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*9 LEGAL IMPLICATIONS FOR FAILURE TO SCREEN FOR COLORECTAL CANCER

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AMASSIVE EPIDEMIC IS OCCURRING in this country everyday. It is an epidemic of ignorance and failure to utilize noninvasive, inexpensive, commonly used screening devices to detect colorectal cancer ("CRC") early when CRC is most treatable. Such screening and detection would save thousands of lives, billions of dollars and grief and agony of patients and families coping with late stage CRC.

The following will outline: (i) the indisputable and staggering statistics for deaths related to CRC in the United States; (ii) efficacy in early detection of CRC; (iii) organized screening programs; (iv) the history of screening tools; (v) legal implications for failure to screen; (vi) the enormous costs incurred by Medicare, Medicaid, and major health care insurers for failure of the medical community to utilize screening to detect CRC; (vii) the Standard of Care for CRC detection and the impending tsunami of medical malpractice actions for the deviation of the standard of care by thousands of doctors, clinics, and hospitals; (viii) potential subrogation claims by insurance carriers to recover the costs for late detection and treatment of CRC; and (ix) *Daubert/Frye* standards.

Implementation of a screening program is crucial to raise the level of awareness of CRC detection before it affects you, your family members, friends and millions of lives across America.

***10 I. CRC Deaths in the United States** CRC is "the second leading cause of cancer death in the United States and the third leading cause of cancer death among both men and women." [FN1] An estimated 142,570 people will be diagnosed with CRC in the United States in 2010, and 51,370 people will die from it. [FN2] The incidence rate of CRC varies from race to race. For instance, in white males, the incidence of CRC is 54.4 people per 100,000 and white females is 40.2 women per 100,000. [FN3] In stark contrast, the incidence rate of CRC is 67.7 for African American males per 100,000, and 51.2 for African American women per 100,000 people. [FN4]

The death rate for Caucasian males is 20.6 per 100,000; and 14.4 Caucasian women per 100,000. [FN5] In even more stark contrast, is the death rate for African Americans from CRC. The death rate for African-American males is 30.5 per 100,000, and 21.0 for African-American women per 100,000. [FN6] Therefore the death rate is 50% higher for African Americans than the Caucasian population. The death rates in the United States from CRC is reflected in the Age Adjusted Death Rates Map for the United States 2008, which includes all races, both genders and all ages. [FN7]

Due to improved screening for CRC, the death rates have decreased over the last several years. [FN8]

II. Early Detection of CRC Saves Lives

CRC is most often preceded by a growth or "adenoma" which is a pre-malignant condition that exists for a prolonged period of time (*i.e.* years) which makes CRC an ideal target for early detection and treatment through screening. [FN9] Indeed, increased screening results in decreased CRC incidence and mortality. [FN10] This decrease in CRC mortality rates by state are strongly associated with increased screening. [FN11] However, many doctors and medical providers are either oblivious to the screening tools available for early detection, or consciously disregard such screening tools for economic reasons. [FN12] Physicians will often make recommendations which are not consistent with the United States Preventative Service Task Force ("USPTF") practice guidelines which are authoritative practice guidelines to be followed in the medical field.

The USPTF recommends four different screening options as follows:

1. High Sensitive FOBT (i.e."FFIT'D');
2. Colonoscopy;
3. Sigmoidoscopy;
4. Combination of FOBT and Sigmoidoscopy. [FN13]

According to the Center for Decease Control ("CDC"), "when colorectal cancer is found early and treated, the 5-year relative survival rate is 90%." [FN14] However, "because screening rates are low, less than 40% of CRC is found early. One U.S. clinical trial reported a 33% reduction in CRC deaths and a 20% reduction in CRC incidence among people offered an annual fecal occult blood test (FOBT)." [FN15] Additionally, "... *11 among people who can comply with frequent testing, highly sensitive and inexpensive non-invasive testing may be comparable to much less frequent screening with colonoscopy" [FN16]

III. Organized Screening Programs

CRC lends itself to early detection due to its long development time, which can be detected and therefore prevented through organized screening programs. [FN17] A study from Norway indicated that screening for CRC can reduce mortality by as much as 80%. [FN18]

Recognizing the importance of organized screening programs, Kaiser Permanente Northern California ("KPNC") began CRC screening in the 1960s, initially using flexible sigmoidoscopy. [FN19] Sigmoidoscopies and colonoscopies vary in cost throughout the United States. [FN20] Sigmoidoscopies can be performed by family practioners and/or internal medicine physicians who view the rectum through sigmoid portion of the colon. [FN21] Colonoscopies are performed by a gastroenterologist and are performed in endoscopy suites and view the rectum through the entire colon. [FN22] The average total cost for a sigmoidoscopy ranges from $300 to $700. [FN23] The average total for a colonoscopy performed in an endoscopy suite runs between $3,000-7,000. [FN24]

KPNC utilized FIT tests and increased CRC screening rates between 2005 and 2010 from 41% to 78% in the commercial and Medicare populations. "Organized FIT test screening has been associated with an increase in annually

detected CRCs, almost entirely because of increased detection of localized-stage cancers." [FN25]

IV. History of iFOBT and Noninvasive Screening Tests

Noninvasive screening tests for CRC are the guaiac Fecal Occult Blood Test ("guaiac". or "gFOBT") and the Fecal Immunochemical Test ("FIT" or "iFOBT"). Fecal occult blood testing is the most recognized form of CRC noninvasive screening worldwide. FIT, first developed in 1986, [FN26] is a more sensitive test for the detection of CRC than the guaiac method. FIT has higher patient acceptance and compliance, and is now the most widely used noninvasive method to screen and detect human hemoglobin from the lower gastrointestinal tract which is then used to detect early CRC or pre-cancerous conditions in the colon. [FN27]

iFOBT/FIT was a significant improvement for the detection of human hemoglobin from the lower GI in stool samples from gFOBT, which was widely used in the U.S. market in the late seventies through the 1980's and 1990's. The major impediments of gFOBT are that it requires three separate daily stool samples from patients, requires the patient to restrict certain medicines and food products three days prior to screening and to maintain those dietary and medicinal restrictions during the three-day screening. Even when a patient complied with these restrictions, the gFOBT lacked both sensitivity and specificity for human blood.

Key advantages of FIT over guaiac are: (i) improved patient acceptance and improved specificity; (ii) FIT is specific for human hemoglobin; (iii) FIT is not affected by diet and medications; (iv) FIT generally requires fewer samples than guaiac tests with better sensitivity; (v) since hemoglobin is frequently degraded as it passes through the gastrointestinal ("GI") tract, FIT is more specific for lower GI bleeding. Consequently, FIT specificity is not affected by anticoagulant or nonsteroidal medications because such medications induce upper GI bleeding. [FN28] More importantly, FIT is utilized more frequently because "patients invited to screen with FIT are more likely to use it, compared with the guaiac test, in part because of improved collection devices, fewer required samples, and no dietary restrictions." [FN29]

FIT screening methodology is an immunochemical reaction to human hemoglobin due to a very specific and sensitive set of antibodies and is ten times more sensitive to the presence of human hemoglobin in the stool than its predecessor the gFOBT. Also FIT screening does not require patients to have any dietary or medicinal restrictions prior to usage. FIT testing, because it demonstrated in studies to be more sensitive and specific for human hemoglobin, with no medicinal or dietary restrictions, was adopted in the Japanese market in the early nineties. [FN30] It also became the test of choice in Western Europe and in some South American countries in the mid nineties. [FN31] Studies in these countries have proved that annual FIT testing of patients over the age of 50 was able to reduce colorectal cancer deaths by 30-50%. [FN32]

V. Legal Implications for Failure to Screen for CRC

Since CRC "is one of the most commonly diagnosed cancers in the United States, and is one of the most preventable forms of cancer, as the second leading cause of cancer death in the United States in both women and men," [FN33] there is likely to be an avalanche of medical malpractice litigation for failure to screen, or for failure to screen properly.

In the context of medical malpractice, failure to diagnose has been a dominant malpractice allegation particularly where patients presented with symptoms of CRC. The most frequent allegation now is "failure to screen" and ""failure to properly screen." Patients who are at increased risk should be recommended to undergo a colonoscopy. While in many colorectal cancer malpractice cases, plaintiffs were awarded for failure to properly diagnose CRC, there is a growing emphasis on failure to properly screen which would have led to a proper, early diagnosis and therefore early treatment to asymptomatic patients.

Nevertheless, various medical institutions and practitioners have still not recommended or adopted annualized FIT screening for CRC for their patients. Such FIT screening and its ability to shift late stage cancer to pre-cancerous or early stage cancers has simply been ignored. Perhaps the failure to utilize FIT is due to the doctor's lack of education on its efficacy, or to the economic interests associated with treatment. When large health care organizations such as Kaiser Permanente and the American VA aggressively screen their patients with FIT as the SOC on an annual basis, those patients who are diagnosed with CRC should simply inquire if they were ever advised to be screened for CRC.

Worldwide studies and now major studies in the U.S. prove that FIT is inexpensive and noninvasive and could shift as many as 50% of all late stage cancers to early ***13** stage. The CDC found "[a]s many as 60% of deaths from colorectal cancer could be prevented if everyone age 50 and older were screened regularly." [FN34] According to the *American Journal of Managed Care,* "Fecal occult blood testing every year and sigmoidoscopy every 5 years are the most strongly supported by evidence of effectiveness, are the most widely practiced, and are favored by a recent cost effectiveness model." [FN35]

Current Status of CRC Screening Coverage Laws

"The 2009 Colorectal Cancer Legislation Report Card, presented by a dozen leading health professional and patient advocacy organizations, provides a snapshot of each states legislated coverage for CRC screening. Twenty-one states, plus the District of Columbia, received an "A," but 19 states received an "R" revealing that coverage for CRC screening is highly inconsistent across the United States." [FN36]

2009 Colorectal Cancer Legislation Report Card: State Grades

A 21: Alaska, Arkansas, Colorado, Connecticut, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Missouri, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Rhode Island, Virginia, Washington, Washington D.C. States receiving an A reference accepted screening guidelines, [FN37] allowing the legislation to include coverage of future advances in screening methods. [FN38]

B 4: Delaware, Pennsylvania, Texas, West Virginia States receiving a B meet current screening guidelines, [FN39] but no guidelines are specifically referenced. Therefore the legislation may potentially fall short of providing coverage for future advances in screening methods. [FN40]

C 3: California, Minnesota, Wyoming States receiving a C have passed legislation that covers preventative cancer screenings, but the legislation is vague and does not specifically mention which types of colorectal cancer screenings are covered. [FN41]

D 3: Alabama, Oklahoma, Tennessee States receiving a D have passed legislation that recommends in-

surance providers *offer* coverage, but does not *require* coverage. [FN42]

F 19: Arizona, Florida, Hawaii, Idaho, Iowa, Kansas, Massachusetts, Michigan, Mississippi, Montana, New Hampshire, New York, North Dakota, Ohio, South Carolina, South Dakota, Utah, Vermont, Wisconsin States receiving an F do not currently have any legislation that requires insurance providers to cover preventative colorectal cancer screenings. [FN43]

FIT is therefore the standard of care for noninvasive, asymptomatic screening for CRC Therefore, late stage CRC could and should be detected earlier and therefore deaths from CRC should and could be reduced by over 30,000 every year. ***14** Additionally, treatment costs of approximately $500,000/patient should be reduced annually by billions of dollars.

VI. The Cost of Late Stage Detection of CRC

Who stands to benefit from late stage CRC detection? Pharmaceutical companies directly benefit from late stage CRC detection. For instance, chemotherapy drugs such as "Fluoropyrimidines irinotecan, and oxaliplatin are the standard cytotoxic drugs used in treating metastatic colorectal cancer." [FN44]

As reported in the *New England journal of Medicine* ("Journal"), when CRC is detected late, the cost of chemotherapy is staggering. In the United States only, the chemotherapy regimen "costs approximately $30,790 for an eight-week course. Assuming that an average patient continues to receive treatment until the mediantime to progression, 8 months of front-line therapy followed by 4.1 months of irinotecancetuximabtherapy would cost $161,000." [FN45]

The *Journal* also reported that "[i]n 2004, 32,000 people in the United States will receive a diagnosis of stage IV colorectal cancer, and recurrent metastatic disease will develop in an additional 24,000. The drug costs for an eight-week course of initial treatment for these 56,000 patients will be approximately $666 million--or $1.2 billion with the addition of monoclonal-antibody therapy." [FN46] The *Journal's* cost estimates are exclusively for chemotherapy drugs and "do not include the costs of preparation, administration and supervision, or supportive medications." [FN47]

Most importantly, the *Journal* reported in 2004, that while "such costly treatment will not provide a cure, one can only speculate about the relative effect of directing these resources toward screening and prevention. [FN48]

Certainly, therefore, "as the costs of care for advanced CRC increase because of use of novel but costly biological therapies, screening with reasonably effective and inexpensive methods such as FOBT and FIT can be not only cost-effective, but also potentially cost-saving." [FN49]

VII. The Standard of Care

Screening for CRC is the standard of care. While colonoscopies are an effective tool in the screening process, patient acceptance and compliance is highest utilizing FIT as the noninvasive screening method for CRC detection. [FN50] FIT testing therefore appears to be increasing to become the most widely recognized noninvasive tool for CRC screening throughout the world. [FN51] As such, FIT testing is becoming the standard of care ("SOC") in noninvasive

screening for CRC. FIT is simple, inexpensive, noninvasive and widely accepted within the above-referenced patient communities with patient compliance rates of 60-80%.

Routine, annual FIT screening on age appropriate patients identified those patients with human hemoglobin in their stool. Such screening has led to patients having colonoscopies which identified problems or disease in the colon which ranged from small polyps, larger polyps, adenomas, Crohns, diverticulitis, early stage cancer and late stage cancer. Dr. Jim Allison, a leading gastroenterologist associated with the ***15** University of San Francisco and KPNC, advised that "when all patients eligible for screening are screened with colonoscopy, the fraction with no colorectal neoplasia (new growth) is consistent, ranging from 75% to 83%; thus most patients screened with colonoscopy will have neither adenomas nor cancers. ' [FN52] However, those screened with FIT who test positive, will necessarily require colonoscopy follow-up.

Conversely, another study in Japan provided that "in 1998 the government organized a nationwide mass screening which involved 3.3 million people throughout Japan using FIT. 6.7% of those patients were positive. [FN53] The study demonstrated that through its screening process with FIT, it was determined that approximately *66% of* all cancers found (4,548) were at the early stage." Such cancers were therefore treatable. The American Cancer Society found that 37-39% of CRCs in the United States are detected at the early stage as well. Accordingly, the lives saved by screening and specifically FIT testing is indisputable.

KPNC generated even more compelling data corroborating the efficacy of FIT testing. In a retrospective look from 2005 to 2009 of 640,000 patients, KPNC's conclusions were as follows:

- A 50% increase in screening rates (49% in 2005; 73% in 2009)
- 30% increase in Stage 0/I colorectal cancers
- 30% decrease Stage IV colorectal cancers
- Of 5,100 cancers detected approximately 1,530 shifted from late stage IV, with an 8% five-year survivability rate to early stage 0/I with a 92% five-year surviv-ability rate [FN54]

A recent four-year study in the United States, performed by KPNC which serves over 3 million patients was conducted with astounding results. [FN55] FIT testing in patients age 50 to 80 years in age, generated the following key observations:

a. The screening test of choice was FIT performed annually; with follow up of positive tests with colonoscopy, and adherence with screening policies tracked by regional electronic data;

b. Between 2004 and 2010, there were vastly improved screening rates: commercial population screening rates (non Medicare) doubled from 34% to 69% and the Medicare rate increased from 46% to 78% over the same time period;

c. From 2007 to 2009, an average of nearly 200 more localized cancers were detected annually in KPNC population compared with the baseline in place from 2006 and before.

Therefore, healthcare providers "will be expected not only to offer screening programs but also to perform them well." [FN56]

***16 VIII. Failure to Screen for CRC and Medical Malpractice**

As demonstrated above, FIT is the standard of care for noninvasive, asymptomatic screening for CRC. If internists, gastoenterologists and other professionals in healthcare continue to fail to utilize FIT, they are exposed to liability for medical malpractice. As reflected in the *American Journal of Managed Care,* "[a]s the evidence for colorectal cancer screening builds, and becomes more widely codified in nationally respected guidelines, cancers developing in people who have not been screened will become an ever-growing embarrassment to managed care organizations." [FN57]

The trend to codification as referenced above are revealed in the following Bills introduced to the 111th Congress:

• ***HR 1189: Colorectal Cancer Prevention, Early Detection, and Treatment Act of 2009***

The bill would amend the Public Health Service Act to establish a national screening program at the Centers for Disease Control and Prevention and to amend title XIX of the Social Security Act to provide states the option to provide medical assistance for men and women screened and found to have colorectal cancer or colorectal polyps. The bill would authorize $50 million in funding for grants to the states.

• ***HR 1330: Colorectal Cancer Screening and Detection Coverage Act of 2009***

The bill would amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and Title 5, and if the United States Code, to require that group and individual health insurance coverage and group health plans and Federal employees' health benefit plans provide coverage of colorectal cancer screening.

• ***HR 2291: Medicare Early Detection of Cancer Promotion Act of 2009***

The bill would amend title XVIII of the Social Security Act to eliminate the 20 percent coinsurance for screening mammography and colorectal cancer screening tests in order to promote the early detection of cancer.

• ***HR 3591/S 1511: Colorectal Examination and Education Now (SCREEN) Act of 2009***

The bill amend titles XVIII and XIX of the Social Security Act to improve awareness and access to colorectal cancer screening tests under the Medicare and Medicaid programs, and for other purposes. Among other provisions, it authorizes the Secretary of Health and Human Services (HHS) to make grants to states and Indian tribes for colorectal health programs.

*17 • ***S717: 21st Century Cancer ALERT (Access to Life-Saving Early Detection, Research and Treatment) Act***

The bill would modernize cancer research, increase access to preventative cancer services, provide cancer treatment and survivorship initiatives, and for other purposes. It would expand coverage of colorectal screenings, including through providing grants and allowing states to provide coverage for such screenings under Medicaid. [FN58]

Establishing malpractice and deviations from the SOC will become more common, until screening becomes mandated and physicians and healthcare providers comply.

In order to establish the liability of a physician for medical malpractice, a plaintiff must prove:

i. the physician owed a duty to the plaintiff;

ii. the physician deviated or departed from accepted community standards of practice;

iii. that such departure was a proximate cause of the plaintiffs injuries and;

iv. that the Plaintiff suffered injuries. [FN59]

IX. *Daubert/Frye* Standards

The *Daubert* standard is a rule of evidence regarding the admissibility of expert *testimony* to preclude unqualified *evidence* or "junk science" to the *jury*. [FN60] The *Frye* standard, or "general acceptance" provides that expert opinions based on a scientific technique is admissible only where the technique is "generally accepted" as reliable in the relevant scientific community. [FN61] In *Daubert*, the Supreme Court held that the *Federal Rules of Evidence* superseded *Frye* as the standard for admissibility of expert evidence in federal courts. Many states, however, still adhere to the *Frye* standard. [FN62]

Daubert/Frye motions to preclude experts from testifying will, however, be met with indisputable evidence clearly demonstrating the following:

1. FIT has been tested in actual field conditions and has a documented rate of success, including false positive and false negative analysis;

2. FIT has been subject to peer review and publication; [FN63]

3. The known or potential rate of error has been established in FIT testing; [FN64]

4. Standards exist for the control of FIT testing; [FN65]

5. FIT is generally accepted within the relevant scientific community as the preferred screening method to detect blood in the stool and therefore the presence of CRC. [FN66]

***18 Conclusion**

In spite of the all of the obvious benefits to early detection of CRC, the billions of dollars that would be saved if screening were more widely used and most importantly the lives that would be saved, CRC screening "still remains underutilized, despice the availability of effective, non-invasive, inexpensive screening tests." [FN67] Screening for colorectal cancer lags far behind screening for breast and cervical cancers. [FN68] About half of the U.S. population aged 50 and older has not been screened for CRC. In fact, according to 2005 data from the National Health Interview Survey (NHIS), only 46.8 percent have had a FIT test in the past year, a sigmoidoscopy in the past five years or a colonoscopy in the last 10 years. [FN69]

"Screening for CRC was also particularly low among those respondents who lacked health insurance, those with

poor access to healthcare services, and those who reported no doctor's visits within the preceding year." [FN70] "By contrast, in 2005, 67.9 percent of all U.S. women age 40--64 had a mammogram in the past two years." [FN71]

Currently, "ninety-five percent of physicians routinely recommend colonoscopy screening to asymptomatic, average-risk patients; 80% recommend fecal occult blood testing (FOBT). Only a minority recommend sigmoidoscopy, double-contrast barium enema, computed tomographic colonography, or fecal DNA testing. Fifty-six percent recommend two screening modalities; 17% recommend one." [FN72]

While colonoscopy is now the most frequently recommended test, only 50% of patients will comply "[M]ost physicians do not recommend the full menu of test options prescribed in the national Guidelines and inform patients to alternatives to colonoscopy. Few perform sigmoidoscopy ... [and] office systems to support CRC screening are lacking in many physicians' practices." [FN73] In fact, "[w]ith excellent annual adherence, sensitive and inexpensive stool-based testing such as FIT may be comparable to screening colonoscopy." [FN74]

If failing to screen for CRC continues, medical malpractice actions will (i) illuminate the necessity of CRC detection and treatment and force it to the forefront of the governement's priority in passing the legislation referenced above; (ii) compel medical providers to organize and institute formal screening programs, similar to KPNC's voluntary program, with significant results in detection of CRC and reduction of CRC related deaths; and (iii) seek redress for those who have needlessly suffered or died from CRC because they were simply not properly screened, regardless of whether such individuals have health insurance.

Therefore, CRC screening must be implemented immediately across the nation so that hundreds of thousands of lives will be saved, billions of dollars redirected to screening, early prevention and treatment and millions of families across the nation will be spared the unnecessary agony of late stage detection of CRC.

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[FN1]. Rebecca Siegel, Deepa Naishadham & Ahmedin Jernal, *Cancer Statistics, 2010*, 60 CA CANCER J. CLINICIANS 277, 277-300 (2010).

[FN2]. *See Id.*

[FN3]. *See* SEER Stat Fact Sheets: Colon and Rectum, http:// seer.cancet.gov/statfacts/html/colorect.html (last visited Jan. 27, 2012).

[FN4]. *See Id.*

[FN5]. *See Id.*

[FN6]. *See Id.*

[FN7]. *See Age Adjusted Death Rates for United States, 2008 Colon & Rectum* http://statecancerprofiles.cancer.gov/map/map.noimage.php (choose area: US By State; choose data group: Cancer Rates; choose cancer: Colon & Rectum; choose data type: Mortality; choose race/ethnicity: All Races (incl. Hisp); choose sex: Both Sexes; choose age group: All Ages; choose year range: Latest single year (US by state); then Generate Map) (last visited Jan. 27, 2012).

[FN8]. *See* Historical Trends (1975 to 2008), http:// statecancerprofiles.cancer.gov/historicaltrendjoinpoint.noimage.html (choose area: United States; choose cancer: Colon & Rectum; chose data type: Mortality; choose race/ethnicity: All Races (incl. Hispanic); choose sex: Both Sexes; choose age group: All Ages; then Generate Graph) (last visited Jan. 27, 2012).

[FN9]. Bernard Levin, et al., *Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: a Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology*, 58 CA: CANCER J. CLINICIANS 130, 130-160 (2008).

[FN10]. Lisa C. Richardson, et. al., *Vital Signs: Colorectal Cancer Screening Incidence, and Mortality United States, 2002-2010*, 60 MORBITY MORTALITY WKLY REP. 884, 884-89 (2011).

[FN11]. Deepa Naishadham, et al. *State Disparities In Colorectal Cancer Mortality Patterns In the United States*, 20 CANCER EPIDEMIOLOGY BIOMARKERS PRESERVATION 1296, 1296-302 (2011).

[FN12]. Such economic reasons are discussed below and have been examined in Debroah Schrag, *The price tag on progress-- chemotherapy for colorectal cancer*, 351 NEW ENG. J. MED. 317, 317-19 (2004); Miriam Koopman et. al, *Sequential Versus Combination Chemotherapy with Capecitabine, Irinotecan, and Oxaliplatin in Advanced Colorectal Cancer (CAIRO): A Phase III Randomised Controlled Trial*, 370 LANCET 135, 135-142 (2007); Matthew T. Seymour et al. *Different Strategics of Sequential and Combination Chemotherapy for Patients with Poor Prognosis Advanced Colorectal Cancer (MRC FOCUS): a randomised controlled trial* (pts 1 & erratum), 370 LANCET 143, 143-152, 566, 566 (2007).

[FN13]. See U.S. Preventive Services Task Force, *Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement*, 149 ANNALS INTERNAL MED. 627, 627-637 (2008).

[FN14]. CDC-Colorectal Cancer Screening Rates, http:// www.cdc.gov/cancer/colorectal/statisticsscreening_rates.htm (last visited January 27, 2012).

[FN15]. *See Id.*

[FN16]. *See* Murtaza Parekh, A. Mark Fendrick, & Uri Ladabaum, *As tests evolve and costs of cancer care rise:*

reappraising stool-based screening for colorectal neoplasia, 27 ALIMENT PHARMACOL & THERAPEUTICS 697, 709 (2008).

[FN17]. Theodore R. Levin et. al., *Organized Colorectal Cancer Screening in Integrated Health Care Ststrems*, 33 EPIDEMIOLOGICAL REV. 101, 101-110 (2011).

[FN18]. E. Thiis-Evensen et. al., *Population Based Surveillance by Colonoscopy: Effect on the Incidence of Colorectal Cancer: Telemark Polyp Study I*, 34 SCANDINAVIAN J. GASTROENTEROLOGY 414, 414-20 (1999).

[FN19]. *See Id.*

[FN20]. *See Id.*

[FN21]. *See Id.*

[FN22]. *See Id.*

[FN23]. *See Id.*

[FN24]. *See Id.*

[FN25]. *See* Levin, *supra* note 17.

[FN26]. *See* Toshitaka Takeshita, *Immunological FOBT Used for Mass Screening in Japan*, 1 Nagase Med. Update 1, 1--4 (2001) available at http:// www.nagase.com/newsletters/medical/default.asp; *publication of summary of FIT testing since 2003*.

[FN27]. For worldwide results, *see* Victoria S. Benson et al., *Colorectal Cancer Screening: a Comparison of 35 Initiatives in 17 Countries*, 122 INT'L J. CANCER 1357, 357-1367 (2008). For the United States, *see* Levin, *supra* note 17.

[FN28]. Zohar Levi et al., *Sensitivity, but not Specificity, of a Quantitative Immunochemical Fecal Occult Blood Test for Neoplasia is Slightly Increased by the Use of Low-Dose Aspirin, NSAIDs, and Anticoagulants*, 104 AM. J. GASTROENTEROLOGY 933, 933-938 (2009).

[FN29]. *See* Levin, *supra* note 17; *see also* James E. Allison et al., *A Comparison Of Fecal Occult-Blood Tests For Colorectal-Cancer Screening*, 334 NEW ENG. J. MED. 155, 155-59 (1996); James E. Allison et al. *Screening for Colorectal Neoplasms with New Fecal Occult Blood Tests: Update on Performance Characteristics* 99 J. NAT'L CANCER INST. 1462, 1462-70 (2007).

[FN30]. *See Id.*

[FN31]. *See Id.*

[FN32]. *See* Takeshita, *supra* note 20; Eduardo Fenocchi et. al., *Screening for Colorectal Cancer in Uruguay with an Immunochemical Faecal Occult Blood Test*, 15 EUROPEAN J. CANCER PREVENTION 384, 384-90 (2006); S. Crotta, *Feasibility Study of Colorectal Cancer Screening by Immunochemical Faecal Occult Blood Testing: Results in a Northern Italian Community*, 16 EUROPEAN J. GASTROENTEROLOGY HEPATOLOGY 33, 33-37 (2004).

[FN33]. *See The State of Colorectal Cancer Screening and Prevention Whitepaper: National Perspectives and Federal Policies*, (January 28, 2010). http://www.olympusamerica.com/corporate/docs/CRCScreening_Prevention_Whitepaper.pdf

[FN34]. *See* Colorectal (Colon) Cancer, http:// www.cdc.gov/cancer/Colorectal/ (last visited January 25, 2012).

[FN35]. Robert H. Fletcher et. al., *Screening for Colorectal Cancer: The Business Case*, 8 AM. J. MANAGED CARE 531, 534 (2002).

[FN36]. *See State of Colorectal Cancer Screening and Prevention Whitepaper National Perspectives and Federal Policies, supra* note 32.

[FN37]. *See Id.* (noting Screening Guidelines of the American Cancer Society, American Gastroenterological Association).

[FN38]. *See Id.*

[FN39]. *See Id.* (noting Screening guidelines of the American Cancer Society, American Gastroenterological Association).

[FN40]. *See Id.*

[FN41]. *See Id.*

[FN42]. *See Id.* (Noting "this report card grades legislation only. Some states with F grades are working with insurance providers to implement voluntary programs that will ensure widespread coverage for colorectal cancer screening.")

[FN43]. *See Id.* (Noting "this report card grades legislation only. Some states with F grades are working with insurance providers to implement voluntary programs that will ensure widespread coverage for colorectal cancer screening.")

[FN44]. *See* Jolien Tol et al., *Chemotherapy, Bevacizumab, and Cetuximab in Metastatic Colorectal Cancer*, 360

NEW ENG. J. MED. 563, 563-572 (2009); *See also*, Schrag, *supra* note 12; Koopman, *supra* note 12.

[FN45]. *See* Schrag, *supra* note 12.

[FN46]. *See Id.*

[FN47]. *See Id.*

[FN48]. *See Id.*

[FN49]. See Parekh, *supra* note 16.

[FN50]. *See* Benson, *supra* note 21.

[FN51]. *See* Benson, *supra* note 21.

[FN52]. James E. Allison, *The Best Screening Test for Colorectal Cancer Is the One That Gets Done Well*, 71 GASTROINTESTINAL ENDOSCOPY 342, 342-45 (2010).

[FN53]. *See* Takeshita, *supra* note 20.

[FN54]. Study results for Kaiser Permanente Southern California should appear in publication in GUT in the second half of 2011 or early 2012. *See also WSVN, 7News Miami/Ft. Lauderdale* (Sunbeam Television Corp. broadcast Mar. 29, 2010), available at http://www.youtube.com/watch?v=4RpUeao3NOo (Interviewing gastroenterologist Dr. David Weiss of Gastroenterology Consultants).

[FN55]. The study was authored primarily by Dr. T.R. Levin, *see* Levin, *supra* note 17.

[FN56]. *See* Levin, *supra* note 17.

[FN57]. Fletcher, *supra* note 34, at 535.

[FN58]. *See, The State of Colorectal Cancer Screening and Prevention Whitepaper National Perspectives and Federal Policies, supra* note 32.

[FN59]. *See Gross v. Friedman*, 73 NY2d 721, 722-723 (1988); *Heller v. Weinberg*, 77 AD3d 622 (2d Dep't 2010); *Myers v. Ferrara*, 56 AD3d 78, 83 (2d Dep't 2008); *Musiaro v. Clarkstown Med. Assoc*, 2 AD3d 698 (2d Dep't 2003); *Dolan v. Hdlpern*, 73 AD3d 1117 (2d Dep't 2010); *Anonymous v. WyckoffHgts. Med. Ctr.*, 73 AD3d 1104 (2d Dep't 2010); *Dunn v. Khan*, 62 AD3d 828, 829 (2d Dep't 2009); *Rosen v. John J. Foley Skilled Nursing Facility* 45 AD3d 558, 559 (2d Dep't 2007).

[FN60]. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

[FN61]. *See Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (addressing the issue of whether a polygraph test should be admitted as evidence).

[FN62]. The States following the *Frye* standard include Alabama, Arizona, California, Florida, Illinois, Kansas, Maryland, Michigan, Minnesota, New Jersey, New York, Pennsylvania, and Washington.

[FN63]. There are over forty studies which clearly illustrate that that FIT testing has been subject to peer review and publication.

[FN64]. *See* Levin, *supra*, note 17, at 101 and 103. (Noting that "organized fecal immunochemical test screening has been associated with an increase in annually detected CRC's, almost entirely because of increased detection of localized stage cancer" and providing charts outlining the performance of the FIT test in predicting lesions in the lower gastrointestinal tract).

[FN65]. *See* Medical Device Databases, http:// www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm (last accessed January 26, 2012) ("Medical device manufacturers are required to submit a premarket notification or 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected.")

[FN66]. There are over 40 studies which support that FIT testing is generally accepted within the relevant scientific community as the preferred screening method to detect blood in the stool.

[FN67]. *See The State of Colorectal Cancer Screening and Prevention Whitepaper National Perspectives and Federal Policies, supra*, note 32.

[FN68]. *See* CDC--Colorectal Cancer Trends, http:// www.cdc.gov/cancer/Colorectal/statistics/trends.htm (last visited January 26, 2012).

[FN69]. *American Cancer Society, Colorectal Cancer Facts & Figures* 2008-2010 15 (2008), *available at* http://www.cancer.org/acs/groups/content/ @nho/documents/document/f861708finalforwebpdf.pdf (providing in Table 7 the statistics for colorectal cancer screening among adults aged 50 and older based on National Health Interview Survey Public Use Data File 2005, National Center for Health Statistics, Centers for Disease Control and Prevention, 2006).

[FN70]. The *State of Colorectal Cancer Screening and Prevention Whitepaper National Perspectives and Federal Policies, supra*, note 32.

[FN71]. *Id.*

[FN72]. Carrie N. Klabunde et. al., *Colorectal Cancer Screening by Primary Care Physicians: Recommendations and Practices, 2006-2007*, 37 AM. J. PREVENTATIVE MED. 8, 8 (2009).

[FN73]. *See Id.*

[FN74]. *See* Parekh, *supra* note 16, at 709.

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