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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Title:	CHECKPOINT BLOCKADE AND MICROSATELLITE INSTABILITY		

DECLARATION OF DR. RICHARD GOLDBERG

I currently hold the opinions expressed in this declaration. However, my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 1/22/2025

By: DocuSigned by: Richard Goldberg 85DD6D9A5B774E5...
Richard Goldberg, M.D.

JHU 2090
Merck Sharp v. Johns Hopkins
IPR2024-00650

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

TABLE OF CONTENTS

I. QUALIFICATIONS 4

II. LEGAL FRAMEWORK ON WHICH MY OPINIONS ARE BASED 15

III. KEYTRUDA AND ITS MSI-H RELATED FDA-APPROVED INDICATIONS SATISFIED A LONG-FELT, UNMET NEED FOR EFFECTIVE TREATMENTS FOR MSI-H CANCER 18

A. Background of MSI-H Cancers 18

1. History of MSI-H Cancers 18
2. The Epidemiology of Colorectal Cancer and Inherited Cancer Susceptibility 20
   a. Clinical Trial Endpoints 22
3. Cancer Staging and Survival Rates 23

B. Therapies Available for Cancer Patients in 2010-2015 26

1. Chemotherapy and targeted therapy in CRC 26
2. Constructing chemotherapy +/- targeted therapy regimens 31
3. Third and Later Line Therapy 33

C. Available Therapies in Other Cancer Types 2010-2015 34

D. No Effective Immuno-Oncology (IO) Treatments for Cancer Generally Prior to JHU's Clinical Trial 36

1. CRC patients in the Topalian Phase I trial 39
2. Generating a hypothesis to explain why one CRC patient responded to nivolumab 40
3. Thinking outside the box 41
4. Finding support for a trial in MSI-H cancer patients 42
5. The Results of the Hopkins Study 43

E. The Impact of Pembrolizumab for Treating MSI-H Tumors 49

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

1. Individual Patients.....49
2. Impact on Clinical Practice.....52
a. MSI Testing Before and After 2017.....52

IV. NEXUS.....56

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

I. QUALIFICATIONS

1. My name is Richard Goldberg. I am a medical oncologist. A copy of my CV is attached as Appendix A.

2. I received my A.B. *cum laude* from Harvard University in 1975 and my M.D. from the State University of New York Upstate Medical University in 1979. I trained as a Resident in Internal Medicine at Emory University Hospitals between 1979 and 1982 and then completed a fellowship in Medical Oncology at the Vincent T. Lombardi Cancer Research Center at Georgetown University between 1982 and 1984. I am board certified in Internal Medicine and Medical Oncology.

3. I have cared for cancer patients for nearly forty years focusing on patients with gastrointestinal and, particularly, colorectal cancers. Over those years, I have either treated directly or supervised the treatment of thousands of patients, including many patients who were treated with pembrolizumab. After completing my fellowship, I initially worked at the Geisinger Medical Center and Clinic in Danville, Pennsylvania for approximately ten years. While at Geisinger, I was an active practitioner caring for cancer patients, supervised residents, coordinated the research collaboration with the Mayo Clinic, and served as the Assistant and then Associate Director of the Department of Medicine.

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4. Based upon my research and clinical work, I was then recruited to the Mayo Clinic in Rochester, Minnesota, where I worked for almost another decade. While there, I served as Co-Chair of the Mayo Cancer Center Gastrointestinal Cancer Research Program, coordinating the Center's gastrointestinal clinical and research programs. During my time at the Mayo Clinic, I also ran the Gastrointestinal Cancer Committee of the North Central Cancer Treatment Group (NCCTG), an international research consortium funded by the National Cancer Institute (NCI). That group and others with which I have subsequently been affiliated (see below) develop, run, and analyze multi-institutional and often international trials to advance cancer treatment and our understanding of cancer biology. While at Mayo Clinic, while working with an international multidisciplinary research group sponsored by the NCI called the Familial Colorectal Cancer Registry, I developed an interest and expertise in cancer susceptibility syndromes such as Lynch Syndrome. Patients with Lynch Syndrome have an inherited defect in enzymes that repair errors in DNA occurring during cell replication that leads to a condition termed microsatellite instability (MSI). This finding proved to be highly relevant to the development of pembrolizumab. In addition to setting the research agenda in GI cancers for the Cancer Center and the NCCTG, I was active in teaching and mentoring residents and fellows, many of

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whom have gone on to take leadership roles at Mayo Clinic and at other cancer centers in the United States and Canada.

5. In 2003, I joined the University of North Carolina at Chapel Hill, where I served as the Richard M. Goldberg Professor of Gastrointestinal Oncology[1], Associate Director for Clinical Research of the NCI-funded Lineberger Comprehensive Cancer Center, Chief in the Division of Hematology/Oncology, and was the first Physician-in-Chief of the North Carolina Cancer Hospital that we opened during that time. During my eight years at UNC, I became the Chairman of the Cancer and Leukemia Group B (CALGB) Gastrointestinal Cancer Committee, another NCI funded cooperative oncology research group which subsequently merged with NCCTG to form the Alliance for Clinical Trials in Oncology (the Alliance). It is important to note that UNC Health Care System includes the UNC School of Medicine and that UNC Medical Center, the flagship academic medical center of UNC Health Care System, is a teaching hospital.

6. In 2011, I joined The Ohio State University Wexner Medical Center in Columbus, Ohio where I served as the first Physician-in-Chief of The James Cancer Hospital and Solove Research Institute, Associate Director of the OSU James Comprehensive Cancer Center and, for a time, as Acting Chief of the

[1] The funds for this professorship were donated by Sanofi in honor of my research contributions that led to the FDA approval of oxaliplatin in the US.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

Division of Medical Oncology. During my tenure we opened the new James Cancer Hospital, and my role there was to be the lead physician for the third largest cancer hospital in US. I also held an endowed professorship that helped to support my research. In addition, I saw patients, taught medical students, residents, and fellows and conducted research.

7. In 2017, I joined West Virginia University as the endowed DeLynn Professor of Oncology and the Director of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Center. My responsibilities at West Virginia University included managing the clinical cancer program to which we recruited nearly 40 new physicians during my tenure and that role also involved coordinating the efforts of more than 400 employees. I led the basic, clinical, and population sciences research efforts and was responsible for teaching medical and graduate students, residents, and fellows. The Cancer Institute sponsors a Cancer Cell Biology Graduate Program leading to a PhD for which I held responsibility. I retired from medical practice and my role as the Institute director at the end of 2019 to become an emeritus faculty member. I continue to mentor oncology and other faculty members in career development and the conduct of clinical research. I also have founded Oncology Developments LLC in order to provide consulting services for pharmaceutical companies developing new drugs for the treatment of GI cancers, for technology companies developing biomarkers, and to be an expert

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

witness in patent law disputes for companies or universities in need of such services.

8. As the names suggest all my workplaces were "teaching hospitals," including Geisinger Medical Center, Mayo Clinic and Hospitals, UNC Medical Center, Ohio State's James Cancer Hospital, and West Virginia University Hospital. These are institutions that engage in medical education and training, and all have their own or have an affiliation with a medical school. Such institutions are critical to our healthcare system. We rely on teaching hospitals to provide the necessary hands-on learning opportunities for medical students and residents and to provide the most sophisticated and intensive care possible while pioneering new treatments. My time at all five of these institutions thus was spent, in part, helping to train a new generation of physicians and other healthcare professionals. My teaching responsibilities included lecturing medical students, supervising residents and fellows (including in connection with their treatment of cancer patients), and mentoring young faculty members. These efforts were supported through NCI funded training grants that I submitted and was awarded on a competitive basis including a K12, T32, and R25 award. These awards help trainees initiate research careers by supporting both their first research efforts and their continuing education.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

9. Over the years, I also have served on the program and organizing committees for large international symposia, coordinated Continuing Medical Education (CME) events, presented the results of research studies, and lectured on topics related to GI cancers in venues all over the world including North America, Europe, Asia, Australia, South America, and Africa. Some examples of this include the American Society of Oncology (ASCO) annual meeting as well as ASCO's sponsored Annual GI Cancer Symposium. I have served repeatedly on the program committees for these meetings including chairing the committee for the GI Symposium. At the 10th anniversary of that meeting, I was invited to give the plenary lecture entitled Ten Years of Progress in Colorectal Cancer, an honor recognizing my contributions to the field. For nearly a decade, I ran the national Perspectives in Colorectal Cancer Symposium in addition to many other smaller congresses. I have been an invited visiting professor, lecturing and mentoring trainees, at multiple universities including Stanford, Yale, Duke, Oxford, Vanderbilt, University of Chicago, and elsewhere. I also have visited a number of nonacademic centers to lecture to general medical audiences as well as giving endowed lectureships to the public. It has been a great learning experience as well as opportunity to teach these diverse audiences.

10. Over the nearly four decades of my career, I both participated in the development of numerous antineoplastic agents and witnessed the dramatic

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evolution of medical practice, the incredible progress in oncology, and in the treatment of gastrointestinal cancers. When I began my career, there was one drug approved for the treatment of colorectal cancer: 5-fluorouracil. Today, there are more than a dozen. I dedicated much of my career to helping design, conduct, run, and report clinical trials testing new drugs and drug combinations. Some of that work led directly to new drug approvals (irinotecan, oxaliplatin, somatostatin, pembrolizumab etc.) and also supported new indications for approved drugs. Much of this effort focused on research to understand inherited cancer susceptibility syndromes, develop novel treatments, and to unravel the biologic heterogeneity of cancer with all of these efforts dedicated to improving the treatment of patients suffering from gastrointestinal cancers, particularly those with colorectal cancer.

11. I participated in the initial three arm trial funded by Johns Hopkins University and Swim Across America that treated 2 cohorts of patients with advanced, refractory colorectal cancer. Cohort A enrolled patients with tumors that manifested microsatellite instability (i.e. MSI-H) and Cohort B enrolled patients with tumors that were found to be microsatellite stable (i.e. MSS). Cohort C enrolled patients found to have tumors that manifested microsatellite instability (MSI-H) and had originated from organs other than the colon or rectum. This study was reported by Le et al. and I am a coauthor on that paper. The results of

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this trial led to the FDA approval of pembrolizumab for the treatment of tumors that manifested microsatellite instability regardless of their organ of origin. This was the first tumor agnostic (regardless of the site of origin of the primary cancer) indication ever approved by the FDA. This trial is listed on ClinicalTrials.gov and is identified there by its designated number, NCT01876511.[2]

12. I have held committee leadership roles with two NCI supported cooperative oncology groups—the North Central Cancer Treatment Group (NCCTG) and the CALGB (later the Alliance)—and was the first chair of the NCI's Colorectal Cancer Task Force. The Task Force brought together the leading researchers in gastroenterology, surgery, radiation, and medical oncology from the United States and Canada to develop the research agenda for the NCI supported National Clinical Trials Network. I also represented the Task Force on the Gastrointestinal Cancer Steering Committee that coordinated all of the NCI's clinical trial portfolio in GI cancer. As Chair of the Gastrointestinal Cancer Committee of the NCCTG, I was responsible for developing the research agenda for collaborating physicians around the United States and Canada who combined efforts to advance the treatment for our patients. My current role in the Alliance is

[2] NCT01876511, "Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C)," ClinicalTrials.gov (June 10, 2013), available at https://clinicaltrials.gov/study/NCT01876511?tab=history&a=1, (EX1005).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

the Associate Group Chair for Cancer Center Collaborations and I serve on the leadership team and the board of the Alliance and the Alliance Foundation.

13. In my positions with both the NCCTG and the Alliance, I also have worked with a number of additional national clinical trial cooperative groups like the Eastern Cooperative Oncology Group (ECOG, now known as ECOG-ACRIN), The National Surgical Breast and Bowel Group (NSABP), which is now known as NRG, and the Cancer and Leukemia Group B (CALGB) to organize and run trials of various oncology therapies. Cooperative groups are critical to oncology drug development in the United States.

14. In each of the cancer centers that I have worked in we also develop clinical trials with pharmaceutical companies. These studies are often Phase I (designed to assess safety while also evaluating efficacy as a secondary endpoint) or early Phase II studies (designed to assess activity and safety in a more homogenous group of patients such as patients with advanced colorectal cancer). The clinical development of a new cancer therapy is an expensive, meticulous, and difficult process. Large cooperative groups often aid those efforts by running large clinical trials. Not only do these organizations have the resources and relationships necessary to help write, garner approval for, run and analyze large trials, but they generally are comprised of many true experts in the field with decades of experience. Sometimes cooperative groups and individual cancer centers or small

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

consortia of cancer centers will partner with pharmaceutical companies. In most cases the company will provide funding for as well as their drug to conduct such studies. In the study in question, NCT01876511, Merck provided the pembrolizumab used in the study but did not fund the trial which was underwritten by Johns Hopkins University and a charitable group that raises money to fund cancer research, Swim Across America. In general, the pharmaceutical company may work with the cooperative group or cancer center to share its own experience with the drug and its toxicities and collaborate on study design with the cooperative group, the cancer center, the NCI, and the Food and Drug Administration (FDA). In some but not all cases, the ultimate design and protocol are left to the expert oncologists and scientists at the cooperative group or cancer center who are ultimately overseen by the NCI and FDA. In this case, Merck initially only approved the protocol which was written by Johns Hopkins University researchers and provided pembrolizumab for the trial.

15. I also have served and continue to serve on several editorial boards of peer-reviewed journals, and (as detailed in my CV) have more than 700 publications in the field. Many of these papers have been published in high impact journals such as the New England Journal of Medicine, Science, the Lancet, the Journal of the American Medical Association (JAMA), the Journal of Clinical Oncology, the Annals of Oncology and others. I serve as a Section Editor for GI

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Cancers that involves approving and updating multiple chapters across the spectrum for UpToDate and I was recently promoted to Executive Editor for their oncology program. UpToDate is an online comprehensive medical textbook that is frequently used as a reference by MDs at all levels to provide the latest in evidence-based medicine. My CV provides a more exhaustive recounting of my professional experience in the clinical research of gastrointestinal cancers and my contributions to the medical literature in this field.

16. As I noted above, I have cared directly for or supervised the care of many patients receiving pembrolizumab during the conduct of this trial and since its FDA approval to treat MSI-H colorectal cancer and MSI-H tumors originating outside the colon or rectum in the US. Over that period, I also have attended and spoken at dozens of professional conferences, lectures, and meetings at which pembrolizumab, its use, and/or the management of its toxicities were discussed.

17. This is the third patent case for which I have provided expert opinion testimony. Prior to Johns Hopkins University's retention of me as an expert in this case, I have testified by declaration in a patent law dispute on behalf of Genentech in a suit that they initiated against Amgen regarding patent infringement related to the sale of the biosimilar to bevacizumab known as Mvasi. That lawsuit was settled prior to initiation of a trial. I testified in federal court in Delaware on behalf of Taiho in its successful defense of its patents regarding Lonsurf, a drug used to

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treat patients with treatment refractory colorectal cancer and gastric cancer. I have also served as an expert witness in several malpractice trials (none of which occurred within the last four years). I am being compensated at a rate of $900 per hour ($450 per hour for travel). My compensation does not depend in any way on the outcome of this case.

II. LEGAL FRAMEWORK ON WHICH MY OPINIONS ARE BASED

18. I understand that in a proceeding before the U.S. Patent Trial and Appeal Board (PTAB), patent challengers (i.e. petitioners) must prove by a preponderance of the evidence that each Asserted Claim of the Asserted Patents is invalid.

19. I understand that a claim may be found invalid as obvious "if the differences between the subject matter sought to be patented and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

20. I understand that an obviousness inquiry requires consideration of the following factors: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) the objective indicia of nonobviousness.

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21. I understand that alleged prior art references are to be looked at from the viewpoint of a person of ordinary skill in the art. I also understand that a party challenging the validity of a patent claim composed of several limitations does not meet its burden by merely demonstrating that each of the claim's limitations was independently known in the prior art. Identifying a reason why those elements would be combined can be important because inventions in many instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

22. I further understand that to prove obviousness there must be a reasonable expectation of success in making the claimed invention in light of what was known in the prior art.

23. I understand that objective indicia evidence may be the "most probative evidence of nonobviousness," and that a fact finder must consider such evidence before making an obvious determination. A non-exhaustive list of such objective indicia includes: (1) the commercial success of the patented invention; (2) a long-felt but unresolved need that was satisfied by the claimed invention; (3) the failure of others to develop or practice the claimed invention; (4) skepticism of the claimed invention by those in the relevant field; (5) unexpected or surprising results from the claimed invention; (6) copying of the claimed invention by others; (7) acceptance of the claimed invention, as shown, for example, by praise from

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

others in the industry, adoption of the claimed invention, or licensing of the claimed invention; and (8) teaching away from the claimed invention.

24. I understand that for objective indicia to be probative of non-obviousness, the patentee must show a "nexus," or factual connection, between the objective indicia and the claimed invention. For example, there must be a nexus between the claimed invention and its commercial success, i.e., the commercial success must be due to the inventive aspects of the claimed invention. I understand the nexus requirement is satisfied if, for example, the patentee shows that the thing that has commercial success is the invention disclosed and claimed in the patent.

25. I understand that obviousness is analyzed from the perspective of one skilled in the art at the time the invention was made. In other words, the use of hindsight is not permitted.

26. I have been advised by counsel for Johns Hopkins University to base my opinions on the viewpoint of a person of ordinary skill in the art in as of July 2015, and have done so in my analysis below. I understand that Johns Hopkins University contends that a person of ordinary skill in the art on or about the claimed priority date of the '491 Patent would have had a M.D. or graduate-level degree (or equivalent work experience) in the fields of immunology, genetics, or a related field and at least five years of experience (i) conducting immunology research relating to oncology, (ii) conducting genetics research relating to

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

oncology, or (iii) developing and conducting clinical trials on novel cancer therapies in those fields. I understand that less work experience may be compensated by a higher level of education and vice versa. Under this definition, I qualified as a person of ordinary skill well before July 2015.

III. KEYTRUDA AND ITS MSI-H RELATED FDA-APPROVED INDICATIONS SATISFIED A LONG-FELT, UNMET NEED FOR EFFECTIVE TREATMENTS FOR MSI-H CANCER

27. In my opinion, Keytruda (pembrolizumab) and its microsatellite instability-high (MSI-H) related FDA-approved indications,[3] which embody the inventions claimed in the ’491 Patent, fulfilled a long-felt, but previously unmet need for an effective treatment for MSI-H cancer, with the most pressing need being treatments for metastatic cancer.

A. Background of MSI-H Cancers

1. History of MSI-H Cancers

28. The notion that certain families exhibit a propensity to develop colorectal and endometrial cancers, and that these cancers often manifested at much younger ages than usual, was first advanced in the 1960s by Dr. Henry Lynch, a clinical oncologist with genetics training, practicing at Creighton University in Omaha. Dr. Lynch treated many cancer patients who came from large families common in rural Nebraska’s farm communities. Some of these

[3] An “indication” is an FDA approved use of a drug for a specific disease or condition and is described on the drug label.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

families had multiple afflicted members who died of early onset colon cancer or endometrial cancer. The families that had these clusters of young onset CRC and endometrial cancers were designated as having what came to be known as "Lynch Syndrome" based on their clinical histories. He, therefore, hypothesized that these cancers could be the result of an inherited cancer susceptibility syndrome. Dr. Lynch was not a laboratory scientist, so his findings were descriptive. He did not discover the molecular biology that was causative himself. Initially his observations were met with tremendous skepticism by a medical community that favored environmental exposures rather than genetics as the causative force behind the development of cancer.[4]

29. Later, laboratory investigators including Albert de la Chapelle, who I worked with at Ohio State, Bert Vogelstein at Johns Hopkins, and investigators from Sweden elucidated the biologic abnormality of the mismatch repair defect that is the causative genetic abnormality that results in Lynch syndrome and is observed in some microsatellite high colorectal cancers.[5] Other patients with colorectal cancer did not have an inherited genetic susceptibility; they acquired

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[4] Boland, "Henry T. Lynch, MD (January 4, 1928 – June 2, 2019)," Gastroenterology (Oct. 2019).

[5] Aaltonen et al., "Replication errors in benign and malignant tumors from hereditary nonpolyposis colorectal cancer patients," Cancer Res., 54:1645–1648 (1994), (EX2277); Aarnio et al., "Cancer risk in mutation carriers of DNA-mismatch repair genes," Int. J. Cancer 81:214–218 (1999), (EX2278).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

their mismatch repair defect for unknown reasons, likely the result of some interplay between hereditary factors and as yet unidentified mutagen exposure.

30. Despite the awareness of MSI-H cancers for more than 25 years, no treatments tailored for MSI-H cancer were available prior to FDA's 2017 approval of pembrolizumab for treating MSI-H cancers. Moreover, prior to JHU's clinical study, no studies indicated that treatment of MSI-H cancers with PD-1 inhibitors would be successful or that MSI-H would be a useful biomarker for identifying patients who would respond to treatment with pembrolizumab or any other drug regardless of cancer type.

2. The Epidemiology of Colorectal Cancer and Inherited Cancer Susceptibility

31. CRC is a representative specific example used here to illustrate the long felt need for an effective treatment for MSI-H cancers arising from any organ in the human body. CRC is the third most common cancer and the second most lethal cancer in the US and worldwide[6]. While its incidence increases with advancing age, the incidence in older patients is falling as screening tests that detect, and permit excision of, premalignant polyps are more widely implemented[7].

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[6] Bray et al., "Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries," CA Cancer J Clin. (Apr. 4, 2024), (EX2091).

[7] Zeineddine et al., "Survival improvement for patients with metastatic colorectal cancer over twenty years," NPJ Precis Oncol. (Feb. 13, 2023), (EX2092).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

Simultaneously, the CRC incidence rate is rising in younger patients below the age of 50, a phenomenon that remains largely unexplained[8]. A subset of younger patients inherited their cancer susceptibility, and they have a condition such as Lynch Syndrome or another hereditary syndrome that predisposes them to develop CRC at an early age[9]. As discussed above, Lynch syndrome is a familial condition in which errors that occur as DNA is replicated during cell division cannot be repaired as they are in normal individuals. Patients with Lynch Syndrome often develop cancer early in life and are predisposed to develop cancers in multiple organs, but the most common site of disease is CRC. It is estimated that about 3-5% of CRC patients have Lynch Syndrome Cancers, and individuals with Lynch Syndrome tend to develop cancers that are less responsive to standard chemotherapy agents.[10] Regardless of the reason for developing cancer, younger individuals with CRC are characterized as having early onset colorectal cancer.

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[8] Patel et al., "The rising tide of early-onset colorectal cancer: a comprehensive review of epidemiology, clinical features, biology, risk factors, prevention, and early detection," Lancet Gastroenterol Hepatol (Jan. 25, 2022), (EX2093); Sinicrope, "Increasing Incidence of Early-Onset Colorectal Cancer," N Engl J Med (April 21, 2022), (EX2094).

[9] Sinicrope, "Lynch Syndrome-Associated Colorectal Cancer," N Engl J Med. (Aug. 23; 2018), (EX2095).

[10] Sargent et al., "Defective mismatch repair as a predictive marker for lack of efficacy of fluorouracil-based adjuvant therapy in colon cancer," J Clin Oncol. (Jul. 10, 2010), (EX2096).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

32. Most patients with advanced CRC regardless of their age at diagnosis did in 2010-15, and still do in 2024, succumb to their disease within several years of diagnosis. Prior to the discovery that PD-1 inhibitors can be extremely effective in some, but not all, patients in the Lynch subgroup by the JHU research team and their collaborators, Lynch Syndrome patients and patients with an acquired mismatch repair defect with CRC had few effective options to stem the progression of their disease. Even with these discoveries there remains unmet needs for people with CRC, particularly among those with mCRC.

a. Clinical Trial Endpoints

33. Clinical trials endpoints defined by the National Cancer Institute (NCI) in the US include response rate (RR, the number of patients manifesting tumor shrinkage divided by the number of patients given a particular treatment in a study), progression free survival (PFS, the time interval between starting a treatment and the detection of worsening disease), and overall survival (OS, the time from treatment initiation to death). PFS and OS are generally expressed as the median time it takes for the entire pool of patients enrolled in a trial who are treated with a specific intervention to reach these endpoints. The rate of 5-year OS is also an important benchmark as recurrence of CRC is unusual after that long a time interval.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

3. Cancer Staging and Survival Rates

34. CRC, along with other types of cancers, is divided into Stages I-IV using a classification system which is updated regularly through consensus by expert panels convened by the American Joint Commission on Cancer (AJCC).[11] With recent advances in surgery, drug treatments, and radiation the cure rates for localized CRC have been increasing over time. Currently, in 2024, the cure rates for Stage I disease (limited to the inner lining of the colon or rectum) are ~95%, Stage II disease (limited to the two outer layers of the colon or rectum) ~85%, and Stage III disease (limited to the colon or rectum and nearby regional lymph nodes) ~ 72%. These statistics have not improved significantly in the last decade.

35. Stage IV CRC denotes CRC that has spread beyond the colon or rectum and regional lymph nodes to involve organs outside of the confines of the colon adjacent to the site of origin of the primary tumor or to distant organs. A classification as Stage IV CRC indicates that a patient has metastatic disease (mCRC). Almost 25% of CRC cases are diagnosed at a metastatic stage, and 50%

[11] I am the current chair of the AJCC staging panel for appendix, colorectal, and anal cancers and have worked with the AJCC for nearly twenty years. Our expert panel is currently evaluating the current staging system described below. *See* Keung et al., "The eighth edition American Joint Committee on Cancer (AJCC) melanoma staging system: implications for melanoma treatment and care," Expert Rev Anticancer Ther. (Aug. 18, 2018), (EX2097).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

of patients will develop metastasis over time.[12] A subset of patients with Stage IV disease (10-20%) will have limited spread of their cancer that is amenable to resection, ablation, drug treatment, and/or radiation. Patients in this subgroup of Stage IV have traditionally had the greatest potential to become long term survivors among people with mCRC, although the subset of people with MSI-H CRC tumors now have the greatest potential for long term survival due to the JHU team's discovery[13]. Long term survival in patients with stage IV CRC has been and remains rare, however, particularly in patients who are not candidates for resection or ablation of their limited metastatic sites (see below). At least that was the case prior to the discovery that pembrolizumab was highly effective and often curative for treatment of mCRC in patients with tumors that are MSI-H.

36. Survival rates in Stage IV cancers of other types are similarly low, with the exception of testicular cancer.

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[12] Ogunwobi et al., "Biomarkers in colorectal cancer: current research and future prospects," Int. J. Mol. Sci. 21, 1–20 (July 2020), (EX2098).
[13] Kong et al., "Prolonged surveillance of colorectal cancer patients after curative surgeries beyond five years of follow-up," Ann Transl Med (Oct. 8, 2019), (EX2099).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

Cancer Type	New Cases[14]	Estimated Deaths[15]	Stage IV 5-year Survival %[16]
Oral Cavity & Pharynx	45,780	8,650 (18.9%)	33.5 & 39%
Esophageal	16,980	15,590 (91.8%)	4.8%
Gastric	24,590	10,720 (43.6%)	5.2%
Small Bowel	9,410	1,260 (13.4%)	5%[17]
Cholangiocarcinoma	10,910	3,700 (33.9%)	3%[18]
Liver/Intrahepatic Bile Duct	35,660	24,550 (66.8%)	2.4%
Pancreatic/Ampullary	48,960	40,560 (82.3%)	2.7%
Breast	224,190	40,730 (18.2%)	27%
Ovarian	21,290	14,180 (66.6%)	29%
Endometrial	54,870	10,170 (18.5%)	9%
Cervical	12,900	4,100 (31.8%)	17.2%
Prostate	220,800	27,540 (12.5%)	30%
Bladder	74,000	16,000 (21.6%)	4.8%
Testicular	8,430	380 (4.5%)	73.7%

[14] Siegel et al., "Cancer statistics, 2015," CA Cancer J Clin. (Jan. 5, 2015), (EX2251).
[15] *Id.*
[16] Noone et al. (eds), "SEER Cancer Statistics Review (CSR), 1975-2015," National Cancer Institute. Bethesda, MD, based on November 2017 SEER data submission, posted to the SEER web site, April 2018, available at https://seer.cancer.gov/csr/1975_2015/, (EX2252).
[17] Small bowel cancer is not included in the National Cancer Institute SEER Cancer Statistics Review, but one estimate is 5% in 2024. *See* "Survival statistics for small intestine cancer," Canadian Cancer Society, available at https://cancer.ca/en/cancer-information/cancer-types/small-intestine/prognosis-and-survival/survival-statistics, (EX2253); *see also* Chen et al., "Small bowel adenocarcinoma," Clin. Colon Rectal Surg. (2018), (EX2279).
[18] Cholangiocarcinoma is not included in the National Cancer Institute SEER Cancer Statistics Review, but the ACS estimate is 3% in 2024. *See* "Survival Rates for Bile Duct Cancer," American Cancer Society, available at https://www.cancer.org/cancer/types/bile-duct-cancer/detection-diagnosis-staging/survival-by-stage.html, (EX2254).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

B. Therapies Available for Cancer Patients in 2010-2015

1. Chemotherapy and targeted therapy in CRC

37. Again, CRC is an instructive example used here to illustrate the types of therapies available for cancer patients in 2010-2015. Before the priority date of the ’491 Patent, which I have been informed by counsel was July 10, 2015, clinical oncologists had two options for the management of mCRC, relying on two classes of drugs: cytotoxic chemotherapy agents and targeted therapies. Notably, both MSI-H and MSS (microsatellite stable patients) metastatic cancer patients were treated the same way when using these drugs. As previously noted, there was no treatment specifically tailored for MSI-H CRC.

38. Cytotoxic drugs interfere with cell division and their effects often do not discriminate between dividing cancer cells and dividing host cells. These drugs typically cause side effects because of their interference with the division of rapidly dividing cells in organs such as the bone marrow and gastrointestinal tract. Cytotoxic drugs available for the treatment of mCRC in the relevant time interval included 5-FU, capecitabine, irinotecan, and oxaliplatin. The common side effects associated with these cytotoxic drugs included nausea, vomiting, diarrhea, decreased appetite, immune suppression, anemia, susceptibility to infection, numbness and tingling in fingers and toes, fatigue, allergic drug reactions, and other toxicities.

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39. Targeted therapies are designed to engage with a specific cellular process most often by binding to a protein expressed on the surface of tumor cells. Targeted therapies available for treatment of mCRC at that time included bevacizumab, ziv-aflibercept, cetuximab, and panitumumab. Drawbacks of these drugs included increased chances of bleeding or developing blood clots, rash, nausea, vomiting, fatigue, allergic drug reactions, and others.

40. The first active chemotherapy agent used to treat CRC, 5-Fluorouracil (5-FU), was developed in the early 1970s. In the era when 5-FU was the only available active drug for treatment of patients with mCRC, the median survival was ~12 months[19]. Only ~ 1% of patients treated on clinical trials in this era were alive 5 years after diagnosis, *i.e.* 5-year OS of 1%.[20]. A drug that is in the same family of agents as 5-FU that can be administered orally, called capecitabine, was FDA approved in 1998 and is used interchangeably with 5-FU. The addition of a second novel drug that was FDA approved in 1996, irinotecan, is frequently administered in combination with 5-FU, a regimen referred to as IFL. These two

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[19] "Modulation of fluorouracil by leucovorin in patients with advanced colorectal cancer: evidence in terms of response rate," Advanced Colorectal Cancer Meta-Analysis Project (June 10, 1992), (EX2100).

[20] Dy et al., "Long-term survivors of metastatic colorectal cancer treated with systemic chemotherapy alone: a North Central Cancer Treatment Group review of 3811 patients," N0144, Clin. Colorectal Cancer (Apr. 8, 2009), (EX2101).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

agents combined led to an improved median OS of 14.8 months and a 5-year OS to ~3.8%.[21]

41. In 2004 data from clinical trials testing two important new regimens that led to incremental benefits were published. First, the addition of the anti-VEGF (vascular endothelial growth factor) targeted monoclonal antibody bevacizumab to a regimen of irinotecan and 5-FU (i.e. IFL) ushered in the era of targeted therapies using monoclonal antibodies in the treatment of CRC. Bevacizumab targets the development of blood vessels (angiogenesis) that must provide a blood supply to tumors to enable their growth and spread. It was a novel targeted agent at the time it was introduced in that it does not target cancer cells but rather the ingrowth of blood vessels into tumors. Treatment with the IFL plus bevacizumab regimen led to a median OS of 20.3 months (5-year OS not reported).[22]

42. The second advance arose from the development and testing of Oxaliplatin, a platinum-based chemotherapy agent, that must be combined with 5-FU (FOLFOX) or capecitabine (CapeOX) to be effective. Data from the NCI

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[21] Saltz et. al., "Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer," Irinotecan Study Group, N. Engl. J. Med. (Sept. 28, 2000), (EX2102); Sanoff et al., "Five-year data and prognostic factor analysis of oxaliplatin and irinotecan combinations for advanced colorectal cancer: N9741," J. Clin. Oncol. (Dec. 10, 2008), (EX2103).

[22] Hurwitz et al., "Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer," N. Engl. J. Med. (June 3, 2004), (EX2104).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

funded trial N9741 (for which I was the lead author and principal investigator) indicated that patients with mCRC treated with the oxaliplatin-based FOLFOX regimen had a median OS of 20.2 months. A subsequent analysis indicated that FOLFOX treated patients had a 5-year OS of 9.8%.[23] Also, in 2004 a monoclonal antibody targeting a cell surface protein called the EGFR (epidermal growth factor receptor), cetuximab, was approved for treatment of refractory mCRC[24]. That approval was followed in 2006 with approval of a second agent with a similar mechanism of action and efficacy results, panitumumab.[25]

43. Thus, in 2012 the approved drugs for treatment of mCRC included the chemotherapy agents 5-FU and capecitabine, irinotecan, and oxaliplatin, and the

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[23] Saltz et. al., "Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer," Irinotecan Study Group, N. Engl. J. Med. (Sept. 28, 2000), (EX2102).
[24] Saltz et al., "Phase II trial of cetuximab in patients with refractory colorectal cancer that expresses the epidermal growth factor receptor," J. Clin. Oncol. (Apr. 1, 2004), (EX2105); Van Cutsem at al., "Cetuximab and chemotherapy as initial treatment for metastatic colorectal cancer," N. Engl. J. Med. (Apr. 2, 2009), (EX2106).
[25] Van Cutsem et al., "Open-label phase III trial of panitumumab plus best supportive care compared with best supportive care alone in patients with chemotherapy-refractory metastatic colorectal cancer," J. Clin. Oncol. (May 1, 2007), (EX2107).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

targeted therapy agents bevacizumab, cetuximab, panitumumab, ziv-aflibercept,[26] and regorafenib.[27]

44. In 2017, the results of the CALGB 80405 trial that finished accruing patients in 2012 and compared initial chemotherapy paired with either cetuximab or bevacizumab in mCRC patients were published. The median OS for the cetuximab plus chemotherapy regimens was 30 months and for the chemotherapy plus bevacizumab regimens was 29 months.[28] This represented a small but important advance over the previously available treatments, but most patients with mCRC still did then and still do succumb to their disease. Based upon my work with the patient advocacy group Fight Colorectal Cancer, I understand that for patients and their family members these advances were viewed as important but insufficient to meet their needs. They are eager for medical research to find a cure in addition to finding life extending strategies that are non-curative.

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[26] Ziv-aflibercept has a similar mechanism of action as does bevacizumab and was never widely used in the US so I do not discuss it further in this report. *See* Tabernero et al., "Aflibercept versus placebo in combination with fluorouracil, leucovorin and irinotecan in the treatment of previously treated metastatic colorectal cancer: prespecified subgroup analyses from the VELOUR trial," Eur. J. Cancer (Jan. 2014) (EX2108).

[27] Benson et al., "Colon cancer, version 3.2014.," J. Natl. Compr. Canc. Netw. (July 12, 2014), (EX1009).

[28] Venook et al., "Effect of First-Line Chemotherapy Combined With Cetuximab or Bevacizumab on Overall Survival in Patients With KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial," JAMA (June 20, 2017), (EX2109).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

45. Today, in 2024 optimal patient management in patients treated on clinical trials can lead to median OS as high as 35 months, but according to statistics published by the American Cancer Society the 5-year OS now still only approaches 13%. (https://www.cancer.org/cancer/types/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html, accessed 9/24). In contrast, the 5-year OS for mCRC patients in the JHU study treated with pembrolizumab is 57.5%, representing a nearly five-fold boost in that metric.[29]

2. Constructing chemotherapy +/- targeted therapy regimens

46. Once multiple drugs become available for the treatment of a solid tumor such as CRC, the concept of lines of therapy became relevant (i.e. first-line therapy, second-line therapy, etc.). Patients receive first-line therapy until their tumors become refractory to that treatment or the toxicity becomes prohibitive. They then progress to subsequent treatment lines. In CRC, as in the treatment algorithms for most cancers, the usual initial treatment approach is to add several chemotherapy drugs together as the use of multiple agents simultaneously, a strategy that often improves outcomes over single agent treatment.[30] For example, 5-FU (or it oral equivalent capecitabine) is often paired with oxaliplatin (called

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[29] Conversation with Dr. Dung Le.

[30] McRee at al., "Optimal management of metastatic colorectal cancer: current status," Drugs (May 7, 2011), (EX2110); Lucas et al., "A decade of advances in cytotoxic chemotherapy for metastatic colorectal cancer," Clin Colorectal Cancer (Dec. 10, 2011), (EX2111).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

FOLFOX or CapeOX) or irinotecan (called IFL or FOLFIRI). Sometimes FOLFOX and FOLFIRI are combined into a three-drug regimen known as FOLFOXIRI.

47. It is common to add targeted therapies to these chemotherapy backbones. Examples are FOLFOX or FOLFIRI + bevacizumab or FOLFOX or FOLFIRI + cetuximab. In the US, it is most common to use FOLFOX or CapeOx + bevacizumab or cetuximab as first-line therapy. First-line therapy refers to the first regimen employed to treat a patient with metastatic cancer. Typically, second-line therapy would consist of an irinotecan-based regimen if an oxaliplatin-based regimen is used in the first-line or visa versa. The first-line of treatment is generally the most effective as tumors develop resistance to chemotherapy treatments as they are exposed to them. The response rate (RR) (ranging from 55-65%) and progression-free survival (PFS) (ranging from 10-12 months) for first-line therapy is higher than for second-line therapy. Response rates in second-line therapy range from 10-15% with median associated PFS of ~6-8 months and median overall survival (OS) of 10-14 months.[31]

[31] Modest et al., "Treatment sequencing in metastatic colorectal cancer," Eur. J. Cancer (March 2019), (EX2112).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

3. Third and Later Line Therapy

48. Outcomes for patients with mCRC have also been only modestly improved by the testing and FDA approval of several agents specifically for treatment of patients whose disease has become refractory to the first- and second-line regimens as described above. For example, regorafenib, a multitargeted tyrosine kinase inhibitor, was approved in 2012 and the oral agent trifluridine combined with tipiracil was approved in 2015 for treatment of refractory mCRC.[32] As is typical for agents deployed in the treatment of CRC patients with heavily pretreated cancers, the response rates associated with these two drugs were very low (<3%). In these studies, the patients received the experimental agent as third-line treatment after patients' disease had progressed on two prior drug regimens. Effective treatment options were so limited in this setting that the control arms for both studies involved no anticancer therapy and consisted of best supportive care. Patients assigned to the best supportive care arms of these trials received no anti-cancer therapy but were treated as needed according to their symptoms with pain medicines, appetite stimulants, bowel regimens, and received help in meeting their daily needs for physical and emotional assistance. A synonym for supportive care

[32] Grothey et al., "Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial," Lancet. (Jan. 26, 2013), (EX2113); Mayer et al., "Randomized trial of TAS-102 for refractory metastatic colorectal cancer," N. Engl. J. Med. (May 14, 2015), (EX2114).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

is "comfort care", care whose main goal is to help patients with limited life expectancies to live as well as possible given their terminal illnesses.

49. Until regorafenib and trifuridine/tipiracil were approved there was no effective mCRC third-line therapy. The median OS with best supportive care in both studies was ~ 4.5 months. With regorafenib treatment the response rate was 2.4% and the median OS was 6.4 months and with trifluridine/tipiracil the response rate was 1.6 % and the median OS was 7.1 months.[33] While both agents were quickly adopted into practice, the benefits from treatment with either option were limited and patients, patient advocacy groups, and practitioners all were and still are clamoring for more and better treatment options. There was then and remains now an unmet medical need to improve outcomes for patients with mCRC who are not MSI-H/dMMR and therefore are not eligible for treatment with PD-1 inhibitors.

C. Available Therapies in Other Cancer Types 2010-2015

50. The evolution of treatment of other solid tumors originating elsewhere in the body generally follow the principles described above for CRC. (Solid tumors originate in body organs, as distinct from tumors that originate in the bone marrow

[33] Grothey et al., "Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial," Lancet. (Jan. 26, 2013), (EX2113); Mayer et al., "Randomized trial of TAS-102 for refractory metastatic colorectal cancer," N. Engl. J. Med. (May 14, 2015), (EX2114).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

and are characterized mainly by the presence of malignant cells in the bloodstream. Those cancers are often classified as liquid tumors.) Initially cytotoxic chemotherapy agents were developed as single agents in the setting of treatment refractory advanced disease. Once a drug was shown to have efficacy it was most often combined with other cytotoxic agents on the principle that multiple drugs would be more effective (albeit also more toxic) than single agent treatments. Once specific drivers of the development and progression of specific cancers were discovered, drugs were designed and tested to target those drivers. These agents are often antibodies like pembrolizumab that either switch off or switch on relevant biologic processes. Often these targeted therapies are combined with cytotoxic agents. In testicular cancer, for example, combination chemotherapy proved to be highly effective, leading to 5-year survival rates exceeding 70% (see table above) even in the setting of advanced disease. In most other cancers 5-year overall survival rates remained less than 10% for patients with advanced disease despite the administration of combinations of cytotoxic and targeted agents (see table above). In contrast, the 5-year OS for non-CRC patients in the JHU study treated with pembrolizumab according to the method described in the ’491 Patent is 50.3%, again representing a nearly five-fold boost in that metric.[34]

[34] Conversation with Dr. Dung Le.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

D. No Effective Immuno-Oncology (IO) Treatments for Cancer Generally Prior to JHU's Clinical Trial

51. At the same time as cancer patients were facing these limited treatment options, immuno-oncology was beginning to offer a new hope for patients in which it would be effective. The term immuno-oncology treatment refers to manipulating the host's immune system to recognize and destroy tumors. The agents that modulate the immune system are often referred to as IO drugs.[35]

52. Before the priority date of the '491 Patent, Immuno-Oncology (IO) agents were in development by laboratory- and clinic-based research teams working in both academia and industry. Clinical trial findings from that era led to approvals of a new class of IO drugs that allowed oncologists to finally harness the immune system for cancer treatment after decades of study during which there had not been success in that arena. These new drugs work differently than the previously developed chemo- and targeted therapies in that they recruit the patient's own immune system to kill cancer cells. Their discovery and clinical development ushered in a new era in immune system-based cancer treatment. These new agents have been a boon for some patients, often resulting in prolonged complete remissions or cures.

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[35] Topalian et al., "Immune checkpoint blockade: a common denominator approach to cancer therapy," Cancer Cell (Apr. 13, 2015), (EX1013).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

53. These discoveries changed and continue to change the paradigm for treatment of people with solid tumors originating from a multitude of different organs. However, they have only been helpful for a subset of patients. Some tumors prove to be exceptionally sensitive to IO drugs, while others originating in the same organ in different patients remain totally refractory to them.

54. Multiple strategies to uncloak tumor cells so that the immune system could be employed to recognize and destroy tumors cells were tested with minimal success until the discovery of PD-1, PD-L1, and CTLA-4 inhibitory antibodies. Nivolumab and pembrolizumab are monoclonal antibodies that target PD-1, a protein present on the surface of tumor cells and of cells that are members of the immune system that reside adjacent to tumor cells. The binding of these antibodies inactivates the cloaking system that allows cancer cells to evade the immune system. Prior to JHU's clinical trial that demonstrated that PD-1 inhibitors were effective in treating MSI-H/dMMR solid tumors, PD-1 inhibitors had shown promise in melanoma and non-small cell lung cancer but had failed to be effective in treating other cancers, including CRC.

55. BMS scientists developed the first clinically effective PD-1 inhibitor, nivolumab. An initial study on the use of nivolumab, which was led by Hopkin's scientist Suzanne Topalian, enrolled 296 patients who had a variety of tumor types,

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

all with disease refractory, or resistant, to standard therapies.[36] Although this trial was mainly conducted to assess safety and tolerability, the outcomes of the treatment on the tumors harbored by these heavily pretreated patients were also assessed. The response rate (RR) in treated patients who had melanoma was 28% and in those with non-small cell lung cancer the RR was 18%. Lesser efficacy was seen in patients with other tumor types. These results were startling as most often few, if any, responses are seen in this type of a heavily pretreated patient population with tumor types that by their nature have limited sensitivity to standard chemotherapy regimens even in first-line therapy.

56. Based on these promising early indications of activity in these two tumor types and the BMS experience with nivolumab, Merck conducted its own studies using pembrolizumab in melanoma and non-small cell lung cancer. The Merck studies in patients with melanoma and non-small cell lung cancer showed similar activity as that observed with nivolumab in these diseases.[37]

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[36] Topalian et al., "Safety, activity, and immune correlates of anti-PD-1 antibody in cancer," N. Engl. J. Med. (June 28, 2012), (EX1013).

[37] Robert et al., "Pembrolizumab versus Ipilimumab in Advanced Melanoma," N. Engl. J. Med. (June 25, 2015), (EX2116); Reck et al., "Pembrolizumab versus Chemotherapy for PD-L1-Positive Non-Small-Cell Lung Cancer," N. Engl. J. Med. (Nov. 10, 2016), (EX2117).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

1. CRC patients in the Topalian Phase I trial

57. As a part of the Phase I study of nivolumab, the Topalian research team treated 14 patients with colorectal cancer (CRC) none of whom had a response to the drug.[38] During the later stages of the study an additional 19 CRC patients were treated. One of the 33 CRC patients responded to therapy.[39] Treatment of other types of cancer beyond melanoma and non-small cell lung cancer in the Topalian trials similarly failed. A response in 1/33 patients would generally be regarded as too low to justify conducting a Phase II trial to investigate the efficacy in CRC or any tumor type. Also making CRC a less interesting target for ongoing study of a PD-1 inhibitor is the fact that CRC is not associated with known mutagen exposure and therefore those tumors would not likely have the high mutational burden and high level of mutation associated neoantigens thought to possibly explain why PD-1 inhibitors worked in melanoma and non-small cell lung cancers.[40]

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[38] Brahmer et al., "Phase I Study of Single-Agent Anti–Programmed Death-1 (MDX-1106) in Refractory Solid Tumors: Safety, Clinical Activity, Pharmacodynamics, and Immunologic Correlates," J. Clinical Oncology (July 1, 2010), (EX2024).
[39] Topalian et al., "Safety, activity, and immune correlates of anti-PD-1 antibody in cancer," N. Engl. J. Med. (June 28, 2012), (EX1013).
[40] Topalian et al., "Safety, activity, and immune correlates of anti-PD-1 antibody in cancer," N. Engl. J. Med. (June 28, 2012), (EX1013).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

58. CRCs look very similar under the microscope; most are moderately differentiated adenocarcinomas (adenocarcinomas arise from organs with glands- in CRC these glands produce mucous that aids the passage of stool). Around this time, the heterogeneity of tumors was increasingly being recognized despite their homogenous appearance and the potential therapeutic implications of those differences was being explored. This exploration coincided with the improved understanding of the biologic processes that drive tumor development and tumor progression that the Vogelstein lab has focused on for decades.

2. Generating a hypothesis to explain why one CRC patient responded to nivolumab

59. Rather than simply dismissing PD-1 inhibitors' potential in CRC, Dr. Topalian and her team sought to determine if the one CRC patient who had a sustained response to treatment had any distinguishing characteristics. She and her team consulted with Bert Vogelstein and members of his scientific team. The Vogelstein lab has concentrated on elucidating genetic alterations that occur as a part of colorectal cancer carcinogenesis. Luis Diaz, a member of the Vogelstein team, proposed that the responding CRC patient might have a defect in the repair mechanism that corrects errors that occur in DNA replication as an explanation for the sensitivity of that patient's tumor to nivolumab.[41] This defect is known as

[41] David Shaywitz, "The Startling History Behind Merck's New Cancer Blockbuster," FORBES (July 26, 2017), (EX2051).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

microsatellite instability and such patients are classified as having MSI-High or MSI-H tumors. The team went back to that patient's pathologic specimen and learned that the tumor in the responding patient was, indeed, MSI-H.

3. Thinking outside the box

60. The finding that PD-1 inhibitors had the potential to be an active agent for a subset of patients with colorectal cancer (CRC) was unexpected. Even more unexpected was the finding that PD-1 inhibitors had the potential to be an active agent for all solid MSI-H tumors, let alone the sixteen specific cancers ultimately claimed in the '491 Patent. This discovery required teams of scientists at Johns Hopkins University working in different laboratories and clinics who were studying the genetics, immunology, and the treatment of colorectal cancers to go up a flight of stairs to caucus. Together they generated the hypothesis that PD-1 inhibitors would be effective treatment in the subset of CRCs and other cancers that have an inherited or acquired defect in the repair of mistakes that occur during the replication of DNA during cell division. This mismatch repair defect is inherited in patients with Lynch Syndrome but can also be acquired in patients through a process known as epigenetic silencing.[42] The JHU teams posited that this defect in DNA mismatch repair that generates abnormal sections of DNA

[42] Boland et al., "Microsatellite instability in colorectal cancer," Gastroenterology (May 2010), (EX2045).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

called microsatellites would result in an accumulation of mutations in DNA that would translate to the presence of mutated proteins on the surfaces of tumor cells that the patient's own immune system could target, like the BMS and Merck teams had observed in melanoma and small-cell lung cancer patients. Estimates are that MSI-H CRC accounts for 10-15% of people with mCRC.

4. Finding support for a trial in MSI-H cancer patients

61. I understand from conversations with the JHU scientists that when they tried to interest the research teams at both BMS and Merck in funding a trial to test their hypothesis, neither company's teams were interested. Despite this disappointing news, the Hopkins team was determined to initiate a clinical trial in CRC patients and patients with other cancer types to test their hunch. They devised a study with two cohorts of CRC patients: Cohort A: patients with MSI-H tumors and Cohort B: those with MSS (microsatellite stable patients). They included a third cohort, (Cohort C) made up of patients with tumors originating from organs other than the colon or rectum that were MSI-H. Because they were unable to obtain pharmaceutical company funding, they funded it with JHU resources and obtained additional support through a grant from the charitable organization Swim Across America.[43] Merck's support of the study was limited to providing the pembrolizumab. While the Merck team approved the study protocol,

[43] "Issue 38," The Cancer Letter, Vol. 43, No. 38 (Oct. 13, 2017), (EX2121, 4).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

the study was designed, funded, and executed by JHU researchers. To speed accrual in a group of patients with a relatively rare subtype of cancer, MSI-H tumors, they also recruited teams at collaborating institutions (including my own) who helped accrue and treat patients enrolled on the study. Without the dogged persistence of Dr. Vogelstein and his colleagues, this study would not have been done. The JHU team also patented their approach with multiple filings including the filing of the '491 Patent, which claimed a method of treating endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer and oral cancer (hereafter the "Claimed MSI-H Cancers").

5. The Results of the Hopkins Study

62. The seminal JHU sponsored study was designed in 2012 and began enrolling patients in September 2013.[44] The preliminary results were startling and unexpected leading to the publication of an interim report by Le et al published in the New England Journal of Medicine (NEJM) in on May 30, 2015.[45] To put this in context, it is unusual for the NEJM to publish Phase II studies and studies that are still in progress (and this was especially true in that era), indicating that the

[44] Conversation with Dr. Dung Le.
[45] Le, et al., "PD-1 Blockade in Tumors with Mismatch-Repair Deficiency," N. Engl. J. Med. (June 25, 2015), (EX1031).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

expert peer reviewers for the NEJM found the results to be both unexpected and important. Because of studies like this one that show unexpected results and established a new precedent, it is now more common for NEJM to accept papers detailing interim results of early phase trials. In many ways, this study was the breakthrough study that broke the mold. Now the editors at NEJM more commonly publish studies with highly unexpected findings even before those trials have mature results. Such studies are of high interest to their readership and often are practice changing. They also have a favorable effect on the journal's impact factor (a metric used to measure the scientific importance of a journal by calculating the average number of times articles published in the journal are cited in a given year).

63. An update with longer patient follow-up was published in Science in July 2017.[46] These are highly selective journals with high impact factors (NEJM: 158, ranked 3rd of 168 medical journals, Science 44.7) indicating the peer reviewers' estimate of the importance of these findings. In Cohort A, the patients with MSI-H mCRC, the response rate was 40% and the PFS at 20 weeks was 78%. The median OS had not been reached at the time of reporting and, notably, 21% of patients in cohort A had a complete response to their treatment. Complete

[46] Le et al., "Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade," Science (July 28, 2017), (EX2118).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

responses are seldom seen in patients with mCRC even in first-line therapy. The response in Cohort C was similar, with a complete response rate of 14% and a partial response rate of 57%, and PFS at 20 weeks of 67%. As with Cohort A, the median OS had not been reached at the time of reporting.

64. Pembrolizumab was initially tested in the setting of treatment refractory disease and so the efficacy and tolerability data that came from the trials that led to the approval of regorafenib and trifluridine/tipiracil are appropriate comparators. Contrast these outcomes to the previously noted results of the third-line studies that led to the FDA approvals for regorafenib (RR =2.4%, median PFS = 1.9 months, median OS = 6.4 months) and trifluoridine/tipiracil (RR =1.6 months, median PFS = 2.0 months, median OS =7.1 months). In contrast, in the patients with CRC that was not MSI-H (the MSS cohort) the RR = 0, PFS= 2.2 months and OS = 5.0 months. These results were like those seen in the control arms of the regorafenib and trifluoridine/tipiracil studies where patients received best supportive care without active drug therapy.

65. The importance of the results of the JHU study is also reflected in the FDA granting priority review status to expedite the examination of the data regarding treatment with pembrolizumab for MSI-H mCRC was granted priority review status by the FDA. As listed on the FDA website “a Priority Review designation will direct overall attention and resources to the evaluation of

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications." The FDA conditions for priority review include evidence of increased effectiveness in treatment, prevention, or diagnosis of condition; or that provide evidence of an improvement in safety and effectiveness.[47] FDA priority reviews must be completed by the agency within 6 rather than the standard 10 months of the filing of a completed application.

66. The importance of the results of the JHU study is also reflected in the FDA granting Breakthrough Therapy Designation for the treatment of patients with MSI-H metastatic colorectal cancer.[48] The Breakthrough Therapy Designation is "intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints."[49] Merck explained that "the Breakthrough

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[47] "Review Designation Policy: Priority (P) and Standard (S)," Center for Drug Evaluation and Research: Manual of Policies and Procedures, Office of New Drugs, available at https://www.fda.gov/media/72723/download, (EX2280).
[48] "Merck Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for KEYTRUDA® (pembrolizumab) in Advanced Colorectal Cancer," Merck, News Release, (Nov. 2, 2015), (EX2062).
[49] *Id.*

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

Therapy Designation in advanced colorectal cancer is based on data from a Phase 2 study evaluating the activity of KEYTRUDA in cancers with microsatellite instability, a well-established feature seen in cells with certain types of DNA repair defects. Findings from the study, led by researchers from Johns Hopkins Kimmel Cancer Center, were presented at the 2015 American Society of Clinical Oncology (ASCO) annual meeting and were published simultaneously in the *New England Journal of Medicine*."[50]

67. In my experience, attaining Breakthrough Therapy Designation is rare and is reserved for only the most promising therapies. I have authored and participated in hundreds of clinical trials in my career, and the JHU MSI-H clinical trial is the only one that achieved Breakthrough Therapy Designation.

68. It should be noted that these studies were all approved by institutional review boards at the institutions where patients were enrolled. Institutional review boards are specifically tasked with determining if the proposed clinical trial is ethical in its treatment of patients. JHU's study could not have moved forward without independent approval by each participating institution's IRB. Had the results of the trial been obvious before it was conducted, *i.e.* that it was obvious that the MSS cohort would not respond, it would have been unethical to construct such a protocol, let alone enroll patients to cohort B, and the IRBs would not have

[50] *Id.*

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

approved the trial.[51] While those patients did not have MSI-H tumors and the results of the study showed that group did not respond to pembrolizumab, those results were not predictable or known prior to conducting the trial.

69. The activity of pembrolizumab had not been evaluated prior to this trial in a cohort of patients with mCRC to determine if such patients could benefit from treatment. While pembrolizumab is a PD-1 inhibitor like nivolumab, which had been tested in a group of patients with tumors assumed to be MSS,[52] it is a different drug. Therefore, it was important to independently test pembrolizumab's potential for benefit in mCRC patients with MSS tumors. Since MSS tumors make up the vast majority of mCRCs, assessing pembrolizumab's activity in this setting was a vital step in assessing the drug's potential.

70. Indeed, it would have been unethical to treat a cancer patient with a therapy ***expected*** not to work on the patient's cancer. Patients with progressive cancer would risk losing precious time that could be spent receiving an alternative treatment that had some hope of working. During the time spent receiving the ineffective therapy, the patient's cancer may also progress to the point where they

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[51] Ethical Guidelines, "Ethics in Clinical Research," NIH Clinical Center, available at https://www.cc.nih.gov/recruit/ethics, (EX2119); "The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research," Department of Health, Education, and Welfare (April 18, 1979), (EX2120).

[52] I understand that the other 32 CRC patients who did not respond to treatment with nivolumab were of unknown MSI status and therefore assumed to be MSS.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

may not qualify to receive a different therapy. As a result, doctors would not have prescribed a therapy known not to work, and patients would not have wanted to take it.

E. The Impact of Pembrolizumab for Treating MSI-H Tumors.

1. Individual Patients

71. The patients treated on the JHU study by Le et al were remarkably impacted by their treatment. As an investigator on this study, I treated several patients with MSI-H CRC. Two of my patients, both of whom had MSI-H mCRC, are alive, disease free, and have been off all treatment for more than 10 years. One, Beth Carner, was a 26-year-old young woman who had very advanced disease when I met her. When she first saw me, she had tumors in her neck, breasts, and abdomen and really had only two choices: the trial or signing up for hospice. She was in a wheelchair that day because of spread of the tumor to her femur that had recently been surgically repaired. Her Mayo Clinic based oncology team had been given her a life expectancy projection of 2 months the week before we met. Beth's response to treatment with Keytruda was so dramatic that I described it as "The Lazarus effect", referring the parable in the New Testament where Lazarus rises from the dead.[53] Within about a year of starting treatment, she showed no evidence of cancer, and she appears to be cured now a decade after

[53] "Issue 38," The Cancer Letter, Vol. 43, No. 38 (Oct. 13, 2017), (EX2121).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

stopping treatment. Her story was told as a part of an article in The Cancer Letter (June 10, 2022),[54] and she was interviewed in a podcast as a part of the Cancer Letter's Cancer History Project.[55] Her response to this treatment made history.

72. A similar story appeared in the Washington Post on May 28, 2017 relating the story of Stephanie Joho, a CRC patient who received her treatment under the clinical trial at Johns Hopkins University.[56] When Ms. Joho began treatment with Keytruda in August 2014, her cancer was "raging out of control" and she was "in agony from a malignant mass in her midsection."[57] With no other options, she enrolled in the JHU clinical trial for pembrolizumab, and "within just days the excruciating back pain had eased."[58] Over months of treatment, Ms. Joho's tumor shrank and ultimately disappeared. She stopped treatment with pembrolizumab in August 2016, "free from all signs of disease."[59]

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[54] "Issue 23," The Cancer Letter, Vol. 48, No. 23 (June 10, 2022), (EX2122).
[55] "How Beth Carner went from six weeks left to live with stage 4 colon cancer to complete remission," Cancer History Project (June 10, 2022), available at https://cancerhistoryproject.com/article/how-beth-carner-went-from-six-weeks-left-to-live-with-stage-4-colon-cancer-to-complete-remission/, (EX2123).
[56] Laurie McGinley, "'This is not the end': Using immunotherapy and a genetic glitch to give cancer patients hope," Washington Post (May 28, 2017), available at https://www.washingtonpost.com/national/health-science/this-is-not-the-end-experimental-therapy-that-targets-genes-gives-cancer-patients-hope/2017/05/28/cdce31de-365c-11e7-b373-418f6849a004_story.html, (EX2006).
[57] *Id.*, 1-2.
[58] *Id.*, 2.
[59] *Id.*

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

73. The extraordinary results of treatment of MSI-H non-CRC patients with pembrolizumab was also highlighted in the press. The New York Times described how "[t]he 86 cancer patients were a disparate group, with tumors of the pancreas, prostate, uterus or bone."[60] It reported how "[o]ne woman had a cancer so rare there were no tested treatments."[61] Specifically, Adrienne Skinner, "had an extraordinarily rare and deadly cancer, ampullary cancer, that arises at the end of the bile duct," with a "dire prognosis."[62] After being scheduled for a radical and potentially dangerous surgery to remove part of her pancreas, small intestine, and gall bladder, her tumor was discovered to be MSI-H, and she was treated in JHU's clinical study instead of surgery. Three months after her first dose of pembrolizumab, Adrienne's tumor was reported to be gone.[63] Her treatment was so successful Adrienne's doctor told her, "[i]f someone hadn't told me you have ampullary cancer, I would not have known."[64]

74. Circumstances like this when patients with very advanced disease can have their future so dramatically altered from incurable to cured are almost

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[60] "Cancer Drug Proves to Be Effective Against Multiple Tumors," The New York Times (June 8, 2017), available at https://www.nytimes.com/2017/06/08/health/cancer-drug-keytruda-tumors.html, (EX2005, 1).
[61] *Id.*
[62] *Id.*
[63] *Id.*, 4.
[64] *Id.*

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

unheard of, and this is the only such treatment I have encountered in my 35 years of practicing oncology. They, their families, and we as their caregivers sometimes get to participate in miracles, and that is what this discovery felt like at the time. Without JHU's invention, MSI-H CRC patients would have faced a limited set of treatment options that would have quickly run out. JHU's invention met this long-felt need for treating and in many cases curing MSI-H CRC cancers that would have previously been a death sentence for those patients.

2. Impact on Clinical Practice

a. MSI Testing Before and After 2017

75. Prior to the 2017 MSI-H approval for Keytruda, testing for MSI was rarely ordered by clinical oncologists. The most common reason for MSI testing at that time was to determine if a patient has the inherited defect in DNA mismatch repair that was diagnostic for Lynch Syndrome. This condition leads to multiple errors in the DNA of newly formed cells after cells divide and predisposes patients to develop both multiple cancers and earlier onset of disease than typically observed in individuals without this condition. MSI testing in these patients was done for the purpose of recommending early deployment of more intensive than standard cancer surveillance protocols to screen individuals and their family members who were diagnosed with Lynch Syndrome. In patients whose tumors exhibited MSI-H status, but the DNA repair defect was not present in their normal

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

(germline) tissues no special screening strategies were recommended beyond screening for subsequent new cancers. Most often this testing was ordered by a medical geneticist and not a medical oncologist.

76. The 2014 National Comprehensive Cancer Network (NCCN) CRC Guidelines recommended MSI-H screening under two circumstances: (1) screening for Lynch Syndrome and (2) Stage II colon cancers.[65] MSI testing was recommended for Stage II patients because patients with MSI-H tumors have a better prognosis than patients with MSS tumors and oncologists typically would omit postoperative chemotherapy in that limited circumstance. No mention is made regarding any relevance of MSI testing in determining treatment in Stage I, III, or IV colon cancer as the treatment recommendations were not influenced by knowing the status of the tumor's mismatch repair proficiency at that time.[66]

77. The only other NCCN guideline before 2017 that mentions the use of MSI testing is in the guideline for patients with endometrial cancer.[67] The recommendations focus on making a diagnosis of Lynch Syndrome and were, again, targeted at identifying individuals and families with an inherited cancer

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[65] Benson et al., "Colon cancer, version 3.2014.," J. Natl. Compr. Canc. Netw. (July 12, 2014), (EX1009); "Colon Cancer Version 3.2014, NCCN Clinical Practice Guidelines in Oncology," J Natl Compr Canc Netw. (Jan. 27, 2014), (EX1020, 48).
[66] *Id*.
[67] "Uterine Neoplasms Version 1.2014, NCCN Clinical Practice Guidelines in Oncology," J Natl Compr Canc Netw. (Nov. 27, 2013), (EX1089).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

susceptibility syndrome. Endometrial and colorectal cancers are the most commonly occurring cancers in individuals with Lynch Syndrome.

78. There was no discussion of performing MSI testing in patients with endometrial or any other solid tumor for the purposes of influencing treatment decisions (as opposed to identifying familial risk) in NCCN guidelines prior to 2017.

79. After 2017, when the FDA indication for pembrolizumab treatment of MSI high tumors was approved, the standard of care changed dramatically. Prior to that time MSI was not a biomarker that was known to be of any use for determining treatment choices in patients with advanced cancers. Very few oncologists would have ever ordered the test. While many clinical oncologists were aware that patients with Lynch Syndrome had a defect in DNA mismatch repair, they associated MSI testing with young onset colorectal and endometrial cancer and patients with a family history of colorectal and/or endometrial cancer. The test was not used for screening purposes outside of the research setting except in the potential management of Stage II colon cancer as noted above. Based on the data reported in the Le et al paper published in NEJM there was a flurry of interest in applying these dramatic findings in their practices. Oncologists had to learn how and when to test for a tumor's MSI status and hospital and third-party laboratories had to develop testing procedures with rapid turnaround times to meet

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

the needs of their clinical colleagues who were in the trenches making treatment decisions.

80. After the 2017 approval, NCCN guidelines added the recommendation to test patients for MSI-H for the purpose of prescribing pembrolizumab (Keytruda) for multiple cancers including gastric, pancreatic, cholangiocarcinoma, hepatocellular, small intestine, ampullary, anal, prostate, bladder, endometrial, ovarian, cervical, neuroendocrine, thyroid, and breast cancers, among others.[68]

81. As a gastrointestinal oncologist, the finding of the relevance of MSI status as a useful biomarker to indicate potential sensitivity to pembrolizumab and PD-1 inhibitors was a dramatic change. This was especially true considering the incredible responses that I had observed in the colorectal cancer patients that I had personally managed on the JHU study. The prospect of complete and potentially long-term responses led our team and others to order MSI testing on every gastrointestinal cancer patient with advanced (Stage IV) disease at the appropriate time when they met the FDA approved indication for PD-1 inhibitor use in the

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[68] *See* EX2255-2269 (NCCN Guidelines on gastric cancer, pancreatic adenocarcinoma, hepatocellular carcinoma, biliary tract cancers, small bowel adenocarcinoma, ampullary adenocarcinoma, prostate cancer, bladder cancer, uterine neoplasms, ovarian cancer, cervical cancer, neuroendocrine and adrenal tumors thyroid carcinoma, and breast cancer); *see also* EX2270-2272 (NCCN Guidelines on esophageal and esophagogastric junction cancers, testicular cancer, and head and neck cancers).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

course of their disease. Gastrointestinal oncologists such as myself manage 11 different types of cancers that arise in the gastrointestinal tract, including the claimed small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, esophageal cancer, and liver cancer. After the 2017 approval, teams all over the US began testing for MSI on a routine basis for those cancers.

IV. NEXUS

82. As a practicing oncologist until I stopped seeing patients in 2017, I prescribed Keytruda (pembrolizumab) to my MSI-H patients. When I did so, I followed the instructions in the Keytruda label, and I know that other physicians who administer Keytruda do, too. The Keytruda label includes indications, or diseases, for which FDA has approved the use of the drug.[69] These indications on the label dictate the uses for which doctors may prescribe Keytruda and the uses for which Merck may market the drug. These indications are also used by insurance companies to determine whether a treatment qualifies for insurance coverage.

83. Prior to approving Keytruda for use in treating MSI-H cancer, FDA first approved Keytruda for treatment of patients with:

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[69] *See, e.g.,* Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (May 23, 2017), (EX2124).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

- "unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor" in September 2014.[70]

- "metastatic NSCLC [Non-Small Cell Lung Cancer] whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy" in October 2015,[71]

- "recurrent or metastatic HNSCC [Head and Neck Squamous Cell Carcinoma] with disease progression on or after platinum-containing chemotherapy" in August 2016.[72]

- "adult and pediatric patients with refractory cHL [Classical Hodgkin Lymphoma], or who have relapsed after 3 or more prior lines of therapy" in March 2017.[73]

- "locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy" in May 2017.[74]

84. In May 2017, FDA granted accelerated approval "for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient: solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment

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[70] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (Sept. 4, 2014), (EX1055).
[71] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (Oct. 2015), (EX2125).
[72] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (Aug. 2016), (EX2126).
[73] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (Mar. 2017), (EX2127).
[74] Merck & Co., Inc. "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (May 18, 2017), (EX2128).

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

with a fluoropyrimidine, oxaliplatin, and irinotecan."[75] The label noted that "indication is approved under accelerated approval based on tumor response rate and durability of response."[76] The label also cites five clinical trials in which the efficacy of Keytruda was evaluated in MSI-H patients, including KEYNOTE 016, which is JHU's original clinical trial (NCT01876511).[77]

85. Prior to granting the MSI-H indication for Keytruda, the FDA had not granted a drug approval to treat patients with any type of cancer who manifested a particular biomarker, in this case for cancers that were MSI-H and refractory to standard therapies. A new term was coined for this novel approval; the indication was characterized as being "tumor agnostic." The concept of a tumor agnostic approval for any drug was unexpected and groundbreaking.

86. Subsequently, the FDA approved a second indication based on MSI-H status on March 21, 2022, for "for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR…who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation."[78] This approval allowed doctors to prescribe Keytruda to

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[75] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (May 23, 2017), (EX2124).
[76] *Id.*
[77] *Id.*, 41-42.
[78] Merck & Co., Inc., "KEYTRUDA® (pembrolizumab)," Full Prescribing Information (May 2022), (EX2300); *see also* EX2305.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

patients with advanced endometrial carcinoma who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

87. Prior to the May 2017 approval of the MSI-H indication, Keytruda was not approved for any indication that allowed for the treatment of fifteen of the sixteen Claimed MSI-H Cancer patients.[79] Practically, this meant that doctors would generally not prescribe Keytruda to patients with one of the Claimed MSI-H Cancers outside of the context of a clinical trial.[80] Without approved indications for the Claimed MSI-H Cancers, Merck was not able to market Keytruda for use by doctors to treat the majority of these cancers.

88. As a well-known clinician and researcher, I had the opportunity to see patients from across North America who sought my care as their primary oncologist or as a consulting oncologist who would work with their home team on their care strategies. At Ohio State University we rapidly adopted universal MSI testing for our patients and used PD-1 inhibitors when appropriate. For patients

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[79] As I note above, Keytruda was approved to treat recurrent or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC), a subtype of oral cancer. HNSCC patients were generally not tested for MSI status.

[80] If Merck had a compassionate care program for Keytruda, doctors could prescribe the medication off-label, but Merck would not be able to charge and therefore those uses would not contribute to Keytruda sales. Off-label prescriptions outside of a compassionate care program are rare as it is unlikely that the patient's insurance would cover this expensive drug in that circumstance making administration prohibitively expensive for most patients.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

coming for consultations, we would do the MSI testing and guide their local oncologists on the use of pembrolizumab in the patients with MSI-H tumors in accord with Merck's product labeling. I also lectured at meetings and courses worldwide about these new findings and the use of these agents to educate practicing oncologists about these findings.[81] For the first time we could offer the prospect of long-term survival to patients with advanced, treatment refractory mCRC and other metastatic MSI-H solid tumors. Thus, the approval of Keytruda to treat MSI-H cancers completely changed the standard of care for those patients.

89. An oncologist reviewing the Keytruda label would understand that a patient with a Claimed MSI-H Cancer treated under either of these indications would be treated in response to determining that that patient's tumor is either MSI-H or dMMR by testing the patient's tumor.

90. Claim 1 of the '491 Patent claims:

> A method of treating cancer in a human patient, the method comprising: testing or having tested a biological sample obtained from a patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, choloangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer,
>
> thereby determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient; and
>
> in response to determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient, treating the patient determined to have microsatellite instability high or DNA mismatch repair deficient cancer with a therapeutically effective amount of pembrolizumab.

[81] I note that these lectures were not funded by Merck.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

91. I understand that the other claims of the ’491 Patent also include the requirement that the patient’s cancer is MSI-H or dMMR, the patient’s tumor has progressed following a prior treatment, and treating the MSI-H patient with a therapeutically effective amount of pembrolizumab (Keytruda).

92. Each step of the method of treatment described in the ’491 Patent is described in the MSI-H related Indications 1.8 on the Keytruda label (in the June 2020 version of the Keytruda label). Treatment with Keytruda according to Indication 1.15 (Endometrial Carcinoma) added to the March 2022 label also practices the claimed method. The Indications and Usage section describes the use of Keytruda as a second-line treatment for MSI-H/dMMR cancer. The Dosage and Administration section instructs physicians to select MSI-H patients for treatment with Keytruda based on the patient testing positive for MSI-H/dMMR. The Recommended Dosage section identifies the appropriate dosage of Keytruda to administer once the patient’s cancer has been identified as MSI-H/dMMR. The Clinical Trials section includes clinical trial results showing that the recommended dosages of Keytruda® are therapeutically effective among cancer patients with MSI-H or dMMR solid tumors relevant to Indications 1.8 and 1.15. As an example, the disclosure of each step of Claim 1 of the ’491 Patent in the Keytruda label is shown in the chart below.

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

1[pre]. A method of treating cancer in a human patient, the method comprising: testing or having tested a biological sample obtained from a patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer,

The Keytruda® label instructs physicians to select patients for treatment with Keytruda according to Indication 1.8 and Indication 1.15, added in March 2022:

1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

- solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
- colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

This indication is approved under accelerated approval based on tumor response rate and durability of response *[see Clinical Studies (14.8)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Limitations of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

EX2129, 5.

1.15 Endometrial Carcinoma

KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surger radiation *[see Dosage and Administration (2.1)]*.

EX2300, 6.

The Claimed MSI-H Cancers are each solid tumors that a physician would treat under Indications 1.8 and 1.15.

The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is either MSI-H or dMMR for treatment with Keytruda according to Indications 1.8 and 1.15. That section further refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, or TMB-H Cancer

Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in:

- stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation *[see Clinical Studies (14.2)]*.
- metastatic NSCLC *[see Clinical Studies (14.2)]*.
- first-line treatment of metastatic or unresectable, recurrent HNSCC *[see Clinical Studies (14.4)]*.
- metastatic urothelial carcinoma *[see Clinical Studies (14.7)]*.
- metastatic gastric cancer *[see Clinical Studies (14.10)]*. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing.
- metastatic esophageal cancer *[see Clinical Studies (14.11)]*.
- recurrent or metastatic cervical cancer *[see Clinical Studies (14.12)]*.

For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens *[see Clinical Studies (14.8, 14.9)]*.

EX2129, 7; *see also* EX2300, 7 (referring to sections 14.7 and 14.8).

Further, the Dosage and Administration section refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status:

14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests.

EX2129, 73-74; *see also* EX2300, 89-90 (section 14.7).

The Clinical Studies section 14.15 also instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status in endometrial cancer:

Docusign Envelope ID: 8A567908-A056-40BE-BD1F-B7AF997C401D

As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma

The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

EX2300, 114.

1[a]. thereby determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient; and

The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is either MSI-H or dMMR for treatment with Keytruda according to Indications 1.8 and 1.15. That section further refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, or TMB-H Cancer

Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in:

- stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation *[see Clinical Studies (14.2)]*.
- metastatic NSCLC *[see Clinical Studies (14.2)]*.
- first-line treatment of metastatic or unresectable, recurrent HNSCC *[see Clinical Studies (14.4)]*.
- metastatic urothelial carcinoma *[see Clinical Studies (14.7)]*.
- metastatic gastric cancer *[see Clinical Studies (14.10)]*. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing.
- metastatic esophageal cancer *[see Clinical Studies (14.11)]*.
- recurrent or metastatic cervical cancer *[see Clinical Studies (14.12)]*.

For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens *[see Clinical Studies (14.8, 14.9)]*.

EX2129, 7; *see also* EX2300, 7 (referring to sections 14.7 and 14.8).

Further, the Dosage and Administration section refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status:

14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests.

EX2129, 73-74; *see also* EX2300, 89-90 (section 14.7).

The Clinical Studies section 14.15 also instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status in endometrial cancer:

As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma

The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

EX2300, 114.

1[b]. in response to determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient, treating the patient determined to have microsatellite instability high or DNA mismatch repair deficient cancer with a therapeutically effective amount of pembrolizumab.

The Recommended Dosage section of the Keytruda® label provides the recommended dosages of Keytruda®, administered in response to determining that the solid tumor is MSI-H/dMMR, as well as the duration/timing of treatment based on the indication, wherein the indication is directed to cancers confirmed to be MSI-H/dMMR, including the Claimed MSI-H Cancers:

2.2 Recommended Dosage

Table 1: Recommended Dosage

Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment
Monotherapy		
Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months

* 30-minute intravenous infusion

EX2129, 7-8; *see also* EX2300, 8.

The Keytruda® label includes clinical trial results showing that the recommended dosages of Keytruda® are therapeutically effective among cancer patients with MSI-H/dMMR solid tumors, including Claimed MSI-H Cancers, relevant to Indications 1.8 and 1.15:

14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

Table 51: Response by Tumor Type

	N	Objective Response Rate n (%)	95% CI	Duration of Response range (months)
CRC	90	32 (36%)	(26%, 46%)	(1.6+, 22.7+)
Non-CRC	59	27 (46%)	(33%, 59%)	(1.9+, 22.1+)
Endometrial cancer	14	5 (36%)	(13%, 65%)	(4.2+, 17.3+)
Biliary cancer	11	3 (27%)	(6%, 61%)	(11.6+, 19.6+)
Gastric or GE junction cancer	9	5 (56%)	(21%, 86%)	(5.8+, 22.1+)
Pancreatic cancer	6	5 (83%)	(36%, 100%)	(2.6+, 9.2+)
Small intestinal cancer	8	3 (38%)	(9%, 76%)	(1.9+, 9.1+)
Breast cancer	2	PR, PR		(7.6, 15.9)
Prostate cancer	2	PR, SD		9.8+
Bladder cancer	1	NE		
Esophageal cancer	1	PR		18.2+
Sarcoma	1	PD		
Thyroid cancer	1	NE		
Retroperitoneal adenocarcinoma	1	PR		7.5+
Small cell lung cancer	1	CR		8.9+
Renal cell cancer	1	PD		

CR = complete response
PR = partial response
SD = stable disease
PD = progressive disease
NE = not evaluable

EX2129, 73-75.

Table 80: Efficacy Results in Patients with Advanced MSI-H or dMMR Endometrial Carcinoma in KEYNOTE-158

Endpoint	KEYTRUDA n=90*
Objective Response Rate	
ORR (95% CI)	46% (35, 56)
Complete response rate	12%
Partial response rate	33%
Duration of Response	n=41
Median in months (range)	NR (2.9, 55.7+)
% with duration ≥12 months	68%
% with duration ≥24 months	44%

* Median follow-up time of 16.0 months (range 0.5 to 62.1 months)
\+ Denotes ongoing response
NR = not reached

As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma

The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

EX2300, 114-115.

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93. In my opinion, an oncologist prescribing Keytruda to a cancer patient under the MSI-H-related indications described above would necessarily practice the method of treatment claimed in at least Claim 1 of the ’491 Patent. As a result, there is a nexus between the claims of the ’491 Patent and the methods of treating the Claimed MSI-H Cancers according to the Keytruda label.

APPENDIX A

RICHARD M. GOLDBERG, MD
CURRICULUM VITAE

Updated: 7/12/2024

PERSONAL INFORMATION

Richard M. Goldberg, M.D.
3029 Greystone Drive
Morgantown, WV 26508
(614) 507-6232

EDUCATION

Fellowship:	July 1982 to June 1984 Vincent T. Lombardi Cancer Research Center Georgetown University Washington, DC Medical Oncology
Intern/Resident:	July 1979 to June 1982 Emory University Hospitals Atlanta, GA Intern, Junior, and Senior Assistant Resident in Internal Medicine
M.D.:	September 1975 to May 1979 State University of New York Upstate Medical University Syracuse, NY
A.B. cum laude:	September 1971 to May 1975 Harvard University Cambridge, MA

CERTIFICATIONS

- Diplomate, American Board of Internal Medicine - 1982
- Diplomate, ABIM Subspecialty; Medical Oncology - 1986
- Medical Licensure: Current: West Virginia (2017-) 27476 (inactive)
  Past: Ohio (2011-17)
  North Carolina (2004-2011)
  Minnesota (1994-2004)
  Pennsylvania (1984-1994)
  Virginia (1982-1985)
  Georgia (1980-1982)

PROFESSIONAL EXPERIENCE - EMPLOYMENT HISTORY

8/1/2024-present	Editor-in Chief for Oncology, UpToDate
10/8/2021-present	Adjunct Professor, West Virginia University School of Medicine
5/1/2020-present	Professor Emeritus, West Virginia University School of Medicine
7/1/2023-present.	Member, Friends Board of Directors, West Virgina Public Broadcasting
8/1/2023-present	Member, Board of Directors, Exesalibero Pharmaceuticals LLC
1/1/2020-present	Member, Board of Directors, and Director of Clinical Science, Fightcolorectalcancer.org
1/1/2020-present	CEO Oncology Developments LLC, Consultant for academic medical centers, the pharmaceutical industry and expert witness services
8/2011-present	Associate Group Chair Alliance for Clinical Trials in Oncology
1/1/2020-present	Director Emeritus of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Center
1/31/17-12/31/2019	Director of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Institute Professor of Medicine Laurence S. & Jean J. DeLynn Chair of Oncology
10/2011-12/31/2016	Professor of Medicine, The Ohio State University Wexner Medical Center - Columbus, OH - Physician-in-Chief, The James Cancer Hospital and Solove Research Institute at The Ohio State University - Columbus, OH - Associate Director of Outreach for the James Cancer Center and Solove Research Institute at The Ohio State University - The Klotz Family Chair in Cancer Research
4/2015-4/2016	Acting Chief, Division of Medical Oncology, The Ohio State University Wexner Medical Center Columbus, OH
8/2003-10/2011	Professor and Chief, Division of Hematology/Oncology - The Richard M. Goldberg Distinguished Professor of Gastrointestinal Cancer Research University of North Carolina at Chapel Hill - Chapel Hill, NC - Physician-in-Chief, The NC Cancer Hospital at University of North Carolina at Chapel Hill - Chapel Hill, NC - Associate Director of Clinical Research for the UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill - Chapel Hill, NC
2010-2015	Chair and Chief Executive Officer, ARCAD US Foundation (Aide et Recherche en Cancerologie Digestive)
2010-2017	Co-Chair, Society of Translational Oncology

3/2010-8/2011	Associate Group Chair for Intergroup Affairs of the Cancer and Leukemia Group B (CALGB)
6/2006-2/2010	Chair, Gastrointestinal Cancer Committee (CALGB)
6/1998-5/2003	Consultant in Medical Oncology Mayo Clinic-Rochester, MN
1995-2003	Co-Chair, Mayo Cancer Center Gastrointestinal Cancer Research Program
11/1994-8/2003	Chair, Gastrointestinal Cancer Committee (NCCTG)
11/1994-6/1998	Senior Associate Consultant in Medical Oncology Mayo Clinic - Rochester, MN
8/1984-10/1994	Associate in Medical Oncology Geisinger Medical Center and Clinic - Danville, PA
1992-1994	Vice Chairman, Departments of Medicine, Geisinger Medical Center and Clinic - Danville, PA
1990-1992	Assistant Chairman, Departments of Medicine, Geisinger Medical Center and Clinic - Danville, PA
1983-1984	Home Care Physician Hospice of Northern Virginia - Arlington, VA

EXPERT WITNESS EXPERIENCE

2019-2021 Genentech assertion of patent rights for bevacizumab with makers of biosimilars
Resolution: settled out of court in favor of Genentech

2020-2023 Taiho assertion of patent rights for Lonsurf challenged by 4 generic drug makers
Resolution: Federal Judge in the Delaware found for Taiho in all four disputed matters

HONORS AND AWARDS

2021.	Honorary member, Azerbajian Society of Oncologists
2020	Ruesch Center for the Cure of Gastrointestinal Cancers 2020 Luminary Award in GI Cancers
2020	Shafer Memorial Lecture, Georgetown University, Washington DC
2019	Garlove Annual Memorial Lectureship, Lexington, KY
2016	OSU Award for Outstanding Patient Satisfaction
2016, 20-24	ASCO Advocacy Champion
2015	One of five nominees; Giants in Oncology Award for Gastrointestinal Cancer
2013	Bob Pinedo Cancer Care Prize Lectureship: Ten Years of Progress in the Management of Colorectal Cancer at the GI Cancer Symposium Elected to be a Fellow of the American Society of Clinical Oncology
2012	Charles G. Moertel Lectureship, The Alliance for Clinical Trials in Oncology
2011	ASCO Statesman Award Third Susan Treadwell Fellow, Providence Hospital - Anchorage, Alaska
2006-2007	President, International Society of Gastrointestinal Oncology
2007	Volkman Memorial Lectureship, Eastern Carolina University - Greenville, NC
2006	Susan B. Lester Lectureship in Cancer at the University of Kentucky - Lexington, KY

2005	Frisbee Memorial Lectureship, Yale University - New Haven, CT
2003	Mayo Clinic Individual Achievement Award
	Recipient "Cancer Fighting Hero" award from Minnesota State Division of the American Cancer Society
	Identified as one of 318 Leading Cancer Specialists by Good Housekeeping
2001-2020	Listing in The Best Doctors in America
2004-2020	Listing in Best Oncologists
2001-2020	Listing in Castle Connolly Best Doctor
	Listing in Who's Who in Engineering and Science
	Listing in Who's Who in the World
	Listing in 2000 Notable American Men
	Listing in Who's Who
1986 & 1987	Commendations for Teaching Excellence
1989	Fellow, American College of Physicians
1978	Alpha Omega Alpha Membership

BOOKS AND CHAPTERS

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2. **Goldberg R** and Woolley P. Nonsurgical Treatment of Gastric Cancer. In: Moossa AR ed. *Comprehensive Textbook of Clinical Oncology*. Baltimore: Williams and Wilkins; 1986:1042-1052.

3. **Goldberg RM** and Erlichman C. New Agents in the Treatment of Colon Cancer. In: Bleiberg H, Rougier P, Wilke, H-J, ed. *Management of Colorectal Cancer.* London: Martin Dunitz Ltd; 1998:331-344.

4. Loprinzi CL, **Goldberg RM**, Peethambaram P. Cancer Anorexia/Cachexia. In: Berger A, Levy M, Portenoy R, Weissman D, ed. *Principals and Practice of Supportive Oncology*. Philadelphia: Lippincott-Raven Publishers; 1998:133-140.

5. **Goldberg RM** and Loprinzi CL. Cancer Anorexia/Cachexia. In: von Gunten CF, ed. *Palliative Care and Rehabilitation of Cancer Patients*. Boston: Kluwer Academic Publishers; 1999:31-42.

6. McMurrick PJ, Nelson H, **Goldberg RM**, Haddock M. Therapy of Tumors of the Anal Canal. In: Torosian MH, ed. *Integrated Cancer Management-Surgery, Medical Oncology and Radiation Therapy*. New York: Marcel Dekker, Inc.; 1999:195-220.

7. **Goldberg RM**. Gastrointestinal Tract Cancers. In: Casciato DA; Lowitz BB, ed. *Manual of Clinical Oncology, 4th edition.* Baltimore, MD: Williams and Wilkins, Inc.; 2000:172-217.

8. Gunderson LL, Haddock MG, **Goldberg RM**, Burch PA, Trastek V, Donohue J, Nelson H. Alimentary Cancer Chapter. In: *Clinical Oncology, eighth edition*. Philadelphia, PA: W.B. Saunders; 2001:685-764.

9. **Goldberg RM** and Erlichman C. New Chemotherapy Approaches in Colorectal Cancer. In: Bleiberg H, Kemeny N, Rougier P, Wilke, H-J, ed. *Colorectal Cancer: A Clinical Guide to Therapy.* London: Martin Dunitz Ltd; 2002:629-638.

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12. **Goldberg RM**, Martenson JA, Alberts SM. Chemotherapy and Radiation Therapy of Pancreatic Cancer. In: Rustgi AK, Crawford J, ed. *Gastrointestinal Cancers*. Edinburgh: WB Saunders Co.; 2003:449-462.

13. Sargent D, **Goldberg R**, Limburg P. Gastrointestinal Cancers. In: Machin D, Day S, Green S, ed. *Textbook of Clinical Trials.* John Wiley & Sons Ltd; 2003:117-139.

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15. Alberts SR and **Goldberg RM**. Gastrointestinal Tract Cancers. In: Williams, DA, ed. *Manual of Clinical Oncology, 5th edition*. Baltimore, MD: Williams and Wilkins Inc.; 2004:185-232.

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2. **Goldberg RM**, Ayoob M, Silgals R, Ahlgren JD, Neefe JR. *Phase II* Trial of Lymphoblastoid Interferon in Metastatic Malignant Melanoma. Cancer Treat Rep. 69: 813-816, 1985. PMID: 4016791.

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5. **Goldberg R**: *Cured in my lifetime?* Geisinger Quarterly. 4: 28, 1987.

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8. **Goldberg RM**, Jett JR, Therneau T, Johnson PS, Tschetter LK, Krook JE, Veeder MH, Owen D, Etzell PS, Andres DF. *Bolus versus Infusion Regimens of Etoposide and Cisplatin in Treatment of Non-Small Cell Lung Cancer: A Study of the North Central Cancer Treatment Group*. J Natl Cancer Inst. 82: 1899-1903, 1990. PMID: 2174464.

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17. Loprinzi CL, **Goldberg RM**, O'Fallon JR, Quella SK, Miser AW, Mynderse LA, Brown LD, Tschetter LK, Wilwerding MB, Dose AM, Oesterling JE. *Transdermal Clonidine for Ameliorating Post-Orchiectomy Hot Flashes.* J Urol. 151: 634-636, 1994. PMID: 8308973.

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BOOK REVIEWS

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TEACHING RECORD

Lectures:

To Students: Annual talk on Principles of Neoplasia to the UNC second year Hematology and Oncology course
To Residents: Annual talk on Advances in Colorectal Cancer Management to the Internal medicine noon lectur series
To Fellows: Annual talk on Advances in Colorectal Cancer Management to Hematology and Oncology fellows

LECTURES TO ALL SOURCES BY ACADEMIC YEAR:

2005-2006		
Jul 1	*Management of Advanced Colorectal Cancer*	Tokyo, Japan

Jul 3	*Management of Advanced Colorectal Cancer*	Japanese Society of Clinical Oncology - Osaka, Japan
Jul 15	*New Agents in the Management of Colorectal Cancer*	International Society of GI Oncology - Arlington, VA
Aug 5-7	Lecture: *Management of GI Cancers*	Director: Big Sky Oncology Course - Big Sky, MT
Aug 13	*Updates in GI Cancer Management*	NC Oncology Association - Greensboro, NC
Sep 3	Presentation on *Colorectal Cancer*	National Public Radio - Chapel Hill, NC
Sep 22-25	Lecture: *First-Line Therapy of Colorectal Cancer*	Course Director: Perspectives in Colorectal Cancer - Chicago, IL
Oct 1	*Management of Advanced Colorectal Cancer*	Falk Symposium - Berlin, Germany
Oct 14-16	Lecture: *New Agents in Colorectal Cancer as well as CALGB Studies*	Co-Director: Colorectal Cancer Symposium - Aventura, FL
Oct 24	Evening Lecture: *Management of Colorectal Cancer and Liver Resection for Colorectal Cancer*	Grand Rounds: Lehigh Valley Hospital - Reading, PA
Oct 29	*Adjuvant Therapy for Colorectal Cancer*	Atlanta, GA
Dec 2	*Targeted Therapies in the Management of Colorectal Cancer*	ASCO Media Event - New York, NY
Jan 27	*Use of FOLFOX in Elderly Patients with Colorectal Cancer*	2006 GI Symposium - San Francisco, CA
Feb 4	*Management of Colorectal Cancer*	Cowan Symposium - Salt Lake City, UT
Mar 4	*A Decade of Progress in Colorectal Cancer Management*	GI Cancer Summit - Warsaw, Poland
Apr 2	Session Chair & Lecturer: *Clinical Implications of Genetic Discoveries in Colorectal Cancer*	American Association for Cancer Research - Washington, DC
May 8	Oncology Grand Rounds: *Management of Colorectal Cancer*	Long Island Jewish Hospital - New Hyde Park, NY
May 20	*Challenging Cases in GI Cancer*	New York, NY
May 4-7	Session Chair/Oral Abstract Presenter/Poster Discussion Leader: *Differences in Outcomes and Polymorphisms in African American and Caucasians Treated for Advanced Colorectal Cancer*	American Society of Clinical Oncology Meeting Chicago, IL
Jun 24	*Challenging Cases in GI Cancer*	New York, NY
2006-2007		
Jul 7	Colorectal Cancer Think Tank for Research to Practice	Key Biscayne, FL
Aug 5-6	*Update on GI Cancer*	Course Director: Big Sky Oncology Course - Big Sky, MT
Aug 8	*Management of Advanced Colorectal Cancer*	Amgen Training Program - Miami, FL
Sep 16-17	Meeting Chairman: *Optimal Management of Advanced Colorectal Cancer*	Perspectives in Colorectal Cancer - Scottsdale, AZ
Sep 21-22	*Which Strategies will Lead to Progress in GI Cancer, Adjuvant Colorectal Cancer Trials in the US, Colorectal Cancer Cases*	Int'l Society of GI Oncology - Washington, DC (Installed as President)
Oct 7	Managing Advanced Colorectal Cancer	St. Louis University School of Medicine - St. Louis, MO

Nov 8	*UGT1a1 Testing with Irinotecan Therapy and Use of Fecal DNA for Colon Cancer Diagnosis*	Institute of Medicine - Washington, DC
Nov 17-18	Susan B. Lester Lectureship	University of Kentucky - Lexington, KY
Jan 9	Grand Rounds*: Advances in the Treatment of Colorectal Cancer*	AHEC, Moses Cone Hospital - Greensboro, NC
Jan 19-21	Panel Member: Colorectal Cancer Think Tank	ASCO GI Meeting - Orlando, FL
Jan 20-22	Session Chair & Program Committee Member	GI Cancer Symposium - Orlando, FL
Jan 25-26	*Management of Colorectal Cancer* (Public) - *Advances in the Management of Colorectal Cancer* (Med School)	Volkman Lectureship - Greenville, NC
Feb 7	*Managing Colorectal Cancer*	Sanofi-Aventis Training Program - Washington, DC
Feb 17	*Integrating Targeted Agents in the Management of Colorectal Cancer*	Las Vegas, NV
Mar 30-31	*Case Presentations and Recently Approved Agents for Treatment of GI Cancer, and Essentials for Excellence: Clinical Support*	ISGIO Fellows and Junior Practitioner's Meeting - Arlington, VA
Apr 13	*Targeted and Novel Therapies in Colorectal Cancer*	Gibbs Cancer Center - Spartanburg, SC
Apr 14-16	*Plenary Session Commentary: Cetuximab in Colon Cancer*	AACR Meeting - Los Angeles, CA
Apr 27	*Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer*	OSU James Cancer Hospital Grand Rounds - Columbus, OH
May 2	*Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer*	University of Chicago - Chicago, IL
May 3	*Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer*	Rush Medical Center - Chicago, IL
May 9-11	*Cancer Control in Africa*	Sponsored by Oxford University - London, England
Jun 1-4	Program Committee: *Attributes of Successful Clinical Trials, GI Cancer Poster Discussion* *Commentary: A Pooled Safety & Efficacy Analysis Examining the Effect of Performance Status on Outcomes in 9 First-Line Treatment Trials of 6,286 Patients with Metastatic Colorectal Cancer*	Annual American Society of Clinical Oncology Chicago, IL
Jun 14-15	*Managing Older Patients and Symptomatic Patients with Colorectal Cancer*; *Meet the Professor*	Research to Practice - Miami, FL
Jun 22-24	*Molecular Marker Driven Studies*	CALGAB Symposium - Baltimore, MD
Jun 26	*Molecular Marker-Driven Studies*	CALGB Symposium - Baltimore, MD
Jun 28-30	Program Comm./Session Chair: *Optimal Management of Metastatic Colorectal Cancer in 2007*	World GI Cancer Congress - Barcelona, Spain
2007-2008		
Aug 7-9	Course Director: *New Developments in the Management of Gastrointestinal Cancers*	Big Sky Oncology Course - Big Sky, MT

Sep 7-9	Course Director and Lecturer: *First-Line Therapy of Metastatic Colorectal Cancer*	Perspectives in Colorectal Cancer - Miami, FL
Sep 28-30	Outgoing President/Meeting Coordinator/Session Chair/Supervised Present Fellow	International Society of GI Oncology - Philadelphia, PA
Oct 11-13	Session Chair: *Mgmt of Patients w/Untreated Advanced Colorectal Cancer & CALGB Update*	Colorectal Cancer Update - Aventura, FL
Oct 19	*Management of Esophageal Cancer*	Annual Fall Foliage Mtg - Asheville, NC (Sponsored by Wake Forest Univ)
Oct 22	*Management of Colorectal Cancer*	National Cancer Institute of Japan - Tokyo, Japan
Oct 23	*Management of Colorectal Cancer*	Japanese Society of Clinical Oncology - Osaka, Japan
Oct 24	*Management of Colorectal Cancer*	Nagoya, Japan
Oct 25	*Management of Colorectal Cancer*	Tokyo, Japan
Nov 2	*Management of Colorectal Cancer*	Wake Forest University - Winston-Salem, NC
Nov 17-18	*Managing in an Academic Setting and Advances in Treatment of Colorectal Cancer*	ISGIO Fellows Meeting - Washington, DC
Nv 31-Dec1	NCI Pancreatic Cancer State of the Science Meeting	Washington, DC
Jan 17-18	Keynote Speaker: *Advances in Colorectal Cancer Management*	South Carolina Colon Cancer Consortium - Charleston, SC
Jan 25-27	Symposium: *Colorectal Cancer Management*	ASCO GI Symposium - San Francisco, CA
Feb 8-9	*Adjuvant Therapy of Colon Cancer and Integrating Biologic Agents into the Management of Advanced Colorectal Cancer*	Perspectives in Colorectal Cancer - Charleston, SC
Mar 1	*Advances in Colorectal Cancer Management*	Wake Forest Nursing Conference - Greensboro, NC
Mar 10-11	Advocate Training and Keynote Speaker	Colon Cancer Coalition - Washington, DC
Mar 14-15	*Clinical Trials in Advanced Colon Cancer*	Sanofi-Aventis International Investigator's Meeting - Seville, Spain
Apr 26	*Adjuvant Therapy for Colon Cancer*	Rasco Symposium - Little Rock, AR
May 10	*Treating Metastatic Colorectal Cancer*	Hellenic Society of Clinical Oncology - Athens, Greece
May 29-Jn 4	Commentary on Adjuvant Matters. *GI Plenary Session and KRAS in Treatment Decisions*	ASCO Annual Meeting - Chicago, IL
Jun 13	*Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer*	Roswell Park Memorial Cancer Institute - Buffalo, NY
Jun 20	*Genetics in Colorectal Cancer Management*	Myriad - Salt Lake City, UT
2008-2009		
Jul 12	*Colorectal Cancer*	Community Forum - Manteo, NC

Jul 24	Colorectal Cancer Think Tank Meeting	Miami, FL
Aug 15-17	Course Director: *Managing Colorectal Cancer in the Age of Molecular Markers*	Big Sky Oncology Course - Big Sky, MT
Sep 3	*Principles of Neoplasia*	UNCSOM 2nd Year Class Oncology Course - Chapel Hill, NC
Sep 18	Colorectal Cancer Think Tank on Liver Metastases	Research to Practice - Miami, FL
Sep 19-20	Course Director: *Management of First-Line Therapy for Metastatic Colorectal Cancer*	Perspectives in Colorectal Cancer - Miami, FL
Oct 16-18	Co-Course Dir & Lecturer: *First Line Mgmt of Colon Cancer and Molecular Genetic Prognostic Markers in Adjuvant Therapy*	Perspectives in Colorectal Cancer - Aventura, FL
Oct 24	*Advances in the Management of Colorectal Cancer*	Medical Alumni Meeting - University of NC - Chapel Hill, NC
Oct 28	*Advances in the Management of Colorectal Cancer*	Fellows Didactic - University of NC - Chapel Hill, NC
Oct 31	*Update on Adjuvant Therapy of Liver Metastases*	South Bend, IN
Nov 3	*Leveraging Cooperative Group Clinical Trials in GI Cancer*	University of South Carolina - Columbia, SC
Nov 15	Plenary Talk: *Odyssey of a Clinical Researcher*	CALGB Meeting - Tampa, FL
Feb 24-25	2/24: *Advances in the Management of Colorectal Cancer & Managing Liver Metastases* 2/25: *Advances Related to Bevacizumab Use in Colorectal Cancer*	King Faisal Hospital Oncology Program Jeddah, Saudi Arabia
Apr 2	Magisterial Lecture: *Maximizing the Value of a Clinical Trial: US Intergroup Study N9741*	Italian Oncology Society - Florence, Italy
Apr 17	*A Colorectal Cancer Update*	Taipei, Taiwan
Apr 18	*A Colorectal Cancer Update*	Hong Kong
May 1	*Advances and Future Directions in Colorectal Cancer*	Grand Rounds, Lankenau Hosp - Philadelphia, PA
May 31	Chair and Lecturer of Educational Session: *Managing Colorectal Cancer in the Elderly*	American Society of Clinical Oncology - Orlando, FL
Jun 18	*Advances in GI Cancer*	Columbus CCOP CME Meeting - Columbus, OH
2009-2010		
Jul 7	Grand Rounds: *Leveraging Cooperative Group Clinical Trials in GI Cancer: Treatment, Biology, and Methodology*	Leo Jenkins Cancer Center, East Carolina University - Greenville, NC
Jul 16	Course Director: Colorectal Cancer Think Tank for Research to Practice	Colorectal Cancer Think Tank - Miami, FL
Aug 7-8	Course Director: *First-Line Therapy of Metastatic Colorectal Cancer*	Perspectives in Colorectal Cancer - Chicago, IL
Aug 14-16	Course Director: *GI Cancer Update*	Big Sky Oncology - Big Sky, MT

Oct 6	*Advances in the Management of Colorectal Cancer*	University of NC Fellow's Didactic Series - Chapel Hill, NC
Oct 15	*Leveraging Cooperative Group Clinical Trials in GI Cancer: Treatment, Biology, and Methodology*	Ann. Mtg of American Clinical & Climatological Assoc - Hot Springs, VA
Oct 22	*Elder Care: Managing Older Patients with Colorectal Cancer*	EC% Meeting - Montreal, Canada
Oct 30-31	10/30: Debate: *Antiangiogenic Therapy Should Be Included in First Line Regimens for All Patients With Metastatic CRC-Con Side; 10/31: Cooperative Group Trials in Colorectal Cancer*	7th International Colorectal Cancer Congress - Washington, DC
Jan 21-25	Steering Committee Member - 1/23: Chair, *Young Investigators Program*	ASCO GI Cancers Symposium - San Francisco, CA
Feb 8	Visiting Professor and Oncology Grand Rounds	Sunnybrook Cancer Center - Toronto, Canada
Feb 8	*Managing Colorectal Cancer in the Elderly*	Toronto CME Event - Toronto, Canada
Feb 25	Plenary Lecture: *Management of Advanced Colorectal Cancer*	German Cancer Society Meeting - Berlin, Germany
Jun 5-9	Program Committee Member -6/6: Oral Research Presenter & Session Chair: *Managing Elderly Patients w/ Colorectal Cancer* - 6/7: Presenter and Session Chair: *Managing Conflict of Interest* -6/8: Presenter: Results of N0147 Adjuvant Study of FOLFOX +/- Cetuximab in Stage III Colon Canc	ASCO Meeting - Chicago, IL
2010-2011		
Jul 9	*Optimal Integration of Chemotherapy and Targeted Therapies in Managing Colorectal Cancer*	WIN Symposium - Paris, France
Aug 6-7	*Update on New Developments in GI Cancer*	Chair: Big Sky Oncology Course - Big Sky, MT
Aug 13	*Initial Management of Advanced Colorectal Cancer*	Natal, Brazil
Sep 26	*Managing Older Patients with Colorectal Cancer*	Cancer in the Elderly Symposium - Chicago, IL
Oct 11-12	*-Managing Older Patients with Colorectal Cancer* *-A Colorectal Cancer Update* *-Toward an Alaska Appropriate Screening Strategy for Colorectal Cancer*	Treadwell Visiting Scholar: Providence Hospital Anchorage, AK
Oct 16	*Management of Metastatic Colon Cancer*	University of Kansas Symposium - Kansas City, KA
Oct 27-30	*Managing the Interface Between Chemotherapy and Biologics in Patients with Colorectal Cancer*	Colorectal Cancer: Biology to Therapy - AACR Symposium - Philadelphia, PA
Jan 7-8	*Metastatic Disease*	NCI Colorectal Cancer Clinical Trials Planning Mtg - Washington, DC
Jan 20-23	Steering Committee and Session Chair	GI Cancers Symposium - San Francisco, CA
Jan 28-29	*Initial Management of Advanced Colorectal Cancer and Adjuvant Matters in Colorectal Cancer*	Perspectives in Colorectal and Pancreatic Cancer - Charleston, SC
Mar 8	*Managing Older Patients with Colorectal Cancer*	Grand Rounds - London Ontario

Mar 11-12	*Colorectal Cancer: Choosing Treatments in the Era of Molecular Genetics*	Charles William Rasco Symposium on Colorectal Cancer - Little Rock, AK
Apr 5	*Colorectal Cancer: Choosing Treatments in the Era of Molecular Genetics*	Cleveland Clinic Cancer Center Symposium - Cleveland, OH
Apr 29	*Update on Systemic Therapy for Colorectal Cancer*	3rd Annual GI/HepatoPancreatoBiliary Symposium - Winston-Salem, NC
May 2	*Managing Older Patients with Colorectal Cancer*	Carolinas Medical Center Grand Rounds - Concord, NC
2011-2012		
Jul 7	*Predicting Clinical Efficacy: Molecular and Radiographic Markers as Heralds of Drug Response*	WIN Symposium - Paris, France
Aug 15	*Managing Older Patients with Colorectal Cancer*	Oncology Grand Rds, British Columbia Cancer Agency - Vancouver, BC
Sep 9	*Maximizing the Harvest: A Parable Drawn from the Phase III NCCTG N9741 Study in Patients with Metastatic Colorectal Cancer*	Society for Translational Oncology - Belfast, Ireland
Oct 15	*Eldercare: Managing Older Patients with Metastatic Colorectal Cancer*	Oncology Congress 2011 - San Francisco, CA
Oct 26	*Cancer Patient's Quality of Life and Their Genes: Predestination or Predisposition?*	ISOQOL 18th Annual Conference - Denver, CO
Nov 15	Fellows Presentation*: Management of Metastatic Colorectal Cancer*	The Ohio State University - Columbus, OH
Jan 20-22	*Strategies for Managing Resistant mCRC in an Era of Multiple Biologic Drugs* Session Chair*: Esophageal and Gastric Cancer* Abstract Session Session Chair*: GI Cancer* Abstract Session	ASCO GI Symposium San Francisco, CA
Feb 17-18	*Challenges and Choices When Treating Gastroesophageal Cancer: Initial Management of Advanced Colorectal Cancer*	FORCE Meeting - Ho Chi Minh City, Vietnam
Mar 12	*Maximizing the Harvest from a Phase III Colorectal Cancer Clinical Trial: NCCTG N9741*	James Cancer Center Oncology Grand Rounds - Columbus, OH
May 25	*New Developments in the Diagnosis and Treatment of Colorectal Cancer*	Geisinger Medical Center Grand Rounds - Danville, PA
Jun 16	Course Director: *Updates in Colorectal Cancer*	Ohio State's 2012 ASCO Review - Columbus, OH
Jun 21	*Updates in GI Cancers*	Columbus CCOP 2012 ASCO Review - Columbus, OH
2012-2013		
Jul 5-7	ASCO 2012 Update: *Emerging Drugs for the Treatment of Colorectal Cancer*	Japanese Society of Clinical Cancer Research Mtg (JSCCR)-Tokyo, Japan
Jul 6	Presenter: *Treatment for Unresectable Advanced Metastatic Colorectal Cancer*	JSCCR Meeting - Tokyo, Japan
Jul 7	Presenter: *Treatment for Unresectable Advanced Metastatic Colorectal Cancer*	JSCCR Meeting - Tokyo, Japan
Sep 21	Presenter: After ASCO 2012: *News in GI Cancers*	12th Annual Cancer Conference - Aultman Cancer Center - Canton, OH
Oct 12	*Systematic Anti-Cancer Therapy for Elderly Patients with Colorectal Cancer*	1st Ann. Symposium for Treatment & Management of Elderly Patients

		with Cancer - Los Angeles, CA
Oct 21	Presenter: *Screening for Colon Cancer: Impact, Disparities, and New Approaches*	Society of Translational Oncology /Lineberger UNC Fall Symposium University of North Carolina at Chapel Hill - Chapel Hill, NC
Dec 1	*Metastatic Colorectal Cancer w/ Liver-Only Metastases: Has the Optimal Approach Been Defined?*	Expert Practice in Colorectal Cancer Symposium New York, NY
Jan 24	*Regorafinib and Other New Agents in Colorectal Cancer*	Research To Practice Satellite Symposium on Advances in the Treatment of Colorectal Cancer - San Francisco, CA
Jan 25	Junior Faculty Mentorship Event	GI Cancer Symposium 2013 - San Francisco, CA
Jan 26	*Ten Years of Progress in the Management of Colorectal Cancer*	GI Cancer Symposium 2013 - San Francisco, CA
Apr 21	*Personalized Therapies in GI Cancer: Now and in the Future*	UPMC Multidisciplinary GI Cancer Symposium - Pittsburgh, PA
Apr 25	*Maximizing the Harvest from a Phase III Colorectal Cancer Clinical Trial: NCCTG N9741*	Karmanos Cancer Center Grand Rounds - Detroit, MI
Jun 1	*Adjuvant Therapy in the Elderly Patient with Colon Cancer*	American Society of Clinical Oncology Annual Meeting - Chicago, IL
Jun 15	Symposium Co-Chair: Review of Colorectal Cancer Presentations	OSU Annual ASCO Update - Columbus, OH
2013-2014		
Jul 5	Abstract Discussant. Scientific Organizing Committee Member and Session Co-Chair	World Congress on GI Cancer - Barcelona, Spain
Jul 9	-*Advances in the Management of Early Stage Colon Cancer* -Plenary Lecture: *Advances in the Management of GI Cancers*	Advances in Management of Colorectal Cancer 2013 Hanoi, Viet Nam
Jul 15	Symposium Co-Chair*: Targeted Therapies in the Management of Advanced Colorectal Cancer*	Asian Pacific Oncology Conference - Bangkok, Thailand
Sept 20	Gastrointestinal Cancer - Clinical Investigator Think Tank Meeting panel	GI Cancer - Clinical Investigator Think Tank Meeting - Miami, FL
Oct 9	Management of Peritoneal Carcinomatosis	Australian GI Tumor Study Group annual Meeting - Melbourne
Oct 10	Update on CRC Adjuvant Therapy: *Why have biological agents not succeeded?*	Australian GI Tumor Study Group annual Meeting - Melbourne
Oct 11	*Second Line Treatment of Colorectal Cancer and Beyond: 5, 4, 3, 2, 1, or 0 Drugs*	Australian GI Tumor Study Group annual Meeting - Melbourne
Dec 8	*Inclusion of African Americans in Cancer Clinical Trials: Potential Quality of Life, Comorbidity, and Pharmacogenetic-Related Barriers*	6th AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved - Atlanta, GA
Jan 16	*Making Good Choices: Second-Line Treatment for Metastatic Colorectal Cancer*	GI Cancer Symposium - San Francisco, CA
Jan 17	*Jumpstarting your Career: How to give a talk and write a paper*	GI Cancer Symposium - San Francisco, CA

Jan 18	*Chemotherapy for Stage II MSI: To treat or not to treat*	GI Cancer Symposium - San Francisco, CA
Feb 21	*Optimizing the Mgmt. of Liver Metastasis: Advances in the Neoadjuvant and Adjuvant Fronts*	International Cancer Conference - Madrid, Spain
Feb 22	*Challenging Cases in Metastatic Colorectal Cancer*	International Cancer Conference - Madrid, Spain
Mar 15	*Eldercare: Managing Older Patients with Metastatic Colorectal Cancer*	Oncology Outlook 2014 CME Conference - Point Clear, AL
Apr 10	*Tickets to Academic Success: Delivering Outstanding Oral Presentations & Publishing High-Impact Articles*	2014 Colorectal Cancer Meeting - Dublin, Ireland
Apr 11	*Moving Beyond RAS as a Predictive Biomarker in Colorectal Cancer*	2014 Colorectal Cancer Meeting - Dublin, Ireland
Apr 12	*Stage II Colon Cancer: To Treat or Not to Treat? That is the Question*	2014 Colorectal Cancer Meeting - Dublin, Ireland
Jun 26	*Co-Chair, Session VI: Cancer of the Liver*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
Jun 27	*What are Resectable Liver Metastases?*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
Jun 28	*Discussant, Session XVIII: Metastatic Colorectal Cancer*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
Jun 28	*Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 1: First-Line Therapy of de Novo mCRC*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
Jun 28	*Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 2: Second-Line Therapy of mCRC*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
Jun 28	*Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 3: First-Line Therapy for mCRC after Adjuvant Relapse <6 months*	ESMO 16th World Congress on GI Cancer - Barcelona, Spain
2014-2015		
Oct 17	*Era of Molecular Risk Stratification in the Adjuvant Setting*	12th Annual West Coast Colorectal Cancer Symposium - Seattle, WA
Jan 28	*Colorectal Liver Metastases Management*	Symposium on Hepatic Oncology at Whistler- Whistler, British Columbia
	Case Reviews	
	What is the role of locoregional therapy in the setting of extrahepatic colorectal cancer	
	Keynote Lecture: Update and future direction of systemic and locoregional therapy in the liver	
Apr 10-11	*Symposium Chair: Perspectives on Progress: Using Genomics to Guide Clinical Therapy*	Society for Translational Oncology, Columbus OH
	Integrating pathologic &genomic factors to make treatment decisions in patients with GI cancers	
	Managing colorectal cancer: Second Line therapy and beyond	Assessing recent data and future therapy for advanced gastric, pancreatic, and colorectal cancers
June 2	*Chair, Clinical Science Symposium: Targeted therapies: Does the disease matter?*	Annual Meeting of the American Society of Clinical Oncology

2015-2016		
Jul 3	*Presentation of selected abstracts*	ESMO World GI Cancer Symposium, Barcelona, Spain
Jul 4	*How to improve adjuvant therapy of colon cancer?*	ESMO World GI Cancer Symposium, Barcelona, Spain
Oct 18	Talk: *"Neoadjuvant and Adjuvant Chemotherapy for Rectal Cancer"*	ASTRO Presidential Symposium - San Antonio, TX

2016-2017		
Jan 19	*Drilling Down On Immunotherapy in CRC: What We Know and What We Need To Know*	Dawn of Immunotherapy in Gastric and Colorectal Cancers, Symposium San Francisco, CA
Feb 9	*Immunotherapy in GI Cancers*	University of Iceland, Rejkavik, Iceland
Mar 14	*In memorium to Daniel J Sargent Ph.D.*	Biometrics Society, Washinton DC
Apr 4	*Current and Emerging Mutation-based Treatment Strategies for Advanced Metastatic Colorectal Cancer*	Southside Regional Medical Center, Petersburg , VA
Apr 6	*Current and Emerging Mutation-based Treatment Strategies for Advanced Metastatic Colorectal Cancer*	Shadyside Hospital, Rockville, MD
May 8	*In memorium to Daniel J Sargent Ph.D.*	Society for Clinical Trials, Liverpool, England
Jun 27	*Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers*	Webcast
Jul 11	*Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers*	Webcast
Jul 19	*Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers*	Webcast
Aug 18	*An Update on Progress in GI Cancers from ASCO 2017*	Oklahoma Society of Clinical Oncology Cancer Conference, Oklahoma City, OK
Nov 14	*Progress with Immuno-oncology agents in GI oncology*	European Society of Medical Oncology, Singapore
Dec 19	*Progress with Immuno-oncology agents in GI oncology*	Inova Schar Cancer Institute Grand Rounds, Fairfax, VA

2018-2019		
Feb 15	*A Case Study and Review of the Literature on PD-1 Inhibitors in GI Cancers*	21st Annual TRCCC meeting, Seven Springs PA
Feb 21	*At Long Last: Immunologic Approaches to the Treatment of GI Cancers*	University of South Carolina, Columbia, SC
Mar 18	*Getting Behind a Cure: New and Noteworthy Information on Colorectal Cancer*	Fight Colorectal Cancer annual call on congress meeting, Washington DC

Jul 31	*A Career Punctutated by "C" Words*	Plenary lecture, Annual INBRE meeting, Morgantown, WV
	The Utility of PD-1, PD-L1, and CTLA-4 Antibodies in Colorectal Cancer	WVU Internal Medicine Grand Rounds, Morgantown, WV
Aug 25	*The Utility of PD-1, PD-L1, and CTLA-4 Antibodies in Colorectal Cancer*	Northside Hospital Cancer Institute Symposium, Atlanta, GA
Oct 26	*Colorectal Cancer ASCO Update 6/2018*	Plenary lecture Roger Maris Cancer Center Symposium, Fargo, ND

2019-2020		
Mar 18	*GI Cancers Update*	Cancer Cell Biology Course, Morgantown, WV
Apr 6	*Rechallenging Advanced Colorectal Cancer Pateints with EGFR Targeted Moncolonal Antibodies*	Amgen Continuing Education Symposium, Cancun, MX
Nov 6	*At Long Last, Progress in the Immunotherapy of GI Cancers*	Garlove annual lecture, Lexington KY

Training Grant Director: A K12, A T32 and R25 (see below)						
Lab or Research Teaching/Mentorships:						
Name	***Dates Mentored***	***Degree***	***Grad Year***	***Graduated From:***	***Mentoring Assistance with:***	***Current Position***
Mohammed Salem MD	**2016-present**	**MD**	**2008**	**University of Alexandria Medical School**	**Research**	**Attending Physician, Levine Cancer Institute**
Hannah Hazard Jenkins	**2017-present**	**MD**	**2011**	**West Virginia University**	**Career Development**	**Associate Professor, WVY School of Medicine**
Narmin Talibova	**2015-present**	**MD**	**2011**	**University of Azerbajain**	**Career plans and research**	**Assistant Professor, University of Azerbajain**
Daniel Ahn	**2015-2016**	**DO**	**2008**	**University of North Texas Health Science Center, University of North Texas**	**Research**	**Assistant Professor, Mayo Clinic**
Macrae, Erin	**2011-2015**	**MD**	**2005**	**Case Western Reserve Univ School of Med Cleveland, OH**	**Research**	**Attending Physician, OSU**
Mrozek, Ewa	**2011-Present**	**MD**	**1983**	**M.D. Medical Academy Gdańsk, Poland**	**Research**	**Assistant Professor, OSU**
Mikhail, Sameh	**2011-2015**	**MD**	**2006**	**American University of Beirut**	**Research**	**Assitant Professor, OSU**
Ciombor, Kristen	**2011-Present**	**MD**	**2005**	**Univ of Miami, FL Miller School of Med**	**Research**	**Assistant Professor, OSU**
Haraldsdottir, Sigurdis	**2012-2015**	**MD**	**2004**	**Univ of Iceland**	**Articles & Projects**	**Senior Fellow, OSU**
Wu, Christina	**2012-Present**	**MD**	**2002**	**Trinity College Dublin, OH**	**Articles & Projects**	**Asst Professor, OSU Div of Medical Oncology**
Shapiro, Charles	**2011-2014**	**MD**	**1984**	**State Univ of New York Buffalo, NY**	**Career Mentoring**	**Professor, OSU**

McRee, Autumn	2009-2011	MD	2005	Univ of Texas	Articles & Projects	Sr Fellow, UNC-Chapel Hill
Davies, Janine (Post)	2008-2011	MD	2003	McMaster Univ	Articles & Projects	
Raftery, Laura (Post)	2007-2010	MD	2004	UNC-Chapel Hill	Articles & Projects	Fellow, UNC-Chapel Hill
Shah, Usman (Post)	2005-2008	MD	2003	Med College of Wisconsin	Case Studies	Fellow, UNC-Chapel Hill
Beaven, Anne (Post)	2004-2006	MD	1993	UNC-Chapel Hill	Review Articles in GI Cancer Trials	Fellow, UNC-Chapel Hill
Kelly-Sanoff, Hanna (Post)	2003-2006	MD	2000	Univ of PA School of Medicine	Developmental Therapeutics in GI Malignancies	Asst Prof, UNC Div of Hematology/ Oncology
O'Neil, Bert (Post)	2003-2005	MD	1994	Univ of CA	Clinical Trials in GI Malignancies	Asst Professor, UNC-Chapel Hill
Penland, Shannon (Post)	2003-2006	MD	2000	Univ of Pittsburgh	Current strategies in Advanced Colon Cancer	Great Falls Clinic, Montana
Gill, Sharlene (Post)	2000-2003 (Mayo Med School)	MD	1996	Univ of British Columbia	Colorectal Chemotherapy	Asst Prof of Oncology, Univ of British Columbia, Vancouver
Alberts, Steven (Post)	1996-2003	MD	1996	Univ of Washington	GI Cancers	Professor of Oncology
Goetz, Matthew (Post)	2000-2003 (Mayo Med School)	MD	1999	Univ of North Dakota	Pharmacokinetics of Colorectal Chemotherapy	Asst Prof of Oncology, Mayo Medical School
Jacobson, Stacey (Post)	2000-2003 (Mayo Med School)	MD	1995	UC Davis	Adjuvant Chemotherapy in Elderly Patients with Colorectal Cancer	Asst Prof of Oncology, UC Davis
Hobday, Timothy (Post)	1996-2000 (Mayo Med School)	MD	1995	Mayo Med School	Molecular Markers in Metastatic GI Neuroendocrine Tumors	Asst Prof of Oncology, Mayo Medical School
Kumar, Shaji (Post)	1996-2000	MD	1995	India Institute of Medical Sciences	Adjuvant Chemotherapy for Colorectal Cancer	Asst Prof of Hematology, Mayo Medical School

	(Mayo Med School)					
Okuno, Scott (Post)	**1996-2000 (Mayo Med School)**	**MD**	**1989**	**University of Illinois**	**Small Bowel Adeno-carcinoma: A Review of 106 Consecutive Cases from the Mayo Clinic 1985-1993**	**Assoc Prof of Oncology, Mayo Medical School**
Fonseca, Rafael (Post)	**1996-1999 (Mayo Med School)**	**MD**	**1991**	**Universidad Anahuac School of Medicine, Mexico**	**Phase I Study of the Combination of CPT-11/5-FU and Leucovorin**	**Assoc Prof of Hematology, Mayo Medical School**
Galanis, Evanthia (Post)	**1994-1997**	**MD**	**1990**	**University of Athens**	**Phase I Trial of Sequential Administration of Raltitrexed (Tomudex) and 5-iodo-2'-deoxyuridine (IdUrd)**	**Assoc Prof of Oncology, Mayo Medical School**

GRANTS

Prior:

1U10CA180850-01 (Goldberg) 05/06/2014-02/28/2019 20% effort
NIH/NCI
National Clinical Trials Network - Network Lead Academic Participating Sites (U10)
This grant funds the OSU cooperative group academic participation and accrual program

5K12CA133250-07 (Byrd) 06/01/2015-05/31/2019 1% effort
NIH/NCI
Training grant for junior faculty in Hematology and Oncology

CA128590-01A1 (Goldberg) 09/01/2008-08/31/2013 10% effort
NIH/NCI
Academic Training in Oncology at the University of North Carolina at Chapel Hill
This T32 provides funds for training fellows interested in careers in academic oncology during their second and third fellowship years.

5R25CA116339-02 (Goldberg) 09/01/2008-08/31/2013 10% effort
NIH/NCI
National Cancer Institute (NCI) Cancer Education and Career Development Program
This R25 provides funds for training fellows and postdoctoral students interested in careers in public health.

1K12CA120780-01A1 (Goldberg) 09/12/2007-8/31/2012 10% effort
NIH/NCI
UNC Oncology Clinical Translational Research training Program
This K12 provides funds for training young investigators interested in cancer research for careers in that arena.

P30 CA16086-30 (Earp) 12/01/2010-11/30/2011 20% effort
NIH/NCI
Lineberger Comprehensive Cancer Center Support Grant
The CCSG provides support for Cancer Center research programs, core facilities, administration, and related activities.

No assignment # (Bertagnolli) 09/01/2004-open ended 10% effort#
Alliance for Clinical Trials in Oncology Foundation
National Cancer Institute (NCI) Cancer Education and Career Development Program
Funds position as Associate Group Chair for Intergroup Affairs for this national, NCI funded, cooperative oncology trials group

PROFESSIONAL SERVICE

Administrative Experience:

WVU (WEST VIRGINIA UNIVERSITY)- MORGANTOWN, WV

- Director, WVU Cancer Institute
- Chair, Cancer Institute Executive Committee
- Member, School of Medicine Executive Council
- Member, Clinical Research Executive Council

OSU (THE OHIO STATE UNIVERSITY) - COLUMBUS, OHIO

- Chair, James Medical Staff Administration Committee (2012-
- Chair, James Executive Clinical Leadership Team (2012-
- Attendee, Wexner Medical Center Board of Trustees 2014-2016
- Member, Internal Medicine Board of Managers (2015-2016)
- Member, Patient Satisfaction Committee (2011-
- Chair, Hematology and Oncology Operations Council (2011-
- Member, Comprehensive Cancer Center Associate Directors (2011-
- Member, Resource Utilization Committee (2011-
- Member, Wexner Medical Center Chief Medical Officers Council (2011-
- Member, Teletracking Steering Committee (2015-
- Member, James Medical Staff Bylaws Committee (2011-
- Member, Leadership Council for Clinical Quality Safety & Service (2012-
- Member, James Netweork Steering Committee (2011-
- Member, Health System Quality and Professional Affairs Committee (2011-
- Member, James Clinical Quality Review Committee (2011-
- Member, G-5 Leaders Group (2011 -
- Member, Value-Based Clinical Integration Steering Committee (2011-
- Member, OSU Wexner Medical Center Board (2012-2014)
- Member, OSU Wexner Patient Experience Council (2012-
- Member, James Cancer Hospital Board (2012 -2014)
- Member, James Foundation Board (2012 -
- Member, OSU Wexner Medical Center Professional Evaluation Committee (2012-

- Member, OSU Wexner Medical Center Schwartz Rounds Steering Committee (2013-
- Member, OSU Wexner Medical Director's Forum, (2013-
- Member, OSU Wexner Critical Care Executive Committee (2012-
- Executive Sponsor, James Expansion Transition Steering Committee (2012-2014)
- Chair, James Service Line Advisory Committee (2014-
- Chair, Palliative Medicine Division Chief Search Committee (2013-2014)
- Member, Wexner Medical Center Chief Medical Officer Council (2013-
- Member, Ex-Officio, Wexner Medical Center Practitioner Evaluation Committee
- Member, Wexner Medical Center Credentialing Committee (2012-
- Member, Wexner Medical Center Clinical Resource Utilization Committee (2013-
- Member, Wexner Medical Center Clinical Hematology and Oncology Operations Committee (2012-
- Member, Wexner Medical Center Digestive Disease Executive Steering Committee (2013-
- Member, Wexner Medical Center Clinical Operations Working Group (2013-

UNC (UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL) - CHAPEL HILL, NORTH CAROLINA

- Member, Ambulatory Operations Group, 2004-2011
- Member, Dean's Executive Council
- Attendee, UNC Health System Board of Trustees
- Member, Steering Committee for UNC Clinical Trials Office, 2005-2011
- Member, Hospital Building Projects Oversight Group, 2004-2011
- Chair, Lineberger Clinical Cancer Center Executive Committee, 2004-2011
- Chair, North Carolina Cancer Hospital Executive Committee, 2006-2011
- Chair, Oncology Process Improvement Group, 2004-2011
- Member, GI SPORE Executive Committee, 2005-2011
- Member, Lineberger Comprehensive Cancer Center GI Cancer Tumor Group, 2004-2011
- Member, Lineberger Comprehensive Cancer Center Executive Committee, 2004-2011
- Member, Lineberger Comprehensive Cancer Center Program Leaders Group, 2004-2011
- Director, Clinical Protocol Office, 2005-2007
- Chair, Clinical Protocol Office Executive Committee, 2005-2011
- Member, Oncology Advisory Council, 2004-2011
- Member, Radiation Oncology Chair Search Committee

MAYO CLINIC - ROCHESTER, MINNESOTA

- Member, Cancer Center Clinical Research Committee, 1994-1997
- Member, Mayo Clinic Public Affairs Committee, State, 1997-2001
- Member, Cancer Center Planning Task Force
- Member, Oncology Clinical Guidelines Group
- Initiator and Coordinator, Oncology, New Patient Gastrointestinal Cancer Clinic
- Member, Medical Management Group for Mayo Medical Services Incorporated (MMSI), the Mayo HMO, 1997-2000
- Member, Mayo Medical Services Incorporated Medical Management Executive Committee, 1998-2000
- Member, Mayo Clinic Web Site Task Force, 1994-1996
- Member, Editorial Board, Mayo Clinical Updates, 1995-1999
- Member, Zumbro Valley Medical Society Legislation Committee
- Member, Cancer Center Industry Interaction Task Force

- Member, Mayo Clinic Marketing Committee
- Co-chair, Cancer Center Multidisciplinary GI cancer planning effort
- Chair, Multidisciplinary GI practice integration effort

GEISINGER PHYSICIAN'S ELECTED REPRESENTATIVE

- Member, Geisinger Clinic Board of Governors, 1988-1990
- Member, Combined Medical Center and Clinic Governance Committee, 1989-1990
- Member, Geisinger Medical Center Finance Committee, 1988-1991
- President of Medical Staff, 1989-1990
- Vice-President of Medical Staff, 1988-1989

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

- Member, Board of Directors for Alliance for Clinical Trials in Oncology (3/2014- present)
- Member, Board of Directors for the Alliance Foundation (2/2012- present)
- Member, Executive Committee for Alliance for Clinical Trials in Oncology (3/2012- present)
- Member, Gastrointestinal Cancer Committee for Alliance for Clinical Trials in Oncology (3/2012- present)
- Member, Cancer in the Elderly Committee for Alliance for Clinical Trials in Oncology (3/2012- present)
- Chair, Gastrointestinal Cancer Committee Cancer and Leukemia Group B (CALGB) (2007-2011)

NATIONAL MEMBERSHIPS AND INTERNATIONAL OFFICES OR COMMITTEES

- Alpha Omega Alpha Honor Medical Society
- American Association of Cancer Research
- American Clinical and Climatological Association
- American College of Physicians (Fellow)
- NCI Colorectal Task Force, 2000-
- American Joint Committee on Cancer
  - Co-Chair Colorectal and Anal Cancer Staging Committee 2013- present
  - Board of Directors 2005-2013
  - Finance Committee 2008-2013
  - Promotions Committee 2008-2013
  - Co-Chair, Colorectal Cancer Staging Working Group for the 8th Edition of Cancer Staging - 2014
- American Medical Association
- American Society of Clinical Oncology (ASCO):

  Member, Annual meeting Program Committee, 1991-1992, 2000-2002, 2007-2011
  Member, Education Committee, 1997-2000
  Member, Publications Committee 2003-2006
  Member, Program Committee for the GI Cancer Symposium 2006-2007
  Member, Steering Committee for the GI Cancers Symposium 2010 and 2011
  Chair, Steering Committee for the GI Cancers Symposium 2012
  Editorial Board, GI cancer editor, Cancer.Net 2005-2014
  Editorial Board, Journal of Clinical Oncology 2001-2003
  Member, Ethics Committee, 2007-2010

  Mentor, ASCO International Development and Education Program (IDEA), 2007-10
  Recipient, ASCO Statesman Award, 2011
  Fellow, American Society of Clinical Oncology, 2013

Member, Governmental Affairs Committee, 2013-

- Member, Dana Farber/ Harvard Cancer Center External Advsory Board, 2010
- Society for Translational Oncology, Board of Directors, 2009-
- Zumbro Valley Medical Society, 1996-2003
- Minnesota Medical Society Annual meeting, Delegate, 1999
- Association of Program Directors of Internal Medicine, 1992-94
- American College of Physician Executives, 1992-94
- ASCO Representative to the American Society for Radiology Oncology (ASTRO) Rectal Cancer Best Practice Expert Panel Meeting - Washington, DC - 2014

LEGAL CONSULTING

- Patent law expert witness for Genentech, Taiho 2019-20

INVITED REVIEWER

- Annals of Gastroenterology and Hepatology
- Anti-Cancer Drugs
- British Journal of Cancer
- CA, A Cancer Journal for Clinicians
- Cancer
- Cancer Chemotherapy and Pharmacology
- The Cancer Journal, Scientific American
- Cell
- Clinical Cancer Research
- Clinical Colorectal Cancer
- Clinical Drug Investigation
- Diseases of the Colon and Rectum
- Drug Safety
- Expert Review of Anticancer Therapy
- Expert Review of Pharmacology
- Expert Review of Vaccines
- Gastroenterology
- Gastrointestinal Cancer Research
- Health Policy
- Investigational New Drugs
- JAMA
- JAMA Oncology
- Journal of Clinical Gastroenterology
- Journal of Clinical Oncology
- Journal of Oncology Practice
- The European Journal of Cancer
- The European Journal of Oncology
- European Journal of Cancer and Clinical Oncology
- International Journal of Cancer
- International Journal of Gastrointestinal Cancer
- Italian Journal of Gastroenterology and Hepatology
- International Journal of Metabolic, Molecular and Laboratory Medicine

- Journal of the National Cancer Institute
- The Lancet
- The Lancet, Oncology
- Mayo Clinic Proceedings
- Nature Clinical Practice Oncology
- The New England Journal of Medicine
- Oncology
- Clinical Pharmacokinetics
- Pharmacogenetics

GRANT REVIEWS

- European Commission on Cancer, Quality of Life grants 2001
- Italian Association of Cancer Research, grants 2001, 2006, 2008
- Canadian Institutes of Health Research grant 2006
- Cancer Research UK grant 2006
- Cancer Research UK grant 2007
- Cancer Research UK grants 2008
- Dana Farber/Harvard Cancer Center External Advisory Board 2010
- Cancer Research UK grant 2014
- American Society of Clinical Oncology Foundation 2018-19
- NIH National Center for Advancing Translational Sciences (NCATS) Special Emphasis Panel/ Scientific Review Group 2019/05 ZTRI RD-8 (01) for Rare Disease Clinical Research Consortia for the Rare Diseases Clinical Research Network

EDITORIAL BOARDS

- Physician Data Query (PDQ) Adult Treatment Editorial Board, 1998-2000
- Physician Data Query (PDQ) Adult Treatment Advisory Board, 1996 - Present
- Journal of Clinical Oncology, 2001-2003
- Clinical Colorectal Cancer, 2001 - Present
- European Journal of Clinical and Medical Oncology 2010-2014
- The Oncologist, Section Editor for GI Cancer 2006-2016
- The Oncologist, Senior Editor 2014-2016
- ONCOLOGY, 2002-2007
- Oncology Business Review, 2011- Present
- Clinical Advances in Hematology & Oncology, 2002- 2009
- Mayo Clinic Proceedings, 2005-2015
- Gastrointestinal Cancer Research, 2005 - Present
- UpToDate Gastrointestinal Cancer, Section editor, 2006-Present
- Targeted Therapies in Oncology, 2013-2015
- Oncology Payers, Policy Makers and Prescribers, 2013-2015
- Cancer.Net: Associate Editor for GI Oncology 2005-2011