Cancer Treatment Centers of America®

Comprehensive Cancer Care Network

Hospitals
Atlanta
Chicago
Philadelphia
Phoenix
Tulsa

Outpatient Care Centers
Downtown Chicago
North Phoenix
Scottsdale

March 28, 2019

VIA U.S. MAIL AND EMAIL

Laura Smith, Esq.
Bonnie Patten, Esq.
Truth in Advertising, Inc.
P.O. Box 927
Madison, CT 06443

<u>Re: Cancer Treatment Centers of America Advertising</u>

Dear Ms. Smith and Ms. Patten:

Further to my November 14, 2018 letter, I am writing on behalf of CTCA to provide a more detailed explanation as to why we believe the concerns expressed in your letter to the FTC are unfounded, as they do not take into account the complex medical, legal, and practical realities of cancer treatment. Respectfully, we believe that a deeper understanding of those realities will allow you to appreciate why CTCA does not and cannot undertake the practices for which you advocate.

CTCA categorically rejects the allegation in your letter that CTCA is engaged in "deceptive marketing…promoting atypical patient experiences in testimonials without legally sufficient disclosures". In fact, CTCA takes great care to present patient experiences to the public responsibly, along with appropriate information regarding the atypicality of cancer treatment, and we believe that cancer patients and their families value and appreciate these experiences shared by other cancer patients. We also believe that patients and their families greatly value information about a wide variety of potential treatment options, even though they understand that not every treatment option may be available to or work for them. In short, we find that cancer patients and their families seek and value as much information as possible that may help them, knowing that ultimately their specific treatment plan must be tailored to their specific situation after careful deliberation with their doctors and other health care professionals.

TINA's main concern appears to be the fact that CTCA's advertisements with patient testimonials do not display aggregated average five-year survival rates, such as the survival rates from Surveillance, Epidemiology, and End Results ("SEER") data. TINA believes that such survival data are necessary to be consistent with the FTC's Endorsement Guides, and that CTCA's current disclosure ("No case is typical. You should not expect to experience these results.") is not sufficient. There are significant misunderstandings reflected in that position.

1. **It would be inappropriate and even misleading to represent five-year survival statistics as "typical" results.**

TINA appears to believe that aggregated five-year survival data provide "typical" cancer care results, and that such data should be provided in any advertisements that contain patient testimonials.

Survival data, however, does not present "typical" results. Instead, it is a broad aggregated data set that cannot be applied to individual cancer patients, and thus, we respectfully submit that it does not accomplish the objective that TINA seeks to achieve. In fact, the National Cancer Institute of the National Institutes of Health ("NCI") acknowledges limitations of summary or aggregate patient data in providing meta-analyses of cancer survival statistics:

> Because statistics are based on large groups of people, they cannot be used to predict exactly what will happen to you. Treatments and how people respond to treatment can differ greatly. Also, it takes years to see the benefit of new treatments and ways of finding cancer. So, the statistics your doctor uses to make a prognosis may not be based on treatments being used today.[1]

Notably, NCI does not hold out its own SEER survival data as demonstrating typicality. Indeed, NCI goes into great detail as to the limitations of the SEER data, including without limitation: the universe of patients included in the data (including patients who do not even seek treatment for their cancer), the wide variety of demographic factors that can affect survival outcomes, the fact that it is a convenience sample collected from regional registries, and the potential for incomplete and inaccurate data in the regional registries.[2]

Further, five-year survival statistics are, by definition, out of date by more than five years given that the relevant treatments were state-of-the-art five years prior to the date the data were collected. The American Cancer Society notes that five-year survival rates should be "interpreted with caution" because, among other reasons, they "do not reflect the most recent advances in detection and treatment because they are based on patients who were diagnosed several years in the past."[3] Because cancer care is dynamic, this limitation is critical to consider when attempting to present to the public what is "typical" for today's cancer patient. There is also a period of time

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[1] *See* https://www.cancer.gov/about-cancer/diagnosis-staging/prognosis.

[2] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5106320/#S11title.

[3] *See* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf.

before the collected data are published, and then that information remains in publication for some time before it is updated. This significant gap in time between when the cancer was treated and when the data is made available can bring dramatic improvements in treatment, as recognized by NCI.[4] Indeed, we have seen important, significant advancements in the last two to four years, such as immunotherapy for lung cancer,[5] the discovery of new drugs, including targeted therapies, to treat breast cancer,[6] and the first new treatment for bladder cancer in three decades,[7] which are not reflected in five-year survival statistics. Studies have already found that an advancement like the 2016 FDA approval of a checkpoint inhibitor for patients with metastatic non-small cell lung cancer whose tumors express PD-L1 improves survival,[8] and it will take years for the data to reflect this important change to the statistical outlook for these patients.

Moreover, there are other significant limitations regarding the typicality of the five-year survival rate, including:

- For previously treated ("non-analytic") patients there are no "five-year survival" data, as the data only applies to newly-diagnosed patients;
- There are no published data applicable to survival for the vast majority of cancer patients because the data does not apply to those with recurrence of the disease;
- The data does not show "five-year survival" of all known subsets (*e.g.*, ER positive or negative breast cancer; HER-2 positive or negative breast cancer; triple negative breast cancer; EFGR positive or negative lung cancer; ALK positive lung cancer, BRAF mutation positive melanoma, *etc*.);
- The data does not account for recently discovered precision-medicine-based subsets, often representing one to two percent of patients with a specific cancer; and
- Significant variations in the data diminish the value of the statistic, relaying only the average of disparate data points.

As we note below, there is value and utility in five-year survival data, but no value is derived when presenting such data as "typical" or "generally expected" for an individual patient.

2. As we clearly state in our advertisements, no cancer case is typical.

TINA alleges in its letter that certain patient testimonials from CTCA fail to "clearly and conspicuously disclose what is typical for such patients." What TINA fails to understand in this allegation is that cancer and cancer care are extraordinarily complex. There simply are no

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[4] *See* https://www.cancer.gov/about-cancer/diagnosis-staging/prognosis.

[5] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4607819/; *see also* https://www.cancer.gov/news-events/cancer-currents-blog/2018/pembrolizumab-lung-cancer-first-line.

[6] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6010518/.

[7] *See* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm501762.htm.

[8] *See* https://www.nejm.org/doi/full/10.1056/NEJMoa1606774.

"generally expected" or "typical" outcomes of cancer care. All cancer patients—with disparities in age, genetics, co-morbidities, lifestyle, socioeconomics, and demographics, to name a few—and all cancers, treatments, and treatment plans are different, and nothing is "typical" or "generally expected." In fact, numerous studies illustrate cancer patient disparity,[9] and the American Cancer Society highlights "Cancer Disparities" in its Cancer Facts & Figures publication to demonstrate the vast difference in cancer burden among the population.[10]

As a result, no disclaimer or explanation can possibly provide a "typical" cancer outcome that is meaningful to each viewer of an advertisement. CTCA's disclosure is a good-faith attempt to communicate fairly and accurately with people and to follow FTC guidance on testimonials, given the reality that there is no typical or generally expected result that applies to all the different people who view CTCA's advertising materials.

Cancer patients and their families are careful consumers who talk to their own doctors and do research before selecting a provider. The complexity of cancer and cancer care is well known, and patients and caregivers are careful in their choice of providers. It is understood that one patient's story is not representative of the disease as a whole. CTCA actively reinforces that understanding by including the statement that "No case is typical. You should not expect to experience these results." In that regard, CTCA goes further than most of its peers by including this non-typicality statement. We understand that TINA sent similar letters to 42 other cancer hospitals, and that most (if not all) of those hospitals do not use any such statement. Accordingly, CTCA presents information about treatment options, true stories about patient's experiences, while also explicitly acknowledging the intricacy of cancer care. The principle of respect for a patient's autonomy is engrained within the medical profession. Cancer patients have a right to understand the full extent of their options while they make a decision about which health care interventions they will or will not receive and by what provider.

3. Not only does survival data *not* show typicality, its complexity is likely to mislead patients absent appropriate context.

Survival data, such as the SEER data, without proper context may be easily misunderstood and overvalued as a predictor of survivorship. This is especially true given that the data comes from the U.S. government and therefore greater weight may be attached to the SEER survivorship information when viewed as part of a statement in an ad. As explained above, however, SEER data alone is not a "typical" result or strong predictor for survivorship and NCI recognizes that fact. Representing the data as such, without proper context, would be misleading.

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[9] *See* http://ascopubs.org/doi/full/10.1200/JCO.2013.54.9329; *see also* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2360690/; *see also* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4209573/.

[10] *See* https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf.

In addition, the SEER data is complex. Any meaningful explanation in an ad as to what the SEER database is—and why the data is being shown despite the fact that it does *not* represent a typical result—would necessarily be long and difficult to read or understand in the short period of time that someone views an ad. Such a lengthy, complex explanation, read in the span of a few seconds, would defeat the purpose of including the statistics in the first place.

CTCA will continue to follow advances made in the area of survivorship prediction and will provide patients with any new sources of information that may be helpful in making difficult cancer treatment decisions. However, CTCA strongly believes that inclusion of five-year survival data, such as the SEER data, in ads without appropriate context and limitation statements (which would be impractical or impossible to do) would be counterproductive and likely to mislead patients.

4. CTCA supports access to survival rate data *with appropriate context,* which it already provides on its website and in other materials.

Despite the limitations of survivorship data standing alone, such data can provide useful historical context and a starting point for gathering information and discussing a prognosis with doctors. In fact, the very data that TINA asserts should be disclosed is already disclosed contextually on our website.

CTCA supports the notion that cancer patients, their loved ones, members of the medical community, and members of the public at large should have access to the survival rates of patients treated by any cancer care provider, and that these data should be collected, analyzed and reported in a methodologically consistent and replicable manner by all providers to enable accurate comparisons. Such reporting should also provide the appropriate context and limitations of the data so as not to suggest typicality. When responsibly reported in proper context, such statistics can help inform patients' decisions about cancer care.

As TINA acknowledges, CTCA does provide survival data on its website and in other materials—both from the SEER data and from its own treatment outcomes—but it does so with careful explanations of the limitations and applicability of the data. Such materials also direct patients to NCI's official SEER website to learn more about the data and its limitations. CTCA is careful to present such data in a way that does not foster any mistaken beliefs as to typicality.

TINA argues that providing the SEER and CTCA survival data on CTCA's website is not enough to address TINA's concerns with patient testimonials. What this argument fails to recognize is that our patients do not start cancer treatment at CTCA after simply seeing a patient testimonial in an ad, without doing further research. Cancer care is not "purchased" on an impulse after viewing one ad, but rather only undertaken after careful research and deliberation with doctors, other healthcare professionals, even patients who have been treated for a similar diagnosis. It is likely that many patients will visit the CTCA website or otherwise have the opportunity to review CTCA's treatment results well before making any treatment decisions.

TINA also alleges that CTCA's own survival statistics are biased or unreliable. With respect, that allegation is manifestly false. CTCA has gone to great lengths to prepare and validate its statistical information, including engaging independent biostatisticians and leading independent organizations to conduct various analyses of its treatment results. A detailed breakdown of CTCA's statistical methodology and the qualifications of its independent researchers can be found here: https://www.cancercenter.com/become-a-patient/our-treatment-results/survival-statistics-and-results.

Like the SEER data, CTCA's own data can be a useful piece of information for a patient to begin a discussion with their physician about survival rates and expectations. CTCA does not, however, hold out its data as showing typicality. In fact, CTCA clearly states on its website that its treatment results are *not* claimed to be "typical" or applicable to other patients, but rather are provided for information purposes only. For example, each treatment results page states:

> We also want to be sure you understand that cancer is a complex disease and each person's medical condition is different; therefore, CTCA makes no claims about the efficacy of specific treatments, the delivery of care, nor the meaning of the CTCA and SEER analyses. Not all cancer patients who are treated at a CTCA hospital may experience these same results.[11]

CTCA provides the SEER and CTCA survival data for the sake of transparency and to provide access to information that many (but not all) patients seek. The survival data is available to those who want it, but not forced upon those who do not. Again, some patients are motivated to pursue and endure treatment by a resolute sense of hope they will prevail in the fight with their disease, and CTCA respects those wishes. CTCA tries to strike a careful balance by making the data available, but not making it the focal point of every communication. As explained by NCI:

> Many people want to know their prognosis. They find it easier to cope when they know more about their cancer. You may ask your doctor about survival statistics or search for this information on your own. Or, you may find statistics confusing and frightening, and think they are too impersonal to be of value to you. It is up to you to decide how much information you want. If you do decide you want to know more, the doctor who knows the most about

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[11] *See, e.g.*, https://www.cancercenter.com/cancer-types/breast-cancer/statistics.

> your situation is in the best position to discuss your prognosis and explain what the statistics mean.[12]

Simply put, the SEER and CTCA survival data provided by CTCA *with appropriate context* and explanation is beneficial to and sought after by many patients.

5. Patients benefit from mention of the existence of new and evolving treatments.

TINA argues that “novel treatments” such as immunotherapy and genomic testing should not be mentioned in advertising without detailed information regarding risks and limitations. To be clear, there is science showing that these treatment options can be helpful in appropriate cases. Indeed, NCI notes such favorable results from these types of treatments.[13]

Moreover, these additional treatment options are just that: potential *options*. No reasonable person would think the mere mention of these options in an ad is a guarantee that they always work for everyone. No patient would, or even could, just “sign up” for such treatment without first having detailed discussions with his or her doctors to establish clinical eligibility for the option under consideration, its availability, efficacy, risks, and other considerations. Again, all patients, cancers, and treatment plans are different, and some treatment options may or may not be available or useful for some patients. We believe this is generally understood among patients and their families. More fundamentally, there are of course risks and limitations with *all* cancer treatment options, and all medical treatments generally. It is important to note, however, that breakthrough discoveries in the treatment of many types of cancer have occurred with greater frequency in recent years, and even more exciting discoveries are anticipated in the years ahead. Patients are entitled to know about these treatment options, and advertising is, and will remain, an effective way in which to communicate this information.

Patients and their families want access to information, and one way to share information is through advertising. It is not practical or appropriate for an ad to substitute for a full medical consultation with doctors, and thus an ad cannot be expected to provide full medical detail regarding all possible risks and limitations anytime a treatment option is mentioned. Instead, it is entirely appropriate to mention the existence of treatment options and allow patients to explore the viability of those options in their particular case with their doctors.

Conclusion

CTCA has been, and will continue to be, an industry leader in providing information to patients and their families in a transparent and responsible way, to allow them to make informed decisions. We trust that TINA will find this information helpful in its evaluation of medical

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[12] *See* https://www.cancer.gov/about-cancer/diagnosis-staging/prognosis.

[13] *See* https://www.cancer.gov/research/progress/discovery.

advertising practices, and we invite further discussion to the extent you have any remaining questions.

Please feel free to contact me directly with any questions.

Very truly yours,

Timothy E. Flanigan
Chief Legal Officer

Cc: Andrew Smith, Director, Bureau of Consumer Protection, Federal Trade Commission
Mary Engle, Associate Director, Division of Advertising Practices, Federal Trade Commission