Why Should I Create My Own PMA?

Are you an alternative or natural medical or mental healthcare practitioner, a dentist, doctor, chiropractor, midwife, homeopathic healthcare or any other type of healthcare provider? Do you really need your own PMA?

While it is true that not all devices or products intended for human use require prior FDA approval or clearance, the FDA can, and has, "changed its mind" and extended its regulatory reach in unpredictable ways.

What if you or your healthcare practice/operation could be generally immune from the FDA’s control and regulation of offerings that are made to the public concerning claims to "diagnose, treat, cure or prevent any disease" would you like to know more about how it can be done?

PMAs operate within the private domain and have an established history and maintain a significant and unique standing in law; they are generally immune from most, if not all, state and federal Public Laws. You can Enjoy a general immunity to public laws, regulations and internal rules of local, state and federal administrative agencies (including, but not limited to, the FDA) that protect the public health.

Recently I have had several members asking why they should be creating their own PMAs. They understand the importance of a properly formed PMA and the protections afforded by the PMA however several are also members that are currently operating under a license from another PMA.

Any effort to provide protections for yourself and your business are beneficial however relying on a “License” from another PMA is not likely to provide the complete protections they are assuming come with all PMAs.

Most of the existing PMAs I see regularly were created with foundational documentation that is statutory compliant. This is very common, especially since it’s common to seek the assistance of an attorney in creating this foundational documentation. Any attorney who is currently a member of the BAR Association (another PMA) is an officer of the court. As an officer of the court, any documentation they draft for you will be subject to statutory compliance and subject to the court. If the PMA issuing your license is statutory compliant, your business, under their license will be reliant upon statutory compliance.

Any protections not accessible to the PMA issuing a license cannot be afforded to you and technically your clients will become members of the PMA issuing the license, not your clients unless you maintain that license.

As a licensee, you will be required to adhere to the terms, conditions, rules, bylaws, and any other regulation imposed by the PMA issuing the license. You are still giving someone else the authority to regulate and control your business and they can force you to cease operating your business under their license at any time they choose.

With your own PMA, you are implementing your own bylaws so you make the rules with no requirement to follow someone else’s rules and no other entity has the authority to interfere with the operation of your PMA or to force you to cease operation of your business based upon a licensing agreement.

If you intend to operate under the restrictions of someone else’s license you may as well just remain under the jurisdiction of public law and be subject to the State. If you want the freedoms afforded to a Private Association, you’ll only accomplish those freedoms and protections unobstructed with your own PMA.