Fact Sheet on Regulatory Agency Warning Letters During COVID-19 Pandemic
June 5, 2020

The AANP has teamed with professionals in the integrative medicine, dietary supplement, and legal fields to analyze the sudden increase in regulatory activity around natural approaches to improving immune resiliency, and treating viral infections and/or COVID-19. This resource provides information on the various laws at play, offers suggestions for providers to mitigate risk, and highlights where regulatory actions may cross the line into scope of practice - with the unintended effect of limiting the ability of licensed providers to discuss important and appropriate non-pharmacological methods to mitigate COVID-19 and its symptoms.

The state of the law is ambiguous and the current environment presents novel regulatory issues involving a number of federal and state agencies. Oregon NDs please refer to the special notice at the end of this document. Enforcement of laws is uneven, and there is a continuum of risk in how to appropriately discuss prevention of and treatments for COVID-19. At particular risk are providers who are advertising and selling supplements to the public and any practitioners making over-stated claims.

As this is a developing area of law, this document is only advisory. Decisions about specific language to use depends on risk tolerance in this novel regulatory environment. Practices which intend to maintain COVID-19 discussions on their website that may implicate these concerns should consider obtaining legal advice. This document supersedes and replaces the AANP's prior guidelines: "*Template Language Guidelines for Providers During COVID-19 Pandemic.*"

Possible Consequences of FTC/Regulatory Agency Warning Letters:

Clinics and providers must first understand the potential serious consequences that can occur as a result of receiving a letter from the FTC and/or other regulatory agency, including:

- **Federal Actions -** The FTC can take non-compliant parties to federal court and can obtain penalties, such as a disgorgement of profits alleged to have been earned from what they consider deceptive advertising;
- **State Investigations -** FTC letters may be picked up by state regulatory agencies such as departments of justice or consumer affairs, which may issue additional investigative letters of alleged violations **(Important notice for Oregon NDs below)**;
- **Licensing Boards -** State agencies may refer alleged violations to your state medical/naturopathic licensing board;
- **Bank/Merchant Service Freeze -** FTC letters are shared with the banking system, and some banks may temporarily or permanently freeze your merchant service account;

- **Difficulties with Malpractice Carriers** - Where legal defense becomes needed, malpractice policies may not cover regulatory issues based on advertising violations.

To mitigate risk from these regulatory actions, the AANP strongly advises that clinics operate with an abundance of caution with their published material (both advertising and educational) and social media.

Patterns and Trends in the FTC Warning Letters:

- 100% of the warning letters from the FTC spoke directly to COVID-19 treatment or prevention claims ***specifically tied to marketing a nutrient ingredient or dietary supplement***, whether "direct" or "implied." Most warnings relate to an "implied claim."
- "Implied claims" = statements are read in context. If you discuss the importance of the immune system in minimizing COVID-19 damage, and refer to or link to a dietary supplement with what would otherwise be a proper general immune statement, the two will be read together and considered an implied (and illegal) claim for the mitigation or prevention of COVID-19. ***Word combinations do not need to be in the same paragraph, they can be anywhere on the page or website.*** Graphic images can have the same impact as words. In some cases, FTC's algorithm has picked up discussion about COVID-19 clinic *policies* (i.e., sanitation, masks, etc) with unrelated discussions about respiratory health, and connected the two as being an "implied claim" to treat COVID-19. *The AANP is actively working to defend the rights of NDs where regulatory challenges like this seem excessive, inappropriate, or overly ambiguous.*
- Webcrawlers seem to look for some combination of language and words (including meta keyword tags for SEO) which can flag your content, especially related to implied claims.
- ***Most of the FTC complaints appear to be valid*** - many direct or implied statements are overly exuberant and linked to the sale of supplements. This requires providers to have a strong understanding of FTC deceptive advertising laws, unsubstantiated claims and DSHEA restrictions on claims made for dietary supplements. ***Read more in Appendix B***. However there are enough instances where the warnings overreach and impinge on scope of practice or freedom of speech to warrant concern as outlined below.
- Any discussion of COVID-19 mitigation, prevention or cure using dietary ingredients or herbs, ***connected to the sale of those products, is a direct violation of the prohibition against disease claims for dietary supplements.***
- NDs in unregulated states should exercise special precaution as they do not have a state-authorized scope of practice.

Understanding the Various Laws:

Federal Trade Commission
FTC is responsible for enforcing advertising laws. Advertising must be truthful and not misleading. All claims must be substantiated. The primary violation cited in the FTC COVID-19 warning letters allege a finding that advertisement(s) for products or services that claim to be

coronavirus-related prevention or cure are unsubstantiated and therefore deceptive. ***Read Appendix B for more detail and background.***

Dietary Supplement Health and Education Act of 1994 (DSHEA)
The ban on linking disease states to dietary supplements far predates COVID-19. With few exceptions, it is illegal to claim a dietary supplement can treat or prevent a disease; such claims are prohibited "health claims." Some key elements to understand about DSHEA include:

1. Any ingestible material intended to diagnose, prevent, mitigate, treat or cure a disease is a drug, and requires FDA approval to make such a claim related to the disease.
2. **DSHEA allows "structure/function" claims for dietary supplements, i.e., about what it *does*, not about what disease it *treats*.** Calcium can be marketed to "build healthy bones" (function claim) but cannot be marketed to "prevent or relieve osteoporosis" (disease claim).
3. DSHEA only applies to information ***tied to the sale of a product***. If a practice is educating about herbal products but not selling them, that is OK under DSHEA. However, FTC could still raise issues with statements they consider untruthful, misleading or contrary to public health messaging given the pandemic emergency.
4. **Immune claims for dietary supplements are important to understand in the COVID-19 context**. General statements about support of the immune system do not convey a specific reference to disease treatment or prevention, and may be made. A claim that Vitamin A is necessary to maintain a healthy immune response or that it supports lung health does not imply that a specific disease or class of diseases will be prevented. In contrast, if that claim is made as part of a discussion about COVID-19 it will be expressly flagged by FTC. Likewise, a claim that Vitamin A "supports the body's antiviral capabilities" implies a specific *class of diseases*, those caused by viruses (e.g., colds, hepatitis, HIV, or COVID-19), and may also be flagged by FTC as making a specific claim to treat disease rather than support function. The safest statements will stick to physiology, i.e., immune support and function as opposed to diseases or disease classes.

Areas Where the Laws are Less Clear:

Some of the FTC letters have targeted advertisements for services that are only performed with patients after an evaluation, such as intravenous Vitamin C. While FTC regulates advertising, findings that consumer advertisements for professional services are inherently deceptive - when the services are only provided to patients who are evaluated for appropriate care constitute an **unusual new area of enforcement**. This is especially the case for therapies such as IVC, which are also being offered in major medical centers.

Given the novelty of this legal development, practices must determine how to best navigate legal risk versus the benefits of sharing information. If the practice recognizes that there is currently some legal risk and chooses to mention COVID-19, it should take care to not overstate the evidence or leave an impression that the therapy mitigates, prevents or cures COVID-19.

This is another area where AANP will work to defend the rights of NDs where regulatory challenges seem excessive, inappropriate or overly ambiguous.

Practices seeing potential COVID-19 patients should follow CDC, Department of Health and OSHA requirements. Disclaimers should be used to make clear that these services are only provided to appropriate patients who have been seen in-person. ***Sample disclaimer language is provided in Appendix A.***

Suggestions for Practices to Mitigate Risk:

READ CAREFULLY: Language decisions to make are based on your risk tolerance, your understanding of laws, and your business model

OK: NDs can educate the public about COVID-19 treatment approaches ***without product sales*.**

OK: NDs can sell dietary supplements/products ***without making specific prevention or treatment health claims, including but not limited to COVID-19, antiviral*** or other disease treatment or prevention properties.

NOT OK: Do not make claims about COVID-19 treatment approaches ***with product sales or a link to an online dispensary*** in either a direct or implied manner.

Care should always be taken to reinforce public health messages and not make claims about the prevention, mitigation or treatment of disease for natural product sales to the public.

Providers should also be aware that the FTC is targeting certain therapies, such as IV Vitamin C, Ozone, and stem cell therapy. Care should be taken to not go beyond the evidence in making claims about therapies that federal agencies currently consider have insufficient substantiation.

Implied claims for products can easily cross this line: even simply stating that an herb is superior to a pharmaceutical is viewed as a drug claim, as it legally implies that it serves the same purpose as the drug. Such discussions are fine between a doctor and patient in the treatment room; **the limitation is on advertising to the public.**

Examples:
Lower Risk: “Our clinic treats all kinds of diseases with a variety of treatment protocols tailored to the individual patient’s needs after an appropriate intake in accordance with our scope of practice.”

Higher Risk: If you claim that Vitamin D reduces the likelihood of getting coronavirus (a disease prevention claim) AND link to a third-party dispensary like FullScript, this would be viewed as advertising based upon the claim and would be viewed as an unsubstantiated, untruthful and misleading drug claim.

Highest Risk: “We treat/prevent COVID-19 with IV Vitamin C.”

Concerns about Infringement on Scope of Practice:

The AANP supports the FTC’s enforcement actions with respect to false or deceptive advertising, as well as the regulations around DSHEA. While many of FTC’s complaints appear to be valid, in too many cases FTC and other regulatory bodies are overreaching and crossing into the jurisdiction of legitimate scope of practice of regulated healthcare providers and the ability of physicians to communicate important and appropriate information about mitigating COVID-19 and managing it’s symptoms. Our concerns focus on the following issues:

- FTC letters requiring changes to advertising of services offered only to patients, such as IV Vitamin C, are an unusual jurisdictional reach and one that is being unevenly applied to restrict naturopathic and integrative physician services otherwise openly practiced in major medical centers.
- The discussion of immune enhancement, when explained in a straightforward and accurate manner without being tied to product sales, is an important public health message that should be encouraged, not suppressed. Naturopathic physicians are qualified by education, training and experience as learned intermediaries who can consider the totality of available evidence regarding dietary supplements to form general clinical recommendations, and to properly express their professional opinions to consumers and make specific recommendations to patients.
- We do not believe FTC has jurisdiction to regulate statements that are made by state-regulated health care professionals that would only be implemented as part of a patient-specific treatment plan. This regulatory authority has ordinarily been reserved for state medical boards.
- FTC’s actions are a restraint on professional speech. Courts have said that commercial speech that can be corrected with a disclaimer rather than restricted should be allowed with the disclaimer. We provide various forms of disclaimer language in Appendix A, but also recognize that reliance on disclaimer language alone is not sufficient and recommend that overly exuberant and improper claims must be moderated.

Note for Oregon NDs: While FTC can require that claims must include scientific evidence, the Oregon Department of Justice has adopted a temporary rule to protect consumers from unsubstantiated claims that a good is effective against COVID-19. Effective April 17, 2020, OAR 137-020-0260 makes it unfair or deceptive for sellers or advertisers to represent that a good (which includes dietary supplements) prevents, treats, diagnoses, mitigates or cures coronavirus, COVID-19, or a related condition, without first having competent and reliable scientific evidence (also known as "substantiation") upon which to base a reasonable belief in the truth of the representation. Note that what constitutes "substantiation" is itself somewhat subjective, but care should especially be taken when connecting claims to COVID-19.

Because research directly related to COVID-19 is extremely limited, NDs in Oregon should recognize that making claims of prevention, treatment, diagnoses, mitigation, or cure for coronavirus, COVID-19, or a related condition could expose them to higher risk of regulatory action in the current environment, and should consider only addressing the management of symptoms (respiratory illness, fever, headaches, digestive issues) to be based upon patient evaluation when providing general treatment recommendations.

Under the temporary rule, making such allegedly unsubstantiated claims is considered a violation of the Unfair Trade Practices Act and the Oregon Department of Justice has issued numerous Civil Investigative Demands to clinics, including to those who received FTC Warning Letters.

Appendix A - Sample Disclaimers

Below are sample disclaimers you can mix and match and edit to suit based upon your situation. Disclaimer language might be placed in smaller segments with a website to make them more readable, and should be placed on every page that includes discussion about COVID-19 and dietary ingredient sales or references to sales.

The products and services discussed regarding COVID-19 are solely to enhance immune function or help manage symptoms and are not offered to prevent or cure the novel infection causes by SARS-CoV-2 Our clinical experience suggests that products or services offered may mitigate the consequences and alleviate some of the complications of the illness. The FDA has not approved these therapies expressly for use in COVID-19 or any viral disease and suggested use may be “off-label” or may lack approval for and are not intended to treat any disease indication but only offer symptomatic relief. While there is evidence supporting such use, that evidence may not rise to the level necessary for acceptance by medical associations,health institutions, or regulatory bodies. There may be active professional disagreement and some professionals and regulatory bodies may be of the opinion that some recommendations are not helpful or inappropriate.

For dietary supplement sales, by law the minimal disclaimer is: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” The disclaimer must appear on each panel or page where there is a structure/function claim. It is best practice to include that statement in an online store on all dietary supplement pages that include structure/function and/or nutrient repletion claims (in, per the regs, “boldface type in letters no smaller than one-sixteenth inch.” (21 CFR 101.93.c(2)).

In addition, additional language might include: “Consumers [or patients] should not rely upon dietary supplements to prevent or treat COVID-19. Always check with a medical professional if you have any symptoms or exposure and follow CDC guidelines and governmental authorities’ instructions with regard to social distancing, self-isolation or use of masks and other personal protective equipment.”

Individual responses vary considerably and depend upon the stage of disease, age, and pre-existing conditions and other individual differences. Individual results vary, and discussion of successful cases is intended to educate about what may be possible and do not indicate that they will be successful in all patients. Particularly given the novel and difficult health issues that can present with COVID-19, there are no guarantees that benefits will be obtained, or adverse events will be avoided. Patients should not assume any level of safety as a result of treatments or products discussed on this site and should always follow CDC guidelines and governmental authorities’ instructions with regard to social distancing, self-isolation or use of masks and other personal protective equipment.

For Regulated NDs: The use of treatments discussed on this site require doctor evaluation, laboratory testing and consideration of the risks, benefits, and other options before they are recommended or prescribed. No offer is being made for any treatment without undergoing a proper clinical work-up, discussion about the nature of the evidence, risks, and benefits for a therapeutic approach specific to the patient including a discussion of treatment options. Therapies may be designed to strengthen your immune system to reduce the risk, duration, and intensity of infectious and inflammatory disease rather than as specific treatments for the coronavirus that causes COVID-19.

For Regulated NDs: As your doctors, we will conduct an initial assessment, optimize your personalized treatment plan, provide our recommendations, and outline your options. Working together, we will only do what is right for you. Discussion of any specific disease or a treatment on this website does not mean it would be appropriate for your particular situation; medical decisions require evaluation and consideration of options for a patient's situation and needs.

APPENDIX B

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MEMORANDUM

Given the unusual number of regulatory letters being sent by the Federal Trade Commission and the Food and Drug Administration instructing practitioners to remove website material making claims for the mitigation, prevention, or treatment of COVID-19, the following discussion is intended to assist practitioners who want a deeper understanding of best practices and the legal basis for these enforcement letters.

Federal Trade Commission:

The primary violation cited in the FTC COVID warning letters allege a finding that an advertisement for products or services is unsubstantiated, misleading and deceptive and that FTC does not believe there is competent and reliable scientific evidence for the claims highlighted on your website. The focus is on coronavirus-related prevention or cure claims regarding products or services. Most of these letters concern dietary supplements and incorporate the restrictions on disease claims as a basis for finding the statements are deceptive, as discussed below.

· FTC is focused on the commercialization of claims that products or services treat or prevent COVID specifically. The rules for the Internet, as a public forum, are different than practice; it is not a private office where you have the freedom to speak privately with your patients. If you are making COVID claims regarding a product you are selling to the general public, it would be wise to promptly discontinue either the claims or the product sales to avoid potential difficulties. Practitioners should either educate without product sales or sell the products without reference to COVID or any antiviral or other disease claims. For those that have received a warning letter, such actions are necessary to demonstrate compliance. Even educational material can be considered an improper claim when positioned with sales on the same website. Related sales includes links to other sites; if you claim that Vitamin D reduces the likelihood of getting coronavirus (a prevention claim) and link to a third-party, such as Fullscripts, this would still be viewed as advertising based upon unsubstantiated claims and considered not in compliance with FTC rules.

· Even where there is evidence, such as a recent study that suggests that vitamin D deficiency is a prominent factor in deaths from COVID, that is not the same as evidence that taking vitamin D will in fact prevent, mitigate or cure COVID. Especially given the public health emergency, care has to be taken not to extend claims beyond the evidence.

· Neither the FTC nor the FDA have jurisdiction over the practice of any form of medicine. The restrictions on health claims do not reach into discussions or treatment decisions with patients.

· If you are an ND practicing in an unregulated state, you need to exercise special precaution as you do not have a state authorized scope of practice. Compliance with FTC requirements is especially important for such practitioners.

· For materials that are part of the description of the practice's services, FTC is taking the position that it has jurisdiction even over such advertising. If you are making COVID claims regarding treatment services for COVID, such as intravenous vitamin C, the FTC exercise of jurisdiction is novel and ambiguous and polices conduct that has traditionally been reserved to the states and one that is being addressed as a of public policy. The AANP Fact Sheet on Regulatory Agency Warning Letters During COVID-19 Pandemic provides information on addressing this issue under the current FTC posture, including sample disclaimer language.

· If you are making public COVID claims regarding products you are only making available to patients, the safest course is to cease publicly advertising such sales. Recipients of warning letters can consider raising with FTC placing such claims and products behind an access wall solely for patients. If you are describing the treatment effects of zinc on COVID and selling zinc, the discussion and purchase should require a password secured with patients to see. Whether FTC will accept this is uncertain and will likely depend in large part on the actual language used. Efforts should be made to conform to DSHEA for dietary supplements, as noted below, but if FTC does not react favorably, we expect they would give you time to comply.

Dietary Supplement Health and Education Act of 1994 ("DSHEA"):

While FTC has not been citing the DSHEA in its enforcement letters, FTC correspondence shows they are enforcing DSHEA restrictions on dietary supplements ("DS") as part of this effort. The FDA has also been sending warning letters requiring the removal of COVID claims from DS marketing. The ban against linking diseases to DS products makes such advertising inherently deceptive, allowing FTC enforcement of restrictions even if the claims are arguably supportable. This limitation on disease claims is long-stranding and far predated COVID. While enforcement on non-COVID claims is sparse given FDA/FTC resources, the DSHEA does give FTC authority to ban advertising disease claims for DS, even where there is substantial evidence that the claim is valid, as disease claims require drug approval by FDA.

· Any ingestible material intended for use to diagnose, prevent, mitigate, treat or cure a disease is a drug. A suggestion that one buy licorice because it tastes good is an offer for a food; a suggestion that one purchase licorice for it glycyrrhizic acid to improve respiratory health is an offer for a drug that would require the full level of approval following clinical trials and evidence required to achieve such a claim, a matter of enforcement interest given COVID.

· DSHEA does allow structure/function claims to be made for DS. An example of this distinction is that calcium could not be marketed to "prevent or relieve osteoporosis," or to impliedly treat osteoporosis with a claim that a product "prevents bone fragility in post-menopausal women." A product could, however, be marketed with the structure/function claim "helps build healthy bones." Similarly, a claim might be made that antioxidants help detoxify the body, but could not, without approval as a health claim, state that antioxidants have a beneficial effect in treating infection. This includes claims that it aids the body in resolving the consequences of infection, such as inflammation, as that is considered part of disease treatment.

· DSHEA only applies to information tied to the sale of a product. If a practice is educating about herbal products but not selling them, it is free under DSHEA to offer full education. How to frame educational discussion in an acceptable manner by a practice that also sells supplements is an issue raised by FTC's current enforcement initiative.

· Immune claims for DS products are important to understand in the COVID context. The FDA notes that an intact immune system has several functions, not only defending against pathogens but also in functional roles such as phagocytosis and disposal of aging red blood cells. General statements about support of the immune system, have, by themselves, therefore been allowed because they do not make a specific reference to disease treatment or prevention. A claim that vitamin A is necessary to maintain a healthy immune response or that it supports lung health does not imply that a specific disease or class of diseases will be prevented. When a disease is mentioned in the discussion about immune support, however, it becomes an improper disease claim. A claim that a product "supports the body's antiviral capabilities" represents a claim of treatment or prevention of a specific class of diseases, those caused by viruses (e.g., colds, hepatitis, or HIV infection). This FDA position was articulated in the 2000 Federal Register, long before COVID. Claims for immune support combined with a discussion of COVID becomes an illegal drug claim.

· Note that statements are read in context. If you post a discussion about the importance of the immune system in minimizing COVID damage, and then refer to or link to a DS with what would otherwise be a proper general immune statement, the two will be read together and it will be seen as an illegal claim for the mitigation or prevention of COVID. Having a banner discussion of COVID in the same site on which there is a store selling DS is sufficient to make the discussion, valuable as it may be, into labeling for the supplements available for purchase.

· A related issue central to our present circumstances is whether a claim that is not targeted at "prevention or cure of a disease" but merely at mitigation of symptoms, can be an acceptable DS claim made to the general public. Under ordinary circumstances and without reference to a specific disease, the answer depends on whether the symptoms are plainly linked to disease. Minor symptoms that could be brief in duration or have multiple causes and do not in themselves appear to denote a known disease state can be an acceptable claim. "Antacids" can make "relief of sour stomach" as an acceptable structure/function claim because they refer to a nonspecific

group of conditions that have a variety of causes, many of which are not disease- related. Although "relief of heartburn" is not an appropriate structure/function claims, FDA concluded that "occasional heartburn" arises from overindulgence and other sporadic situations. As soon as COVID is mentioned, however, discussions about improving immunity, reducing fever or alleviating respiratory distress introduce a disease claim and cannot be made for a DS that the speaker is also selling. Further, the serious symptoms often referred to, such as cytokine storms, would still be considered medical conditions requiring drug approval.

The Oregon Department of Justice

Naturopathic doctors in Oregon are facing specific challenges as that state's Department of Justice is aggressively seeking to curtail claims and perhaps even treatment offered by naturopathic doctors. Doctors in that state should be especially rigorous about not mentioning or making any claims about COVID. The only COVID statements on your website should be about office protocols protecting against contagion and other public health messages. Each clinic should absolutely have the required clinic policies for screening patients and staff, maintaining social distancing when possible, using PPE and requiring patients to use face coverings, sanitation of surface areas and equipment, etc. Note that OSHA wants to see these when they investigate; and they are conducting site visits.

Types of Claims

With all this in mind, note that:

· The sale of dietary supplements with any discussion of COVID or anti-viral or other disease related properties is the area FTC is most clearly correct in addressing. We recommend that you scrub your website of such connection, including metadata and SEO terms, and consult counsel when in doubt.

· Some statements about DS or other methods that the doctor is recommending are an act of education in which the doctor is not marketing those products. These cases would turn primarily on two issues: 1) does the practice have sufficient scientific support for its statements, an issue that runs into paradigm and other professional differences of opinion about evidence and 2) whether such education is in fact "advertising" under FTC jurisdiction.

· Hewing closely to the facts is, of course, more supportable. As one example, accurately describing case reports of treatment successes with patients, rather than generalizing, is more defensible. Care should be taken to give accurate expectations rather than use such reports as innuendo that everyone will get the same results. Some FTC letters involve truthful statements about successes practices have had, perhaps with some recommendations, but no more, so there

is an unusual degree of risk of a demand to desist such statements. If using testimonials, also consult the FTC rule:
https://www.ecfr.gov/cgi-bin/text-idx?SID=b2629192f05fc816a345bb9a877ae3dd&mc=true&node=se16.1.255_12&rgn=div8

· Statements that involve advertising for services, such as intravenous vitamin C, have been targeted by FTC enforcement letters even though these are professional practices that require a consumer first become a patient and be assessed and treated in-person. Discussion should not exaggerate claims and make it clear that such services require determination of whether a patient is an appropriate candidate. There are a number of legal issues presented by FTC's actions, including differences of opinion about the nature of the evidence and use of IVC, whether it is arbitrary to allow it's use in hospitals while finding that advertising by ambulatory practices is deceptive as well as the primary jurisdiction that state boards have over professional practice. How to respond to such demand letters is a judgment call. Websites that advertise treatment services available from doctors should, at the very least, prominently note on all relevant pages that "All such services referenced on this website are only made available to active patients after a comprehensive diagnostic intake is performed consistent with standard medical practice."

· A central concern is certainly a regulatory reaction to what are seen as deceptive products and services, but another public health concern is that consumers will believe that they can discount CDC and local health department requirements because they believe that the product or service has conferred immunity or that they can be easily treated if they become ill. This has to be addressed both in disclaimers and in the text itself. If these public health concerns are reduced it should make intervention less likely.

· Doctors should also be mindful of potential investigations by state medical boards. Assume that what you write will end up before your state's Department of Justice and professional licensing board, so care should be taken about admissions. If changes are made in response to a regulatory letter, state that you appreciate the note and are making those changes but that you make no admission of violation of any law or regulatory requirement and maintain that the information provided was accurate.