary recommendation should more clearly define what is included in the "cascade of events" that follow the initial exam, as mentioned above. Undoubtedly, this summary will be used as the benchmark for which many screening coverage decisions are made. While the Departments of Labor and Health and Human Services have clarified that certain events should be considered part of screening colonoscopy (pre-colonoscopy exam consultation, anesthesia, pathology, and polyp removal , for instance), it remains unclear if a follow up colonoscopy after a positive stool test is still considered part of the screening continuum. We believe that it is, given that if a stool blood test is not followed by a follow up colonoscopy, the process was essentially a worthless exercise. As the USPSTF stated in 2008: "Follow-up of positive screening test results requires colonoscopy regardless of the screening test used."

4) *Saini SD, Vijan S, Schoenfeld P, Powell AA, Moser S, Kerr EA. Role of quality measurement in inappropriate use of screening for colorectal cancer: retrospective cohort study. BMJ. 2014 Feb 26;348:g1247.*
5) *van Hees F, Habbema JDF, Meester RG, Lansdorp-Vogelaar I, van Ballegooijen M, Zauber AG. Should Colorectal Cancer Screening Be Considered in Elderly Persons Without Previous Screening?: A Cost-Effectiveness Analysis. Ann Intern Med. 2014;160:750-759.*

Rationale

Benefits of Screening and Early Intervention

- We disagree with the inclusion of the statement on page 2, "To date, no method of colorectal cancer screening has been shown to decrease all-cause mortality in any age group." It is unrealistic that screening for CRC *could* affect all-cause mortality; these statements reinforce the use of a hopelessly inefficient benchmark of effectiveness that critics of screening commonly invoke to diminish the value and importance of early cancer detection. In fact, the USPSTF may be diminishing the promise of screening with this statement, given that we know incidence from colorectal cancer screening for those 50 and older has dropped 30% in the last decade, in large part thanks to screening. (6) The USPSTF should show leadership and not raise the issue of all-cause mortality unless it is pertinent, i.e., the test is associated with an increase in other-cause mortality that was identified as associated with diagnosis or treatment, or was associated with a drop in all-cause mortality because screening identified collateral disease, or treatment favorably affected other disease conditions. If the Task Force elects to leave the statement on all-cause mortality in the final draft, it would be useful to the reader to state either that no all-cause benefit is expected, and thus the observation should not be taken in any way to diminish the value of CRC screening.

6) *Siegel R1, Desantis C, Jemal A.Colorectal cancer statistics, 2014.CA Cancer J Clin. 2014 Mar-Apr;64(2):104-17. doi: 10.3322/caac.21220. Epub 2014 Mar 17.*

Harms of Screening and Early Intervention

- We applaud the USPSTF for describing colonoscopy after positive findings on other CRC screening tests as "follow-up colonoscopy," rather than "diagnostic colonoscopy." However, the descriptors are not used consistently (i.e., page 10, for example). The ACS and ACS CAN believe that it is important to not continue describing follow-up, problem solving tests as "diagnostic," since they do not truly result in a diagnosis. Additionally, due to current approaches to coding, these procedure labels result in patient co-pays. These tests should be regarded as part of the screening continuum.

- We are wondering how harms can range from "small to moderate," unless it depends on the test used, i.e., that harms are significantly higher when older adults undergo colonoscopy. If that is the case, that clarification would be informative, i.e., that harms range from small to moderate depending on the screening test, or the age of the adult being tested (7).

7) *Levin TR, Zhao W, Conell C, Seeff LC, Manninen DL, Shapiro JA, et al. Complications of colonoscopy in an integrated health care delivery system. Ann Intern Med. 2006;145(12):880-886.*

Clinical Considerations

Fecal Occult Blood Test and Fecal Immunochemical Test

- What is the source for the assertion that "The Hemoccult II® test (Beckman Coulter, Inc., Brea, CA) has largely been replaced in the United States by higher-sensitivity stool-based tests, such as the Hemoccult II SENSA", and the related statement in the Discussion section "the Hemoccult II test has largely been superseded by higher-sensitivity stool-based tests, such as the Hemoccult II SENSA or FITs."? We see this statement on page 7 in the systematic evidence review, and also on page 48, but the systematic evidence review also does not have a supporting citation. Anecdotally, in their work with primary care clinicians American Cancer Society staff are finding extensive use of a variety of generic versions of guaiac tests and relatively limited use of Hemoccult II SENSA. Are there citations or sources to support this statement?

- In the systematic evidence review the authors state, "Stool testing is generally performed on spontaneously voided stool samples, as opposed to in-office stool samples obtained by digital rectal exam, because of the less sensitive or unclear test performance of the latter." In fact, it is not clear that stool testing generally is performed according to manufacturer's instructions, when two studies have shown a very high prevalence of in-office FOBT following digital rectal exam (8, 9). The most recent survey showed that low sensitivity FOBT was the most common stool test used, and that 1 in 4 physicians reported using only in-office tests and 53% report using both in-office and home tests. In-office testing and Hemoccult II have very low sensitivity for cancer and advanced lesions. To the extent that the practice of in-office FOBT was recently reported by 3 in 4 physicians, and the use of Hemoccult II and other low-sensitivity guaiac based tests persists (the rate is unclear), the harm associated with the use of low-sensitivity testing should be described as high.

8) *Nadel MR, Shapiro JA, Klabunde CN, et al. A national survey of primary care physicians' methods for screening for fecal occult blood. Ann Intern Med 2005;142:86-94.*
9) *Nadel MR, Berkowitz Z, Klabunde CN, Smith RA, Coughlin SS, White MC. Fecal occult blood testing beliefs and practices of U.S. primary care physicians: serious deviations from evidence-based recommendations. J Gen Intern Med 2010;25:833-9.*

Starting and Stopping Ages

- The Draft indicates that "Microsimulation analyses performed by CISNET suggest that starting colorectal cancer screening at age 45 rather than 50 years yields a modest increase in life-years gained and a more efficient balance between life-years gained and lifetime number of

colonoscopies". It is also acknowledged in the Clinical Considerations section that "Male sex and black race are also associated with higher colorectal cancer incidence and mortality. Blacks have the highest incidence and mortality rates compared with other racial/ethnic subgroups". The 2015 Systematic Review utilized to develop the Draft Recommendations also points out the strikingly higher rates of CRC among Alaska Natives. Studies have also documented an increased likelihood of CRC diagnosed before age 50 among black men and women. (6.7) In spite of this data, the Taskforce concluded that screening should be initiated at age 50 for both men and women, regardless of race and ethnicity.

These findings indicate a strong need for race-specific and gender specific modelling to determine whether the increase in life-years gained and the balance between life-years gained and lifetime number of colonoscopies may be more favorable in those populations known to experience earlier onset and higher rates of mortality due to colorectal cancer, including men, Blacks and Alaska Natives.

10) *Rim SH, Seeff L, Ahmed F, King JB, Coughlin SS. Colorectal cancer incidence in the United States, 1999–2004: an updated analysis of data from the National Program of Cancer Registries and the Surveillance, Epidemiology, and End Results Program. Cancer. 2009;115:1967–1976.*
11) *Andaya AA, Enewold L, Zahm SH, et al. Race and colon cancer survival in an equal-access health care system. Cancer Epidemiol Biomark Prev. 2013;22:1030–1036.*

Alternative Tests: CT Colonography

- Exclusion of CT colonography from the list of recommended tests, and inclusion in the ill-defined Alternative Tests category does not appear to be consistent with the evidence or with past USPSTF practices. The Draft acknowledges that "Screening with computed tomography (CT) colonography and multitargeted stool DNA (FIT-DNA) testing may be useful in select clinical circumstances. However, there is less mature evidence to support these methods, resulting in greater uncertainty about their net benefits and the most appropriate situations in which to use them." In the following section it goes on to say "CISNET modeling suggests that screening every 5 years with CT colonography (assuming colonoscopy followup for lesions measuring ≥6 mm) from ages 50 to 75 years could potentially yield approximately the same number of life-years gained, with a similar balance of benefits and harms, as the recommended strategies previously listed" (i.e. the unequivocally recommended tests – FIT, gFOBT, flexible sigmoidoscopy + FIT, and colonoscopy).

  In 2008 the USPSTF concluded the evidence was insufficient to assess the benefits and harms of CT colonography as a screening modality for colorectal cancer (an "I" statement). Concerns were cited regarding the perceived limited availability of CT colonography performed by trained and experienced radiographers, the potential harms associated with evaluation of incidental findings, and the cumulative risks of radiation exposure. Since the time of that publication a

plethora of studies have been published on these topics and a variety of other issues related to the use of CT colonography as a colorectal cancer screening tool. The American College of Radiology and the International CTC Standards collaborative have developed CT colonography practice guidelines and quality metrics, as well as specifications around training and certification. The 2015 Systematic Review describes a number of fair- to good-quality studies documenting the test accuracy of CT colonography. All of these studies used colonoscopy as the reference standard. Due to the paucity of other high-quality studies of colonoscopy, four of the cited studies serve as the basis for evaluating not only CT colonography performance, but colonoscopy performance as well. The Review also found the risks of serious adverse events associated with screening CT colonography to be extremely low. No perforations were reported in 11 prospective trials of CT colonography in screening populations. Modeled data based on assumptions in a report from the National Academy of Sciences' National Research Council on the impact of low-emission radiation on human health found that the benefits of CTC screening every 5 years (from age 50 to 80) far outweigh any potential radiation risks. Studies of extra-colonic findings reported "a very wide range of findings needing additional workup; 5 to 37 percent". It is widely accepted that extra-colonic findings represent both potential benefits and harms. The wide range reported in the literature makes it impossible to calculate a ratio of benefits to harms with any reasonable degree of accuracy.

Based on the conclusions from the 2015 Systematic Review the CISNET models assumed no complications due to CT colonography. In their base-case analysis, CT colonography screening every 5 years was included in the set of recommended strategies with age to begin screening of 50 and age to end screening of 75, assuming selection of a 10-year interval for colonoscopy screening. In this model, a CT colonography screening strategy provided 91-96% of the life-years gained with 10-yearly colonoscopy over the same age range, and required significantly fewer colonoscopies. However, a second model was developed that calculated an additional "burden" related to cathartic bowel preparations in addition to the already included impact of needed follow up colonoscopies. Under this model CT colonography was no longer included as a recommended test. The 2015 Systematic Review reportedly "found no evidence of clinically significant adverse effects due to bowel preparation that required hospitalization in average-risk screening populations", and goes on to state "existing systematic reviews on bowel prep for endoscopy suggest similar tolerability as a number of minor adverse events, no difference in efficacy of prep and no clinically significant adverse events from PEG or NaP." It is therefore difficult to understand: a) why the CISNET researchers chose to insert a "burden" with little or no clinically significant outcomes into the CT colonography model, and b) why the USPSTF preferentially used this revised model to exclude CT colonography from the list of recommended screening tests.

It seems clear from the information contained in the 2015 Systematic Review and the CISNET modeling report that the "I" statement applied to CT colongraphy in 2008 is no longer applicable. While some questions remain regarding the balance of benefits and harms related to the detection and management of extra-colonic findings, it is our opinion that the

accumulated evidence clearly supports a "B" grade (high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial) and inclusion of CT colonography in the list of recommended tests.

Alternative Tests: FIT-DNA

- We are concerned that FIT-DNA is included in the alternative test category, in spite of very favorable findings in the updated systematic review, and favorable performance in the CISNET review compared with the recommended tests. In the 2008 recommendation, the USPSTF concluded that there was "insufficient evidence to assess the sensitivity and specificity of stool DNA testing for colorectal neoplasia; therefore, the balance of benefits and harms cannot be determined for this test." Since that time, the sDNA test has evolved from an sDNA test to a multi-target sDNA test (FIT-DNA in your reports) with superior performance. In this update, FIT-DNA was grouped with other stool tests, although an alternative comparison might have been to compare FIT-DNA to the direct visualization tests, since performance also is similar.

  The recommendation summary notes on page 6 that "CISNET modeling suggests that annual screening with FIT-DNA from ages 50 to 75 years could potentially yield approximately the same number of life-years gained as the recommended strategies previously listed." However, it appears that the principle reason that FIT-DNA was placed in the alternative test category is due to a higher burden of colonoscopy arising from the lower specificity associated with annual testing, which the manufacturer does not recommend, is not the current ACS recommendation, and also is not approved by FDA and CMS. Further, the specificity rates are artificially low because they don't include advanced adenomas, for which detection is an important goal of screening since detection and removal of adenomas contributes to prevention.

  On page 7 of the CISNET report, the authors state that 1, 3, and 5 year strategies were compared for FIT-DNA, but the 3 year screening interval was not included in the final comparison between classes of tests. When we examine the findings for FIT-DNA every 3 years in the appendix and compare it with the other tests it looks comparable, but we also note the considerable differences in predicted outcomes between the models. With this much variation (note in the table below that FIT-DNA every 3 years in CRC-SPIN outperforms all MISCAN simulations except colonoscopy every 10 years), it would seem that these and other factors would be sufficiently persuasive to include FIT-DNA among the recommended tests. We also note in Table 10 that 3 year FIT-DNA was dominated, but the appendix data suggest that the differences that led to dominance were small. We wish to stress, and this point also is made below, that it may be that FIT-DNA will appeal to some adults for screening more than other screening options and thus may contribute to the shared goal of increased adherence with screening recommendations.

MISCAN RESULTS (from Appendix)					
Strategy	No. tests	Total COLS	> LYG	< incidence	< mortality
FIT-DNA 50-75 1 (26)	11,025	2,662	246.3	57.3	77.2
FIT-DNA 50-75 3 (9)	5,779	1,714	215.3	43.1	67.5
FIT-DNA 50-75 3 (9) from CRC-SPIN included for comparison	5,927	1,827	226.4	68.2	75.7
FIT 50-75 1 (26)	15,843	1,757	231	46.7	71.8
gFOBT 50-75 1 (26)	12,927	2,287	231.6	49.2	72.9
COL 50-75 10 (3)	2,316	4,101	247.6	62.4	78.8
SIG 50-75 5 (6)	3,807	2,287	221.1	56.3	71.9
SIG-FIT, 50-75 1/10 (3,26)	12,642 + 1,903	2,490	246.2	57.6	77.4

Other considerations

Implementation

- The USPSTF should take advantage of this opportunity to reinforce the importance of and variation in the quality of recommended screening tests. This section should include admonitions against inappropriate and ineffective approaches to specimen collection for gFOBT and FIT, such as the use of in-office testing of samples obtained by digital rectal exam (9,12), and guidance on important colonoscopy quality features (13,14). The inclusion of flexible sigmoidoscopy every 10 years in the list of recommended tests is of particular concern. Significant variation in the quality of flexible sigmoidoscopy and associated outcomes has been documented (15, 16). These factors may well be magnified given that the test is no longer routinely used in most areas of the U.S.

12) *Collins JF, Lieberman DA, Durbin TE,Weiss DG. Accuracy of screening for fecal occult blood on a single stool sample obtained by digital rectal examination: a comparison with recommended sampling practice. Ann Intern Med 2005;142:81–85*.
13) *Fletcher RH, Nadel MR, et al. The Quality of Colonoscopy Services – Responsibilities of Referring Clinicians: A Consensus Statement of the Quality Assurance Task Group, National Colorectal Cancer Roundtable. J Gen Intern Med. 2010 Nov;25(11):1230-4.*
14) *Corley DA, Jensen CD, Marks AR, Zhao WK, Lee JK, Doubeni CA, Zauber AG, de Boer J, Fireman BH, Schottinger JE, Quinn VP, Ghai NR, Levin TR, Quesenberry CP. Adenoma detection rate and risk of colorectal cancer and death. N Engl J Med. 2014 Apr 3;370(14):1298-306.*
15) *Atkin W, Rogers P, Cardwell C, et al. Widevariation in adenoma detection rates at screeningflexible sigmoidoscopy. Gastroenterology 2004;126:1247–1256*
16) *Doria-Rose VP, Newcomb PA, Levin TR.Incomplete screening flexible sigmoidoscopy associatedwith female sex, age, and increased risk ofcolorectal cancer. Gut 2005; 54:1273–1278.*

- We are pleased to see acknowledgment that "In order for colorectal cancer screening programs to be successful in reducing deaths from the disease, they need to involve more than just the screening method in isolation. Screening is a package or cascade of activities that must occur in concert, cohesively, and in an organized way for benefits to be realized,..". We encourage the USPSTF to build on this statement by taking this opportunity to adopt and promote the definition of the required colonoscopy that must follow all positive non-colonoscopy screening test as a continuation of the screening process. A positive gFOBT, FIT, flexible sigmoidoscopy or other test that is not followed by a colonoscopy is an incomplete screening exam; it is only through completion of a colonoscopy after positive findings that the purpose of screening (identification of cancer or adenomas) can be achieved. Colonoscopies performed in this circumstance should not, therefore, be classified or described as "diagnostic".

Discussion

Accuracy of Screening Tests

- Why are confidence intervals included for the sDNA test, and not for gFOBT or FIT?

Effectiveness of Early Detection and Treatment for Recommended Tests

- There is a great deal of rich information in these discussions, but in some respect the level of detail and the disparate outcome measures and degree of information on outcomes by test-type could become overwhelming. For example, along with mortality reductions from the Norwegian trial, life-years gained from the CISNET analysis is presented for flexible sigmoidoscopy with and without annual FIT. These are very different metrics, and one would expect that they complement each other, but without some explanation of when a rate per person (0.X years per person) can be judged as a good buy, it is hard to judge. More commonly the number needed to screen (x times over y years) to prevent one death (with n years of follow-up) is presented, which is more intuitive, but these metrics are not included, nor are parallel outcome indicators presented for gFOBT from the guaiac-based FOBT trials. The reader might wonder, if you get a 32 percent reduction in mortality from a simple rehydrated gFOBT performed (nominally) every year, which also was accompanied with the benefit of prevention, why bother with flexible sigmoidoscopy and annual FIT testing, which produced only a 38% mortality reduction? We suggest consideration of a summary table with, to the extent possible, common screening scenarios and outcome measures for the different tests.

- In the discussion of the Nurses' Health Study, the Recommendation Statement states, "Overall, the study likely overestimates the magnitude of benefit associated with colonoscopy," but there is no explanation why this likely is the case (and probably is), or citation where the reader can

read further about potential confounders. There also is no discussion of the limitations of this study that we could find in the systematic review.

There also seems to be an inconsistent use of unique citations in the Recommendation Statement, and the citation of the systematic review (i.e., reference 3). It seems appropriate to site the evidence review for the conclusion about all-cause mortality since the evidence review would represent a current summary of all of the evidence that led to that conclusion. Yet, there likely are findings in the systematic evidence review that are from a single reference, in which case that reference would be more appropriate to cite in the Recommendation Statement than reference 3, which shows up too often. For example, on page 3, "A positive family history (excluding known inherited familial syndromes) is thought to be linked to about 20% of cases of colorectal cancer. "

Conclusion As previously noted, we are in general agreement with the Task Force that there are several effective CRC screening strategies. We think that the USPSTF should reconsider giving a sweeping "A" grade to CRC screening and implying that the strategies that are recommended all receive A grades (individual grades for tests are not stated), while the "alternative" tests are grade B or grade unspecified. The reader really has no guidance otherwise. Second, the USPSTF is missing an opportunity to give "D" grades to screening tests that it should recommend against, such as screening with low-sensitivity FOBT (both guaiac and immunochemical tests that lack published performance data), single-sample FOBT following a digital rectal exam in the office, guaiac-based toilet bowl tests, and perhaps DCBE, although the latter has nearly disappeared from current practice.

We appreciate the opportunity to comment on the evidence review, modeling analysis, and draft recommendation statement. We hope our comments will be well received and result in prompt reconsideration of the draft position on FIT-DNA and CT colonography. We believe that the performance of these two tests warrants a B recommendation, and that it would be acceptable for the current recommended screening tests to be given an A recommendation. We believe it is important to acknowledge that these tests perform as well or nearly as well as recommended options. They also may be the only test that some adults will choose for colorectal cancer screening.

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