FDA Strategy Document

This is not a substitute for legal counsel

FDA & Medical Liability Reduction

The organization, which secures Federal Contracts on behalf of a Medical Provider and their network of Medical Doctors (MDs) may reduce their liability through complying with FDA Guidance and establishing independent contractor agreements with Physicians who hold independent medical malpractice insurance coverage.

FDA Regulations: Introduction

The FDA requires compliance with agency guidance particularly when disease states are indicated. The FDA's guidance provides several mechanisms for delivering medical care without the review and approval of the agency so long as these guidelines are followed.

FDA's Position on Off-Label Treatments and Rx

The FDA authorizes the use of off-label treatments for disease states when under the care of a Medical Doctor. Therefore, an MD can prescribe any treatment or medication they believe to be safe and effective for treating their patients. This is referred to as 'Off Label Treatment', which is permitted when patients are under direct care of an MD – The FDA's public position is stated on their website as follows:

> *"Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB)."* Source

The FDA has also clarified their position through the below examples.

> "*From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient . . .Unapproved use of an approved drug is often called "off-label" use. This term can mean that the drug is:*

- *Used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer."* Source

FDA's Position on Clinical Studies

The FDA has also clarified that Medical Providers may utilize off label treatments within clinical studies when the following conditions are met.

- *"it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;*
- *it is not intended to support a significant change in the advertising for the product;*
- *it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;*
- *it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];*
- *it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and*
- *it does not intend to invoke 21 CFR 50.24."* *Source*

1. Compliant R&D Contract Procurement

The FDA's regulations permit organizations to advocate for further research into the potential use of the off label treatments. Therefore, the procurement of $1Million, $5Million, $10Million, and $25Million + longitudinal or double-blind study contracts may enable the medical provider to deliver treatment to a large population. This must occur within the context of 'Clinical Studies', which are not prohibited by the FDA.

Through conducting a 'Clinical Study', the company may charge the government for the cost of medical personnel, Rx, project management, training, and other fees associated with conducting scientific research. These studies could range from small to large, and there are no prohibitions on whether the project may produce a profit to the organization, which provides the research services. However, the results of the studies may not be officially utilized in order to further the objective of securing FDA approval for the treatment. *Source*

2. Compliant General Medical Services Contracts

The sale of General Medical Services to the government for the diagnosis and treatment of PTSD under the care of a licensed physician is fully compliant with FDA guidelines. The MD may prescribe an off-label treatment when meeting privately with the patient. To remain compliant with FDA guidelines, the sales and marketing strategy must refrain from advocating an off label treatment when speaking with a Contracting Officer. *Source*

3. Compliant Wellness Service Contracts

The FDA would permit the use of generally accepted low risk medical devices for soldiers who return from combat and enroll in a 'resilience' training program. The administration of a chemical injection is not covered under 'General Wellness Guidance', but EEG and autonomic regulation technology are applicable (Source). However, the contract may not make reference to the treatment's role in the diagnosis or prevention of PTSD. To illustrate how the FDA authorizes the use of this technology, one may review the FDA's official letter to NeurOptimal, which stated:

> *"In accordance with our guidance, CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use as defined in the guidance, and (2) present a low risk to the safety of users and other persons. A general wellness product has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition. Our determination that NeurOptimal is a general wellness product is based on the following information provided in your submission: (i) the intended use of the product is for passive brain training for personal enrichment; (ii) noninvasively records brain activity to provide a brief interruption in the sound of media playing through earbuds. Therefore, we do not intend to enforce any applicable regulatory requirements under the Act, including premarket notification, and its implementing regulations for the NeurOptimal. (Source)*

4. Separating Medical Liability From Prime

The Prime Federal Contractor may procure a contract to render services through a network of trained MDs. The contract with the agency must clarify that Medical Doctors are personally responsible for managing risk and delivering effective medical treatment. The Prime may establish sub-contracts with a network of MDs, which operate private practices. These MDs customarily hold medical malpractice insurance, which will ensure that the MDs assume full responsibility for medical errors. The agency must agree to these terms and attribute all liability to the network of MDs. Source: Dr. Eugen Lipov (This is not a substitute for legal counsel).

5. Compliant Communications

The Medical Provider and any other organization working with an off label treatment are advised to use caution when communicating with the public. The FDA defines a "health claim" as follows:

> "[A health claim is] *an explicit or implied characterization of a relationship between a substance and a disease or a health-related condition. This type of claim requires significant scientific agreement and must be authorized by FDA (Source)."*

Therefore, labeling guidance as related to other products may assist with preventing the Medical Provider from mistakenly engaging in the sales and promotion of treatments for unapproved use through including a disclaimer on all communications. The disclaimer may include 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.' The presence of this statement alone is not exculpatory but demonstrates an intent to avoid making claims, which are not FDA approved *(Source)*.