Regarding In-Office Ultraviolet Blood Irradiation (UVBI) Therapy AKA BioPhotonic or Photo Luminescence Therapy

FDA Device Compliance

To be legally FDA compliant with this technology, the shape and design of any cuvette used with UVBI must have existed prior to March 1976, unless the cuvette used after that date has undergone regulatory approval.

You should be aware that AscEpi Medical is FDA registered and its proprietary cuvette is FDA compliant as we shall explain. It is felt this explanation is warranted as there is currently no tubular cuvette manufacturer registered with the FDA.

Hence, anyone selling a round tubular cuvette for use in UVBI stand in violation of the Federal Device Registration Act and are putting their user clinicians at risk of losing their devices should the FDA act on this as they have done in the past.

The genesis of the cuvette design used by AscEpi Medical has its genesis with the patent of Emmet Knott and Lester Edblom on September 11, 1928, Patent No. 1,683,877.

On January 26, 1943, Emmet Knott was issued another patent for an improved cuvette design. See Patent No. 2,309,124. In this patent, Knott described a chamber having a flat “cover therefor permeable to ultra-violet radiation…” This flat structure of the cuvette (or blood chamber) is consistent with our design.

Thus, the flat design that Knott specified became the standard leading up to March 1976.

To be legally compliant, new designs must be consistent with the philosophy articulated in the pre-March 1976 devices, and in particular, in the above referenced patents. The AscEpi Medical cuvette meets this criteria.

It is important practitioners not overlook this regulatory aspect. The 1976 Device Amendment Act allows previously developed devices to be grandfathered in; but only if certain specific aspects of the original device are captured. This is especially true when pertaining to the “central mechanistic part” of said device.

There are UVBI devices using tubular cuvettes that are being sold in the marketplace which are not compliant and are in violation of the U.S. Medical Device Regulation Act, which in part, addresses the pre-market notification process. (For the information on the 1976 Amendment to the Device Regulation Act, see: https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.)

Knott's original device, which was the genesis for all UVBI devices that followed, used a "Flat Surface" cuvette and to be compliant with FDA regulations, device manufacturers and practitioners must use a flat surface cuvette when engaging in UVBI therapy. Doing otherwise risks adverse regulatory action.

There is an additional exemption relating to the distribution of the AscEpi Medical cuvette set forth in the Code of Federal Regulations at Section 807.65, Subpart D, subsection c, which allows for the distribution of items, whose uses are generally known by those who purchase them. The flat surface cuvette, which has its application for UVBI as well as many other uses, including research, falls within the scope of this provision.

A further word about efficacy...

While UVBI units using round tube cuvettes are not in regulatory compliance, what may be more concerning is the effect this has on lessening positive patient outcomes due to the physics of lesser photon penetration through tubed cuvettes (see Snell's Law reference in the PL2020 brochure).

From a practical standpoint, non-compliant and less effective devices (some resorting to ozone to overcome this) can lead to negative opinions of the overall technology by medical personnel who may have great use for this therapy for their patient base but put it aside because they may have heard or seen this or that negative aspect and hence, do not explore it further.

Our hope is this material will overcome any prior negative associations if such exists. The problems facing health care today due to antibiotic resistance and more makes this technology ever more important for the patient care of every clinic.

FDA Claims Compliance

One purpose of the FDA is to regulate interstate sales of medical devices and diagnostic tests in the United States and monitor their safety.

While anecdotal results using the PL2020 have been highly beneficial for a number of issues, as a device manufacturer, AscEpi Medical cannot make any claims for the

PL2020 until specific 510k approvals have been put into place. AscEpi would ask practitioners using the device to likewise make no claims.

From a general perspective, it appears the PL2020 therapy helps empower the body's innate immune system to a higher level of efficiency and overall, that seems to help a lot of people with many different health issues.

Regarding the FDA controlling a practitioner's health care practice, a most recent appellate court ruling has affirmed that the FDA has no regulatory authority over how a doctor or nurse practices their craft. They have no authority to regulate a physician's or nurse's practice nor to tell a provider what to do when running their business or what they can or cannot tell their patients.

Should a practitioner desire to use the PL2020 for any condition they believe will be beneficial to their patients, this is solely their prerogative and this is not FDA regulated.