JACK D'ANGELO,M.D.,M.B.A
361 EDISON STREET
STATEN ISLAND, NEW YORK, 10306
718-980-0101

I have been a practicing physician since 1988. I attended medical school at St Georges University and completed pediatric residency training at Georgetown University Hospital, a fellowship in pediatric rehabilitation at National Children's Hospital of Washington D.C, and a rehabilitation residency program at George Washington University in Washington D.C. My career has spanned primary care and specialty care and I have seen both the successes and the weaknesses in our present model of care.

It is clear that the conversation of medical cannabis has gained great community and political interest.

In the interest of the public safety it is the responsibility of the medical and public health system to move beyond the political and emotional arguments for the use of medical cannabis and lead the conversation of sound medical practices. Accepted scientific models of research have been hampered by a federal drug policy that has made it impossible to adequately study this drug. Other countries have begun better research and preliminary data has shown the medicinal role of medical cannabis in many areas.

As the state legalization of medical cannabis moves forward we are creating the environment to actually collect data and conduct research to understand this plant in more detail. This is a public safety imperative on behalf of our patients and caregivers who are challenged just to try to promote well being.

At this time the available data suggests the cannabis plant contains over 100 active chemical components called cannabinoids. From a more striking medical point, our own bodies have an internal endocannabinoid system that appears to respond to these chemicals. Much of the conversation over the years has focused on the psychoactive component ,Delta-9-tetrahydrocannabinol, better known as THC. This component was actually first isolated in 1964 and has been studied for side effects extensively. Like all medications studied patients are placed on a medication and then asked if they experience any problems. Traditionally we build a side effect profile in this manner so many accepted medications may do things as cause headaches and relief headaches at the same time. These are not true cause and effect scenarios. So while many people using THC may feel more relaxed, have increased hunger and decreased nausea others may have increased anxiety, mood changes and coordination changes. It is important to note here that most funded studies on cannabis only focused on the side effects. Traditionally when a drug is studied we have the opportunity to assess its efficacy as well as its side effects but funded American research really has been limited to the side effects only. Even with this focus, there has been no noticeable link to mortality or long term side effects.

Most recent data has also focused on the other cannabinoids imparticular CBD. While this substance was originally isolated in 1934, research throughout the last decade has shown that it can mitigate the

JACK D'ANGELO,M.D.,M.B.A
361 EDISON STREET
STATEN ISLAND, NEW YORK, 10306
718-980-0101

side effects of THC, complement the effects of the other cannabinoids and have a direct therapeutic and medicinal effect on several disease states.

The medical community laments the lack of high-quality data supporting the efficacy of medical cannabis and the available studies are rarely double blind and are inconsistent with regard to study endpoints and outcomes. For adequate studies to move forward we need dosing uniformity, thc/cbd ratios and methods of administration so reliable conclusions can ever be sustained in a scientific manner. This can only be corrected by greater political leadership and requires our political bodies to put patients first in this conversation.

This has been most marked and followed in pediatric epilepsy disorders. Preliminary data from a phase 2/3 US clinical trial with GW Pharmaceuticals in 12 children with Dravet syndrome have been promising. As early as 1978, published data suggested that CBD administration was associated with freedom from seizures for 3 months. Since the 1970s, we have known that CBD attenuates many of the undesirable effects of THC. In 1978 the first study looking at the administration of CBD to patients with epilepsy for a 3-month trial period revealed no adverse events.

In 2003, a review article in the Clinics of Rehabilitation revealed a study of patients with intractable neurogenic symptoms from multiple sclerosis, spinal cord injury, brachial plexus injury, and limb amputation due to neurofibromatosis found that pain relief with CBD was significantly improved compared with placebo, without unwanted side effects.

In 2014, Insys pharmaceutical received orphan drug designation for their CBD preparation by US Food and Drug Administration as a treatment for glioblastoma multiforme and glioma, both of which are highly treatment-resistant malignancies.

In 2011, the Journal of Psychopharmacology, CBD was found to be superior to placebo in reducing anxiety in patients with generalized social anxiety disorder. Further data has noted CBD enhanced consolidation of fear extinction when administered after extinction and was superior to placebo in increasing sleep time among patients with insomnia.In its totality this data suggests that CBD may be useful in the treatment of various anxiety disorders, including post-traumatic stress disorder.

The role of medical leadership is to "above all do no harm." We have seen over and over again how traditional and accepted medication practices have resulted in adverse and devastating events including most recently in the growth of narcotic usage . In all the years of cannabis usage, even without the appropriate studies we have not had one death directly linked to the use of cannabis. We cannot say this about alcohol, tobacco or most regulated and approved medications.

JACK D'ANGELO,M.D.,M.B.A
361 EDISON STREET
STATEN ISLAND, NEW YORK, 10306
718-980-0101

Compared with standard treatments for many chronic diseases, the likelihood of problematic side effects or adverse events associated with CBD is small, and discontinuation in clinical studies is uncommon.

Cannabinoid medicine is still in its infancy; thus, dosing is not necessarily scientifically based, and confusion is common among healthcare providers. Medical cannabinoids are here to stay and scientific integrity is imperative if we are going to truly delineate their potential benefits. However, unlike street sources of marijuana , the risks associated with CBD are extremely low, with not a single case report of CBD overdose in the literature.

We believe strongly that sound pharmaceutical practices need to be applied to CBD products. The guidance of good manufacturing practices (GMP) would demand regulations governing labeling, purity, and reliability. There needs to be a guarantee of consistency between products.

However,many studies have suggested that the safety data of CBD are so compelling that there is probably little harm in considering it for treatment-resistant conditions.

In 2003, the British Medical Journal, reported that smoked cannabis and tobacco contain approximately 4000 chemicals and that these chemicals are essentially identical in both plants. There were of course some limitations to the study based on the percentage of comorbid tobacco smokers however it continues to reinforce our public health concern about smoking in general and its effect on pulmonary function and overall health. The use of filtering systems and vaporizing may reduce this overall exposure in the future but safety first dictates that smoking cannabis at this time should not be a medical recommendation. This does not diminish its overall medical benefit but we should work to limit exposure to those chemicals released by smoking that we already have concerns about in the medical community.

In addition, cannabis exposure during pregnancy should be cautiously observed as with all other medications the developing fetal brain is more susceptible to exposures of medications then a fully matured neurological system.

The use of orally administered oils and tinctures are preferred over smoking and edibles such as cookies, candies, etc. The latter run the risk of accidental ingestion and the variation in absorption and dosing can create an environment for more adverse effects.

As with all medications, the appropriate warnings about driving, operating heavy machinery and engagement in risk behaviors needs to be enforced and patient education is crucial until it is clear the effects that these medications will have on a particular individual.

JACK D'ANGELO,M.D.,M.B.A
361 EDISON STREET
STATEN ISLAND, NEW YORK, 10306
718-980-0101

Much of this can be mitigated by a medical model of dispensing the medication under the supervision of a pharmacist or physician who can appropriately guide patients, assess drug to drug interaction, and assure that we can make this a safe and fruitful endeavor.

We are not promoting the legalization of cannabis for recreational usage.

We are hoping that with good medical guidance and intervention we can improve the quality of life for many Americans and demonstrate that we continue to be the leaders in patient care.

Sincerely,

Jack B.D'Angelo,M.D.