STEM CELL LEGISLATION IN NEW JERSEY: A RESPONSIBLE APPROACH TO THE COSTS OF DISABILITY AND DISEASE

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EXECUTIVE SUMMARY

As the rate of chronic illness continues to rise unabated, the field of regenerative medicine is poised to revolutionize the practice of medicine by providing potentially curative solutions to Americans’ most common ailments. Stem cell therapy, specifically, offers those with disabling, painful, difficult to treat or impossible to treat conditions the possibility of relief. The list of diseases that can possibly be treated or even cured by stem cell therapy is exhaustive, with more applications being discovered each day. But while the scientific research is robust, clinical application has been slowed by restrictive federal regulations. This means that, although certain stem cell therapies such as autologous therapies are safe, effective and have been used in private clinics for years, Americans cannot readily access them. Instead, they are forced to travel abroad at extraordinary cost for treatment to improve or save their lives.

Although the precise cost of stem cell therapy is difficult to determine – there are no reliable aggregate data and prices can vary by clinic, by condition treated, by cell type used and by number of treatments required – what is clear is that stem cell therapy is far safer and far more cost-effective than prescription pharmaceuticals or surgery. Indeed, expenditures by states and private employers on employee health care costs continue to increase annually, straining state budgets and compelling employers to re-evaluate their health care programs. The average American is also negatively impacted by the rising cost of health care, drowning in a flood of debt from medical bills that seem to accumulate endlessly. Consequently, they are often forced to choose between purchasing their prescription drugs or food to feed their families.

In the cases of all-too-pervasive conditions like chronic pain, orthopedic conditions and opioid misuse, stem cell therapy offers an option where there are no options. Spurred on by patient advocacy groups and empathetic, forward-thinking state legislators, states like Texas and Arkansas have taken the lead in enacting responsible legislation that can make stem cell therapy more accessible to its residents, while simultaneously providing safeguards to protect patients. These states’ approaches provide useful guidance as to how other states can advance their respective health care agendas to ensure that their residents receive the safe, cost-effective care they need.

The State of New Jersey should be next to pass stem cell legislation. The proposed legislation should be based on the overarching philosophy of making stem cell therapy accessible and affordable to all NJ residents. Legislation should target those New Jerseyans with serious or life-threatening conditions for which there is no recognized medical treatment. Autologous stem cell therapies – those that use a person’s own stem cells – should receive special consideration given their positive safety profile. Mandating stem cell therapy coverage for state employees should be seriously considered. Coordination between agencies such as the State Board of Medical Services and the NJ Department of Health and Human Services will ensure the promulgation of responsible regulations. This effort would be no different than that undertaken to provide sick New Jerseyans with medical marijuana.

The passage of stem cell legislation in NJ can be done and must be done. With its advocacy for an expanded medical marijuana program, and even its outright legalization, the Murphy administration has signaled an openness to new, creative solutions to NJ’s health care problems. The leadership in the state legislature can work with the Governor to pass a stem cell law. The people of NJ are counting on it.
INTRODUCTION

In his 2017 Joint Address to Congress, newly-elected President Donald Trump spoke on an overarching theme of physical resurrection: on the revitalization of dying American industries, on the repair of a crumbling infrastructure and on the rehabilitation of America’s dilapidated inner cities. On the same theme, he chose to highlight the case of Megan Crowley, a young woman whose father had to launch his own drug company to help treat her Pompe Disease. Also in attendance that evening was a second young woman, Sarah Hughes, who was forced to travel to Mexico to use her own stem cells to treat her systemic idiopathic juvenile arthritis. In reference to both cases, Pres. Trump lamented the pain and death caused the “slow and burdensome approval process at the Food and Drug Administration” that “keeps too many advances ... from reaching those in need.” He argued that the restraints at the FDA should be “slashed” so that more Americans could benefit from life-saving therapies.

During his 2018 State of the Union address, he reiterated his theme of a patient-centered, less restrictive approach to medical treatment. He did so by voicing his clear support for “right to try” legislation, legislation that would increase the medical options of the critically ill by helping them avoid an oftentimes slow, burdensome FDA bureaucracy. In an apparent reference to Sarah Hughes and other stem cell medical tourists, Trump stated unequivocally that “patients with terminally conditions ... should have access to experimental treatments that could potentially save their lives” and they “should not have to go from country to country to seek a cure....” He then urged Congress to pass “right to try” legislation, so that Americans can get help “right here at home.”

“In We also believe that patients with terminal conditions should have access to experimental treatments that could potentially save their lives. People who are terminally ill should not have to go from country to country to seek a cure — I want to give them a chance right here at home.”

Pres. Donald J. Trump

Indeed, after conducting several patient-focused drug development meetings, the FDA concluded that patient input can: (1) inform the clinical context and provide insights to frame the assessment of benefits and risks, and (2) provide a direct source of evidence regarding benefits and risks. FDA guidance is now being developed to transform these insights into an actionable framework. Additional efforts by the FDA to enhance the inclusion of patients’ perspective in the drug approval process include: (1) hosting patient-focused drug development meetings; (2) encouraging patient stakeholders to...
host their own externally-led drug development meetings; providing patients, caregivers, advocates and others with more channels to provide meaningful input into drug development and regulatory decision-making; and (4). launching pilot programs to develop more patient-focused clinical trials.

Nowhere is the FDA’s new posture more important than in the field of regenerative medicine. With the increasing prevalence of chronic conditions such as orthopedic and autoimmune ailments, Americans are confronted with a menu of medical options that is severely limited in terms of availability, affordability and effectiveness. A consensus of scientists and physicians agree that regenerative medicine is an emerging field of medicine that promises to offer safe, effective and potentially curative treatments for a number of chronic illnesses. Current treatment modalities for these conditions only manage the disease through medication or surgery, or there may be no known effective treatment protocol. Furthermore, treatments that may demonstrate some degree of effectiveness may only address the symptoms of the illness rather than the root cause, and may have debilitating or even deadly adverse effects. Thus, physicians and patients alike are seeking new avenues for treatment.

Stem cell therapy can be a safe, effective, immediate solution to patients’ needs, and states have a critical role to play in ensuring accessibility and affordability of stem cell therapy. When Former NJ Governor Jim McGreevey signed legislation in 2004 that authorized the use of embryonic stem cells for research purposes, he was accompanied by famed actor Christopher Reeve and his wife, Dana. Known best for his portrayal of iconic superhero Superman, Reeve had been raised by his mother in Princeton, NJ since he was four years of age. He attended the Princeton Day School and later attended Cornell University. Although Reeve passed away later that year from complications from a spinal cord injury that left him paralyzed, he left a legacy of dogged stem cell advocacy through the Christopher and Dana Reeve Foundation. In a 2001 CNN interview, Reeve referenced the 100 million Americans suffering from diseases that could be treated with stem cells. He specifically mentioned how actors Michael. J. Fox and Mary Tyler Moore had testified before the US Congress about the potential therapeutic benefits of stem cell therapy for diseases like Parkinson’s and diabetes. When President Obama lifted the ban on embryonic stem cell research in 2009, he dedicated the act to “Superman” Reeve. At the time, Pres. Obama stated, “Christopher once told a reporter who was interviewing him: ‘If you came back here in ten years, I’d expect that I’d walk to the door to greet you.’” President Obama lamented the fact that Reeve died prematurely, and insisted that “the race is with us ..., seeking the day when words like ‘terminal’ and ‘incurable’ are finally retired from our vocabulary.”

The State of NJ now has the opportunity to help realize Reeve’s dream. Since his death in 2004, the field of stem cell therapy has grown immensely in terms of the volume of scientific research, the types of stem cells with therapeutic potential and the countless numbers of patients around the world who have benefitted directly from stem cell therapy, either through clinical trial or through a private clinic. As the medical technology regarding stem cell therapy has expanded and accelerated, political technology – state and federal legislation and regulations – has not kept pace. Given the demonstrated safety and efficacy of these therapies, a modernization of stem cell rules is warranted. For its part, NJ can follow the leads of Texas and Arkansas and pass sensible stem cell legislation that ultimately makes stem cell therapy available and affordable to all New Jerseyans. Given its pioneering role in embryonic stem cell research and its move to legalize marijuana, a stem cell law is the next logical step in safeguarding the health of NJ residents and reducing the exorbitant financial costs of disability and disease that the state and its residents currently bear.

“[T]he race is with us ..., seeking the day when words like ‘terminal’ and ‘incurable’ are finally retired from our vocabulary.”

Pres. Barack H. Obama
THE COSTS OF DISABILITY AND DISEASE IN NEW JERSEY

Given the prevalence of debilitating and disabling conditions in NJ, and their associated costs, stem cell legislation makes both moral and economic sense. According to New Jersey State Health Assessment Data, the leading cause of death in NJ is heart disease at 25.8%. Stroke is the third leading cause at 4.7%. Diabetes accounts for 2.7% of deaths in NJ. The numbers of adults in NJ with arthritis has been steadily climbing, from 1,493,000 in 2011, to 1,561,000 in 2013, to 1,650,000 in 2015. In 2016, 16% of NJ residents were hospitalized with COPD, a chronic inflammatory lung disease. An estimated 2,000 NJ residents die each year from diabetes, with an overall death rate of 17.9%. While the age-adjusted death rate for diabetes is below the national average, the rate is nevertheless troubling. Over 18,000 New Jerseyans die of heart disease each year, on par with the national average.

Persons with disabilities in New Jersey are disproportionately impacted by lack of availability of stem cell therapies. In a 2012 Cornell University study, the prevalence rate of people with disability in NJ was 10.4 percent. Disability disproportionately affects Blacks and Native Americans in the state. Only 22.8% of working age New Jerseyans with disabilities were employed full time and their median annual earnings were more than $10,000 less than their able-bodied counterparts. Their median annual household income was over $30,000 less and people with disabilities had a poverty rate almost three times higher than those without disabilities. These disparities place an undue financial burden on the state in the form of disability insurance costs. In 2009, New Jersey’s Medicare and Medicaid expenditures were 15% and 60% higher than the national average, respectively.

Chronic pain drives a significant amount of disability in NJ; thus, the cost reduction with regard to chronic pain alone could be significant. Using data from the 2008 Medical Expenditure Panel Survey (MEPS), Gaskin and Richard estimate found that nationally 10% of Americans suffered from moderate pain, 19% suffered from severe pain, 33% suffered from joint pain, 25% suffered from arthritis and 12% suffered from functional disability." Not surprisingly, they found that adults with pain reported higher health care expenditures than adults without pain, and this difference was constant across medical conditions. Patients with severe pain had expenditures $3,210 higher than patients with moderate pain. The authors estimated that at least 100 million Americans suffered from at least one pain condition measures by the MEPS.

The incremental costs of health care for the selected pain conditions ranged from $261 billion annually to $293 billion annually. Severe pain and functional disability were the most expensive at $39.4 billion and $93.5 billion per year respectively. Most of the cost was borne by private insurers, estimated between $112 billion to $129 billion. Medicare covered 25% of the cost, from $66 billion to $76 billion annually. Medicaid paid about 8% of the cost, estimated at $20 billion to $23 billion per year. Individuals’ out-of-pocket costs were estimated at $44 billion to $51 billion per year. The total direct costs for medical care for pain was almost $47 billion with $34 billion spent on back pain.

The indirect costs are likewise substantial. For adults aged 24-64, the mean number of work days missed was 2.14 with 46% missing at least one day of work. Adults with pain missed more work than adults without pain. Those with functional disability worked 1.205 fewer hours than those without disability.
Persons with pain also had lower wages, with the functionally disabled earning $11 an hour less than those without a disability. A significant portion of these costs can be minimized with a stem cell law.

Stem cell therapy can also potentially reduce opioid use, thus reducing the costs associated with opioid addiction, abuse and death. Unquestionably, opioid addiction in NJ is a medical and economic emergency. According to the National Institute on Drug Abuse, in 2016 there were 1409 opioid-related overdose deaths in NJ – a rate of 16 per 100,000. The national average is 13.3. Heroin-related deaths rose dramatically, from 97 in 2001 to 850 in 2016. Deaths from synthetic opioids also rose during the same period, from 35 to 689. In 2015, NJ health care providers wrote 55 opioid prescriptions per 100 persons, totaling 4.9 million prescriptions. The national rate was 70 prescriptions per person.” Data from New Jersey Advance were even more grim; in 2016, at least 1901 NJ residents died of opioid overdose, with heroin outpacing fentanyl. Young adults – who represent a vital part of NJ’s workforce – are disproportionately affected by the opioid crisis, with nearly one-third if deaths occurring in persons 25-35 years of age.”

While the exact number of opioid-related deaths that stem from a chronic pain-precipitated opioid addiction is unknown, it is known that chronic pain can lead to addiction and its consequent financial costs. Volkow and McLellan (2016) maintain that “two major facts can no longer be questioned: First, opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.” They report that more than one-third of the 44,000 drug overdose deaths reported in 2013 were attributable to pharmaceutical opioids. In their view, “(t)he urgency of patients’ needs, the demonstrated effectiveness of opioid analgesics for the management of acute pain and the limited therapeutic alternatives for chronic pain have combined to produce an overreliance on opioid medications in the United States with associated alarming increases in diversion, overdose and addiction.” Data from consumer healthcare company Amino support the authors’ conclusion.

Given the prevalence of disabling conditions in NJ and the costs associated with them, solutions are clearly needed. Stem cell therapy can be part of that solution and NJ should pursue a robust stem cell policy.

**WHAT IS STEM CELL THERAPY?**

Stem cells are primordial, unspecialized cells that have the potential to develop into many different cell types. They function as an internal repair system that can replenish other cells. Stem cells are distinguishable from other cells because: (1) they have the ability to renew themselves through cell division and (2) they can be induced to become tissue-specific cells that can replace damaged tissues.”

There are three main types of stem cells: (1) embryonic, (2) induced pluripotent (IPS) and (3) adult. At this point, neither the embryonic nor the IPS types are commercially or clinically viable. Although research is progressing, and clinical applications may one day materialize, ethical and/or safety concerns preclude these stem cells from being seriously considered as candidates for state legislative authorization. Conversely, adult stem cells are safe, effective and have been shown to treat a variety of chronic conditions. Adult stem cells can be autologous or allogenic. Autologous stem cells are extracted from one person – usually from bone marrow or adipose (fat) tissue – and then administered to that same person. Allogenic cells are extracted from one person and are administered to a different person. These cells may come from bone marrow.
adipose tissue, umbilical cord blood, placental tissue or other sources. Because they are administered to the same person from which they are extracted, autologous stem cell therapies carry little to no risk of rejection and are generally considered to be much safer than allogenic procedures.

Significant research has focused on mesenchymal stem cells (MSCs), a subpopulation of stem cells that have immunomodulatory and transdifferentiation properties. Because MSCs are immunomodulatory they are anti-inflammatory, making them prime candidates for the treatment of asthma, arthritis, chronic pain, and immune system disorders like multiple sclerosis. MSCs may even have the potential to treat serious childhood diseases such as Type 1 Diabetes. Transdifferentiation means that MSCs can change from one cell type to another. Thus, these cells could potentially regenerate heart muscle or other types of tissues such as organs.

**THE BENEFITS OF STEM CELL THERAPY**

Stem cell therapy – in the form of a bone marrow or blood transplant – has been used for decades to treat various forms of cancer such as leukemia, multiple myeloma or some forms of lymphoma. In the case of cancer, hematopoietic (blood) stem cells are used to regenerate new, healthy blood stem cells in a patient who cannot make their own. Either autologous or allogenic stem cells are collected, and, after high doses of chemotherapy, they are transfused into the patient in the hopes that the patient’s red blood cell, white blood cell and platelet counts return to normal. The ultimate goal is to cure the cancer.

However, in addition to cancer treatment, there are several known therapeutic benefits to stem cell therapy, with the full extent of its healing properties yet to be scientifically or clinically documented. Clinical trials involving MSCs are ongoing and the results are encouraging. Theoretical and clinical research in both animal models and human subjects have demonstrated the feasibility of treating common ailments ranging from heart disease and stroke, to diabetes. In particular, stem cell therapy has shown promise in addressing chronic pain, orthopedic conditions and opioid abuse. These three inter-related conditions are especially costly to NJ and its residents.

**Chronic Pain**

A 2015 NIH analysis conducted by Nahin (2015) estimated that 25.3 million adults suffer from chronic pain and nearly 40 million adults have severe levels of pain. A previous report published by the National Academies of Science, Engineering and Medicine estimated that as many as 100 million Americans suffer from chronic pain conditions, with conservative cost estimates ranging from $560 to $635 billion. As much as $99 billion of the cost of treatment is borne by federal and state governments. The report concluded that “the available data suggest that all Americans have a significant chance of experiencing serious pain.”

A brief review of the scientific literature shows that stem cell therapy can attenuate or even eliminate the chronic pain that results from a myriad of medical conditions. In 2014, Franchi et al. made the case for the use of adult stem cells to treat neuropathic pain. The authors concluded that “given the scarce response to the conventional analgesic therapy such as drugs (tricyclic antidepressants, calcium channel ligands, SSNRIIs, and opioids) which lack complete or long-term effectiveness, it is "mandatory to identify and propose novel approaches to [neuropathic pain]..." The authors noted the “fast onset and long-lasting effect on pain relief that one injection [of stem cells] could provide,” an outcome far superior to drugs which require chronic administration, have side effects, require periodic dose increases, have drug interaction risks and require patient compliance.

That same year, a short editorial by Zhou et al. entitled “Stem Cell Therapy: The Future of Pain Medicine” claimed that “[r]ecent advancements for [stem cell therapy] for pain due to degenerative diseases in the spine and joints are promising and indicative that [stem cell therapy] will undoubtedly play a major role in the future of pain medicine.”

**“BMSCs can be used for successful autologous and even heterologous transplantation. Therefore, injections of BMSCs may provide efficient, long-term, and safe therapy for patients with painful diseases.”**

Huh et al. (2017)
role in the future." A subsequent January 2015 mini-review by Labusca et al. examined the plausibility of using MSCs to treat acute, chronic and neuropathic musculoskeletal pain, concluding that stem cells “show promise for several chronic non-life-threatening yet disabling conditions such as [musculoskeletal]-related pain.” In 2017, in a mini review published in *Frontiers in Immunology*, Huh et al. stated:

> [with] the association of neuroinflammation and various painful insults and pathologies, the studies demonstrate the ability of [bone marrow stem cells (BMSCs)] to treat chronic pain. Due to their strong immunoregulatory properties and high expansion potential, BMSCs can be used for successful autologous and even heterologous transplantation. Therefore, injections of BMSCs may provide efficient, long-term, and safe therapy for patients with painful diseases.

Huh et al. highlighted how, due to BMSCs’ immunomodulatory properties, BMSCs have been shown to treat osteoarthritis (evidenced by animal models), degenerative disc injuries, inflammatory bowel disease, neuropathic pain, and pain associated with cancer and radiotherapy.

Stem cells alleviate pain in a myriad of ways including: interleukin 10 and transforming growth factor beta, or TGF-β (powerful immunosuppressive cytokines and neuromodulator), tumor necrosis factor-stimulated gene 6, or TSG-6 (an anti-inflammatory glyco-protein, and hepatocyte growth factor I, or HGF-1. In a recent study published in *Military Medicine*, Liu et al. (2017) found that a single low-dose MSC shot significantly attenuated neuropathic pain in injured rats regardless of whether the cells were delivered via intravenous or intraarticular administration, or whether the cells were derived from bone marrow or adipose tissue. The authors concluded that the therapy “has great potential to emerge as an innovative, safe, efficacious, and cost-effective therapy for the treatment [of] neuropathic pain or other chronic pain conditions.”

The authors took specific note of the pain-related impairments and disabilities suffered by members of the military, and the unsatisfactory nature of current treatment options.

Stem cells have not only treated pain in animal models, but also in human subjects, and for many medical conditions. Regarding overall clinical use in humans, Huh et al. noted that “[t]ransplantation of BMSCs is considered safe and has been extensively tested in clinical trials, including cardiovascular, neurological, and immunological disease, with exciting results.”

More specifically, Ponemone et al. (2017) found that autologous bone marrow concentrate, which contains hematopoietic stem cells (HSCs) and MSCs, resulted in a statistically significant improvement in pain scores in patients with critical limb ischemia. Burke et al. (2017) have remarked upon the potential usefulness of using MSCs to treat pain associated with osteoarthritis. According to the CDC, from 2013-2016, an estimated 54.4 million American adults were diagnosed with some form of arthritis, and osteoarthritis is the most common form of arthritis. The CDC estimates that by 2040, 26% of adults will be diagnosed with some form of arthritis.

In a 2016 study by Pettine et al., 26 patients who suffered from chronic discogenic lower back pain were injected with their own bone marrow concentrate. At 24 months, 26 patients were able to avoid surgery. Oswetry Disability Index (ODI) and Visual Analogue Scale (VAS) scores for pain were significantly lower at a three-month evaluation and were sustained through 24 months. According to Freberger et al. (2009), lower back pain is the second most common cause of disability in the US, and from 1992 to 2006, the prevalence of chronic lower back pain more than doubled, from 3.9% to 10.2%.

Ansary et al. (2014) have used autologous therapy to significantly decrease the resting pain of 122 adults with chronic lower limb ischemia. The therapy also increased pain-free walking distance from 25 ± 8.90 m to 409 ± 104 m. Davies (2012) maintains that 12% of adults suffer from critical limb ischemia, and 20% of adults aged 70 or older are affected. Chronic limb ischemia is a local symptom of a very common disease – atherosclerosis, colloquially known as clogged arteries – and is fatal if untreated. Dash et al. (2009) achieved similar results in 12 patients with non-healing ulcers of the lower limb who received autologous bone-marrow derived MSCs. The patients with diabetic foot ulcers not only had a significant decrease in ulcer size, but also significantly increased pain-free walking distance, from 38.33 ± 17.68 m to 284.44 ± 212.12 m.

There has been success in other areas as well. Szabo et al. (2013) saw a decrease in pain in patients with peripheral artery
disease (PAD) when infused with peripheral blood derived autologous stem cells. Cobellis (2008) achieved similar results with BMSCs. Additionally, in a small study, three patients with incomplete spinal cord injuries also experienced a decrease in or complete disappearance of neuropathic pain following autologous therapy. Finally, in autoimmune diseases, autologous stem cell therapies have been used to heal painful anal fistulas in Crohn’s patients (Panes, 2016). Recent CDC data show that in 2015, 1.3% of American adults reported being diagnosed with ulcerative colitis or Crohn’s, a large increase from 1999 data.

Orthopedic Conditions

Several peer-reviewed studies have confirmed that stem cell therapy has significant therapeutic potential in several orthopedic applications. Although the cost of stem cell therapies generally is difficult to ascertain, the cost for orthopedic conditions is usually between $5,000 and $8000, far less than surgery. Stem cell therapy offers the possibility of tailored approaches to improve patient outcomes and manage or ameliorate the severity of symptoms associated with musculoskeletal injuries. It can facilitate the healing of bone fractures and non-unions. It can assist with spinal surgery, including spinal cord injury, spine fusion and disc degeneration. It has even been shown to stimulate cartilage regeneration. Adult autologous therapy specifically has proven effective in meniscus repair and osteoarthritis with no inordinate risk. Schmitt et al. (2012) remark that conventional treatments for conditions like cartilage damage, arthritis, large bone defects or atrophic tendon ruptures frequently result in diminished musculoskeletal function, loss of mobility and even loss of autonomy. Clearly, new treatments are needed.

Stem cell therapy may be particularly useful in treating lower back pain (LBP). An analysis of the Global Burden of Disease 2010 data showed that LBP ranked as the greatest contributor to global disability, out of 291 conditions studied. The condition tends to peak in older age groups; thus, regions with higher life expectancies are disproportionately impacted. The number of people with LBP is projected to increase in the coming decades, especially in low- and middle-income countries. According to the World Health Organization (WHO), in the US, about 149 million work days are lost every year because of LBP at an estimated cost of $100-200 billion per year. Of course, the costs to the patient – both financial and emotional – can never be adequately quantified.

Although the causes of LBP generally are multifarious, the NIH maintains that the majority of cases are mechanical in nature. The gradual degeneration of the spine as a result of normal wear and tear – referred to as spondylosis – can result in a myriad of painful conditions. These conditions can range from simple sprains, to herniated or ruptured discs, to injuries caused by trauma. The WHO admits that the causes of lower back pain are rarely addressed, and analgesic medications are routinely prescribed to treat these conditions. Commonly prescribed medications include opioids, NSAIDs, anticonvulsants, antidepressants, counter-irritants and epidural steroid injections.

However, these analgesic treatments have shortcomings: dangerous side-effects, adverse drug interactions, addiction, organ damage or only temporary relief. Other treatment options include physical therapy, transcutaneous electrical nerve stimulation (TENS), acupuncture and in extreme cases, surgery. Sadly, neither the conservative management nor the more invasive surgical options yields satisfactory results, simply because they fail to address the underlying disease processes. In fact, some may actually lead to a worsening of the condition in the long term.

Many cases of lower back pain involve structural damage to the intervertebral discs, either by way of a herniated disc or degenerative disc disease (DDD). This condition is quite prevalent among older adults, with one study finding that 95% of older Americans exhibiting some degree of disc degeneration. In the search for treatments beyond analgesics and surgery, several researchers have demonstrated the effectiveness of stem cell therapy in treating disc injuries in large animal studies, with varying results. Leung et al. (2006) and Drazin et al. (2012) have noted the potential for MSCs to treat intravertebral disc degeneration. The authors acknowledged the need for new treatments, as well as the success of MSCs in treating IVD conditions in small models such as rabbits. Orozco et al. (2011) used autologous bone marrow-derived MSCs to treat 10 patients with lower back pain caused by lumbar disc degeneration. Patients exhibited rapid improvement in pain and disability. Similarly, Pettine et al. (2016) have reported significantly reduced pain scores in 26
patients who received autologous bone marrow-derived stem cells, and the patients who received a higher dose experiencing an increased reduction in pain. More recently, Pennicooke et al (2016) reviewed research on the use of several cell types on DDD, including autologous mesenchymal stem cells, autologous hematopoietic stem cells, autologous bone marrow aspirate and allogenic mesenchymal stem cells and allogenic juvenile disc chondrocytes.

**Implications for Opioid Epidemic**

The unfortunate truth is that for many patients suffering from chronic pain and orthopedic injuries, the true medical danger lies in conventional therapies that can be dangerous and even deadly. Currently, the US is in the grip of a widespread and worsening opioid addiction epidemic, and the chronic pain underlying the addiction has no true solution. The situation is so dire that Pres. Trump has declared a National Public Health Emergency and appointed a commission, chaired by former NJ Governor Chris Christie, to find solutions. In a draft of its final report, the Commission made several recommendations, including increased federal funding for state initiatives aimed at combating opioid addiction, redoubled efforts to enhance informed consent among those prescribed opioids, increased monitoring of drug prescriptions, and increased funding for research and development for discovering drugs to treat and reverse opioid overdose. However, the report spent little time discussing an issue that is key to confronting the problems of opioid addiction and overdose – alternatives treatments for chronic pain and disability.

Individual states are also taking action on opioid abuse. On January 10, 2018, Pennsylvania Governor Tom Wolf signed a Proclamation of Disaster Emergency to fight the scourge of opioid addiction in his state. The Declaration took note of the higher-than-average drug overdose rates in Pennsylvania and even named some of those drugs most culpable: morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl and hydromorphone. The Declaration made it clear that "Pennsylvania’s opioid crisis impacts all areas of the state – including urban, suburban and rural communities and all ages including both young people and older Pennsylvanians – and is unprejudiced in its reach and devastation." Virginia and other states have issued similar declarations.

Although no official emergency declaration has been issued in NJ, former Governor Christie did issue Executive Order 219 declaring opioid abuse a public health crisis “necessitating the marshalling of all appropriate resources to combat its harmful effects on the citizens of (NJ).” The order created a Drug Abuse Task Force to develop and execute a strategy to combat the epidemic, and to make drug treatment services more accessible. Governor Christie later allocated $200 million to fund 25 initiatives to address the epidemic. The initiatives included an incentive-based opioid recovery program, supportive housing, increased availability of overdose drug Narcan and prescription monitoring programs. More recently, current Governor Phil Murphy allocated $100 million for prevention, treatment and recovery; supportive housing for persons with opioid abuse disorders; and the development of electronic medical records and workforce development. None of the initiatives proposed by Governors Christie or Murphy is directed at finding alternative treatments for chronic pain.

Not only can stem cell therapies address the chronic pain that can cause opioid abuse, but they can also treat opioid tolerance. "Tolerance" is defined as a decrease in effect following repeated or prolonged administration of a specific dose. According to the National Institute of Drug Abuse tolerance can result in the need for higher doses of the opioid to achieve the same result. For patients suffering from acute or chronic pain, this means that they need more pills to alleviate their pain. This can lead to a dangerous cascade of consequences. According to Volkow and McLellan, "the repeated administration of any opioid almost inevitably results in the development of tolerance and physical dependence." Although not all who become opioid tolerant become addicted, the World Health Organization asserts that people dependent on opioids are the group most likely to suffer an overdose.
Given the seriousness of the problem, researchers have been searching for a way to prevent opioid tolerance and keep opioid users in a state of analgesia. In their quest, some researchers have found an answer in stem cells. In a recent study, Dr. Jianguo Cheng and scientists from the Cleveland Clinic and the Affiliated Hospital of Qingdao University hypothesized that MSCs could prevent or reverse opioid tolerance and opioid-induced hyperalgesia because of their profound anti-inflammatory properties. To prove their hypothesis, they induced opioid tolerance in rats and mice by injecting them with morphine for four weeks. Astoundingly, after administering MSC therapy to the opioid-tolerant rodents, tolerance was reversed within as little as 2 days.

The researchers found the use of MSCs to reverse opioid tolerance to be completely safe. “Over the course of the experiments … all animals showed normal locomotion, food and fluid intake, and body weight gain. Furthermore, “(h)epatic and renal functions were all within the normal range,” and all major organs were found to be normal. The authors concluded that MSCs have “enormous potential to profoundly impact clinical practice and improve opioid efficacy and safety.” This study built on previous research in which the authors concluded that the therapy was “safe and practical.” The previous study also found that “[c]linical studies have convincingly demonstrated that direct injection of MSCs does not produce unwanted side effects and is well tolerated and safe.” Rejection of the stem cells was not an issue because MSCs are immune-privileged.

**FEDERAL POLICY ON STEM CELL THERAPY**

Federal policy on stem cell research and rulemaking has a Janusian quality. On the one hand, it has opened significantly in the past decade as, a result of the relaxing of rules restricting embryonic and other types of stem cell research, and the passage of federal laws aimed at expediting regenerative medicine therapies to market. On the other hand, FDA regulations that define the standards for determining which therapies can be offered without FDA approval and those that require approval – legally deemed “drugs” – interpret such standards narrowly. Thus, few applications of stem cell therapy – even those with good safety and efficacy profiles – can be used by actual patients today.

The 21st Century Cures Act is the foundation of current regenerative medicine and stem cell policy. In December 2016, Pres. Obama signed the Cures Act into law. As its name suggests, the law is intended “to accelerate the discovery, development, and delivery of 21st century cures.” At its core, the Act establishes the NIH and Cures Innovation Fund for funding “biomedical research” and “cures development,” and the streamlining of clinical trials.

However, the Act also contains special provisions – §§ 3033 to 3036 – regarding the “accelerated approval for advanced regenerative therapies.” These provisions include:

3033. **Accelerated Approval for Regenerative Advanced Therapies** – requires the facilitation of the approval of regenerative advanced therapies; permits fulfillment of post-approval requirements for regenerative advanced therapies granted accelerated approval through submission off clinical evidence;

3034. **Guidance Regarding Devices used in the Recovery, Isolation, or Delivery of Regenerative Advanced Therapies** – requires the issuance of guidance clarifying how devices used in the delivery of regenerative advanced therapies will be evaluated;

3035. **Reporting on Regenerative Advanced Therapies** – requires the Secretary of Health and Human Services to submit an annual report to Congress detailing the number of applications for regenerative advanced therapies that were filed and approved; and

3036. **Standards for Regenerative Medicine and Regenerative Advanced Therapies** – requires the issuance of standards and consensus definitions in the regenerative medicine field with a focus on identifying opportunities to help advance the field;

In fulfillment of its obligations under the Cures Act, on November 16, 2017 the FDA released “Regulatory Consideration for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff.” The new framework is intended to “balance the agency’s commitment to safety with mechanisms to drive further advances in regenerative medicine so innovators can bring new, effective therapies to patients as quickly and safely as possible.” The guidance provides the FDA’s interpretation of the
criteria for determining whether a human cells, tissues, and cellular and tissue-based product (HCT/P) is classified as a drug and thus requires premarket approval by the FDA. The regulatory foundation for the rules can be found in 12 CFR 1271.10. Most notably, the guidance interprets the terms “minimally manipulated” and “homologous use,” key standards that determine the availability of stem cell therapies to patients. Unfortunately, the terms are interpreted narrowly, effectively proscribing the therapies altogether.

Stated simply, stem cells that are “minimally manipulated” and used for “homologous purposes” do not need to be approved by the FDA via clinical trial. “Minimally manipulated” means “processing that does not alter the relevant biological characteristics,” which include “properties of the cells or nonstructural tissues in the donor that contribute to the cells or tissue’s function or functions.” This interpretation severely limits the use of culture media, such as is needed to culture MSCs. As discussed, MSCs help reduce inflammation in orthopedic and autoimmune conditions, conditions that cause unbearable pain for countless Americans.

The “minimal manipulation” standard also has relevance to the new final guidance on the “same surgical procedure” exception.2 In 1997, the FDA stated that “the agency would not exert any regulatory control over cells or tissues that are removed from a patient and transplanted back into that patient during a single surgical procedure.” To qualify for the “same surgical procedure” exception, the cells must be implanted into the same individual “without intervening processing steps beyond rinsing, cleansing, sizing, or shaping....” Thus, the type or degree of manipulation of the cells is critical here. The new guidance makes it clear that this exception is to be interpreted narrowly. So, under these rules, processing steps intended to isolate or expand cells would not be exempt. This is a very onerous standard that few regenerative therapies other than platelet-rich plasma (PRP) therapy could meet.

The “homologous use” test is likewise stringent. Even if a stem cell product passes the "minimally manipulated test," the cells used must “perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor.” Under this definition, blood stem cells can be transplanted into a person with a disorder affecting their blood system because the cells are performing the “same basic function” in the recipient as they did in the donor. However, according to the guidelines’ Example 19-1(c), blood stem cells derived from umbilical cord blood cannot be used to repair damaged tissue, as in the case of a child’s cerebral palsy. The FDA’s explanation is that “this is not homologous use because there is insufficient evidence to support that repair of neurologic tissue through paracrine signaling or differentiation into neuronal cells is a basic function of these cells in the donor.”

Ironically, adipose tissues used for cosmetic procedures like breast reconstruction and augmentation do satisfy the “homologous use” test and do not require a clinical trial (Example 19-6(d)). But the stem cells that are derived from that same adipose tissue cannot be used to treat debilitating painful musculoskeletal conditions such as arthritis and tendinitis because “regenerating or promoting the regeneration of cartilage or tendon is not a basic function of adipose tissue” (Example 19-6(b)). Curiously, the guidance seems to miss the fact that the “basic function” of MSCs is to modulate inflammation and differentiate into different cell types. MSCs by their very nature are characterized by their ability to self-renew and differentiate into multiple tissues. These are precisely the properties that alleviate pain and heal tissues.

FDA Commissioner Gottlieb has stated that for the first 36 months following issuance of the final guidance, the FDA will adopt a “risk-based approach” to enforcement of the new rules, “taking into account how products are being administered as well as the diseases and conditions for which they are being used.” While this “grace” period seems reasonable, § (V)(B) of the final guidance makes clear that the FDA will prioritize enforcement of establishments that deliver stem cells via intravenous infusion and those used for the prevention or treatment of serious and/or life-threatening conditions, “because there is less basis on which to predict the product’s behavior in the recipient, and use of these unapproved products may cause users to delay or discontinue
medical treatments that have been found safe and effective through [FDA approval].” However, intravenous stem cell administration has been safely used to treat patients suffering from painful autoimmune diseases like multiple sclerosis and have been used safely in clinical settings for several therapeutic indications.

It is likewise problematic that the FDA guidance does not explicitly acknowledge the distinction between autologous and allogenic uses of stem cells. Section (V)(B) of the final guidance does provide some degree of deference to autologous therapies regarding agency enforcement during the first 36 months after the new rules are issued, but the text remains silent as to any distinction on the period subsequent to the first 36 months. Thus, although the language used does implicitly recognize that autologous use is less of a safety concern, it fails to elucidate a separate, less onerous set of regulatory standards for cells that come from one person and are administered to that same person.

In keeping with its obligations under the Cures Act, the FDA also proposed several programs to expedite the approval of stem cell therapies. These programs are discussed in an FDA document released in November 2017 entitled “Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry.” The programs include:

(1) **Fast Track Designation** – for investigational new drugs that are intended to treat a serious condition and for which non-clinical or clinical data demonstrate the potential to address an unmet medical need in those with such condition;

(2) **Breakthrough Therapy Designation** – for an investigational new drug that is intended to treat a serious condition, and for which preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapies;

(3) **Regenerative Medicine Advanced Therapy Designation (RMAT)** - for regenerative medicine therapies that are intended to treat, modify, reverse or cure a serious condition and preliminary clinical evidence indicates that it has the potential to address an unmet medical need;

(4) **Priority Review Designation** – for Fast Track, Breakthrough or RMAT products that treat a serious condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment of the condition; and

(5) **Accelerated Approval** – for settings in which the disease course is long and an extended period of time would be required to measure the intended clinical benefit of a drug.

Subsequent to the issuance of the final guidance, Commissioner Gottlieb remarked that the FDA must take “an original policy approach to the regulation of a highly innovative field, one in which (the FDA’s) traditional approach to regulation may not be as efficient or effective as in more mature fields.” He remarked further that “working within the existing regulatory framework, the FDA will make use of all available regulatory pathways and will adopt the use of some new principles that (the FDA believes) will make the appropriate premarket evaluation of stem-cell- based therapies more efficient.” Notably, the FDA will be incorporating some “new concepts for how small investigators and firms can seek and meet the approval standard for products through efficient expedited pathways.” Commissioner Gottlieb provided but one theoretical example: the FDA will provide “tools” to allow small firms to work collaboratively to obtain a biologics license for all physicians or groups included in the collaborative. Attempts to expedite the availability of stem cell therapies to the patients who need them should be encouraged. However, given the dearth of detail offered by Gottlieb, precisely how these alternatives will work in practice remains uncertain.

Commissioner Gottlieb asserts correctly that “the field [of regenerative medicine] has moved from a characterization of the properties of these cells toward therapeutic applications.” But, while the FDA acknowledges that regenerative medicine generally, and stem cell therapies, specifically, are revolutionary medical technologies that show promise for treating and potentially curing untreatable or incurable diseases, current federal regulations regarding stem cell therapy are unduly restrictive. These restrictions prevent New Jerseyans from accessing this safe and effective therapy.
THE ROLE OF STATES IN PROMOTING STEM CELL THERAPY

Given the proven clinical success of SCT and the shortcomings of FDA regulations, states have a critical role to play in stem cell policy. Shared authority and cooperation in medical treatment delivery is nothing new. For example, 38 states have passed “right to try” legislation, making it easier for patients suffering from life-threatening illnesses to gain access to experimental drugs that have entered Phase I of the FDA clinical trial process. The US House of Representatives and Senate have passed similar legislation at the federal level, and President Trump will likely sign the bill into law later in 2018. Although “right to try” laws have their detractors who argue that such legislation usurps the authority of the FDA and puts patients at risk of injury from unproven therapies, others hail it as a breakthrough that will expedite potentially life-saving treatments to Americans with no viable alternatives. When asked about “right to try” legislation, FDA Commissioner Gottlieb himself was confident in the agency’s enforcement ability, remarking that when it comes to patient risk and patients being taken advantage of “it’s a small set of bad actors who are recidivists and repeat offenders.”

In 2004, New Jersey became the second state to enact legislation permitting embryonic stem cell research, two years after California did the same. The NJ legislation, Title 26:2Z-7, forbids human cloning but does permit the cloning of embryos for research purposes. In May 2004, former Governor Jim McGreevey signed a bill creating the first state-funded embryonic stem cell research center at a cost of $25 million. In 2005, the New Jersey Commission on Science and Technology awarded 17 stem cell research grants totaling $5 million. The stated mission of the Stem Cell Institute of New Jersey is to “carry out research, training, and clinical studies on the application of stem cells to the treatment and cure of human disease.” Unfortunately, none of the Institute’s research has reached the clinical stage.

Although practical results have yet to materialize, initial expectations for the stem cell initiative were high. Seneca and Irving (2005) estimated that the NJ law would create $1.4 billion in direct economic benefits, 20,000 new jobs and $79.1 million in state revenues. In addition, they predicted a reduction in health care costs, savings in work time lost and a decrease in premature deaths. The health care costs to NJ were estimated to be reduced by $11.3 billion over a ten-year period as a result of stem cell therapies. The estimated savings in worker productivity was $813 million. The reduction in premature deaths would save $60.7 billion. Several other states likely forecasted the same benefits with their respective stem cell initiatives. In addition to NJ and CA, several other states support embryonic and/or stem cell research: Connecticut, Florida, Illinois, Indiana, Massachusetts, Maryland, Ohio, Virginia and Wisconsin.

With negligible or non-existent clinical benefits, NJ needs additional, more practical, stem cell legislation. An augmented stem cell initiative should be aimed at: (1) facilitating the availability and affordability of safe, effective stem cell therapies to patients in an expedient manner; and (2) realizing the cost reduction goals to the state of NJ, its businesses and its residents, as forecasted by Seneca and Irving. The cases of Texas and Arkansas provide instructive examples as to how NJ can proceed with reasonable, forward-thinking stem cell legislation.

Texas – A Case Study

In July 2017, Texas Governor signed H.R. 810 into law, making Texas the first state to sanction the use of stem cell therapy for patients with certain severe chronic condition or terminal illnesses. Also known as Charlie’s Law, the law permits a patient to access an investigational stem cell treatment if the patients treating physician can attest that the patient has a severe chronic disease or terminal illness, and all other treatment options have been considered and deemed unavailable or unlikely to alleviate the condition. To qualify as an “investigational stem cell treatment,” the treatment must be under investigation in a clinical trial and must not yet be approved for general use by the FDA. A physician must also recommend in writing a specific type of stem cell therapy to be administered. Under the law, the developer of the step cell treatment being used receives some insulation from liability for any potential harm that may arise to the patient as a result of the drug’s use. Prescribing physicians also receive some liability protection.

Charlie’s Law passed both the Texas House of Representatives and Senate unanimously. State senator Jose Menendez praised
the law, as his wife suffers from multiple sclerosis. “As soon as [the Texas Medical Board] comes out with the rules, we’ll be in line just like everybody else, but once we’ve discussed it with our doctor. It has to be under the guide the and informed consent and the direction off a doctor.” He further noted that “[we] were very careful not to pass a bill that’s going to just allow people to swoop line from anywhere in the world and try to sell magic cures.” Texas Representative Drew Springer echoed Senator Menendez’s sentiments in a tearful speech. He implored his colleagues to pass HB 810, and “open the door to medical science. His wife is unable to walk and uses a wheelchair. In his speech, he admitted he was “grasping at straws” to help his wife and all Texans with disabilities. Former Texas Governor Rick Perry famously received stem cell therapy to treat a chronic back ailment in 2011.

Arkansas – A Case Study

Arkansas is on course to be the first state to require medical insurance companies to cover stem cell therapy. Arkansas’ 2017 Emerging Therapies Act (Act 12014) grants pilot access to regenerative injection technologies for state employees suffering with orthopedic conditions. After a pilot study conducted by the Employee Benefits division, the ultimate goal is to ensure that all Arkansas residents have access to these therapies. Executive Vice President of Strongside Solutions Morgan Pile, worked on the bill and stated that “this could potentially save the state $100 million using regenerative medicine as an alternative to surgery or pharmaceuticals.”

The overall goal of the legislation is to promote cost effective emerging medical technologies as alternatives to surgical procedures.

Arkansas’ focus on public employees’ health benefits is well-founded. A 2014 Pew report stated that people covered by public sector employers tend to have a higher prevalence of every chronic condition than people covered by private sector employers. Diabetes and hypertension are 48% and 59% more prevalent in the public-sector population, respectively. That same report found that NJ, specifically, had one of the most employee health benefit plans in the nation. The national average monthly premium – the cost borne by the state and its employees – was $363. In NJ it was $1,334.

Any state-led stem cell legislation must address the twin goals of accessibility and affordability. Thus, the best path forward for NJ would likely be some combination of the Texas and Arkansas models. Such an approach would open the door to stem cell therapies for those with no therapeutic alternatives, while ensuring that effective safeguards exist in the form of physician approval, medical board oversight and the patients’ informed consent. In the case of Texas, the Texas Medical Board and the Texas State Department of Health Services are collaborating together and with other stakeholders to draft rules to implement its legislation. Likewise, New Jersey’s State Board of Medical Examiners could coordinate with the NJ Department of Health to implement similar stem cell rules in NJ.

New Jersey has already undertaken a similar effort in its legalization of medicinal marijuana under the New Jersey Compassionate Use Medical Marijuana Act. Despite the existence of federal legislation which restricts the possession and use of marijuana and its derivatives, NJ opted to join with the states that offer medical marijuana because “the health and welfare of its citizens” took priority. In its findings, the legislature recognized that “modern medical research has discovered a beneficial use for marijuana in treating or alleviating the pain associated with certain debilitating medical conditions.” Regarding any potential conflict with federal law, the legislature found that, because states are not required to enforce federal law or prosecute people for engaging in activities that may violate federal law, compliance with the medical marijuana law would not put the state of NJ in violation of federal law. Finally, the legislation makes a crucial distinction between medical and non-medical uses of marijuana, protecting those who prescribe it or use it for debilitating conditions. Both the legislative findings that undergird NJ’s medical marijuana law and the protocol of implementation – patient qualification standards and procedures; certification of authorized use by a licensed physician in good standing; and rules regarding the operation of establishments supplying medical marijuana – lay a solid foundation of institutional knowledge that stem cell legislation can build upon.

Insurance coverage for stem cell therapy would lower the insurance burden on the state. In 2016, NJ spent $14,546,679,583 on Medicaid coverage. The state covered 39.4% of that cost, 24.2% of the state budget. Fifty-four percent of NJ Medicare funding went to managed care, while 20% was spent on long-term care. New Jersey Medicaid per-enrollee spending in 2013 was $3,394, more than $2,000 higher than the national average. Governor Phil Murphy’s
proposed FY 2019 budget actually increases Medicaid spending, providing expanded benefits for autism spectrum disorder, diabetes, family planning and opioid use disorder. In 2015, NJ spent $154.3 million on its Children’s Health Insurance Program (CHIP), a publicly-funded medical insurance program for those who earn too much to qualify for Medicaid. The costs of both programs are alarming and may be mitigated with robust stem cell legislation.

Public employee health benefits are also a serious issue in NJ. The Governor’s FY 2018 Budget – Budget Summary noted that “[o]ne of the main drivers of the unsustainable increases in government costs in recent years has been the unrelenting rise in the cost of providing generous health benefits coverage to current and retired State employees, as well as the retired teachers and local employees....” The budget summary also stated that “[t]hese annual increases, if left unchecked, would significantly erode the State’s ability to address important priorities, including providing critical services to residents in need, making investments that create jobs, and increasing pension payments.” Increases in health care costs also affect, schools, counties, municipalities, fire districts, water authorities and sewer authorities. To stem the increases, the budget suggested “common sense” reforms, such as:

1. changes in prescription drug policy; drug formulary changes, mandatory generic utilization, maximization of Medicare benefits, elimination of high-cost drugs;
2. containment of out-of-network charges for physical therapy – acupuncture and chiropractic services;
3. patient centered medical homes to improve health care delivery and lower benefits spending; and
4. Medicare advantage plans to reduce health care costs by $20 million.

While these recommendations are laudable, they fail to address the inadequate and ineffective treatments that currently exist to address the disabilities and diseases that drive the majority of health care costs in NJ.

CONCLUSION AND RECOMMENDATIONS

Given the high prevalence of disease and disability in NJ, and the concomitant health care costs that burden the state, its employers and its residents, the passage of a law that makes stem cell therapy available and affordable should be a top priority. Legislation from Texas and Arkansas offer useful models in determining the path forward. However, legislation passed in NJ will have to address its specific needs. Any proposed legislation should incorporate the following core objectives:

Immediate Term:

1. Make investigatory stem cell therapies available to NJ residents with serious chronic diseases or life-threatening conditions;
2. Initiate a pilot program to require health insurance companies to cover the cost of stem cell therapies for all state employees under conditions set forth by NJ Department of Health regulations

Long Term:

1. Make stem cell therapies available to NJ residents with debilitating or chronic conditions;
2. Require health insurance companies operating in NJ to cover the cost of stem cell therapy for all NJ residents under NJ Department of Health Regulations.

Both the immediate and long-term objectives should be founded upon the following fundamental findings:

1. Modern medical research has advanced to the point where regenerative medicine and stem cell therapies have the ability to treat or cure chronic conditions or diseases for which conventional medicine offers limited or no treatment options;
2. Clinical application of stem cell therapies has been performed for years for several disease indications in a safe and effective manner;
3. Although federal law has certain prohibitions on the manufacture and medical use of certain stem cell products, Texas and Arkansas have enacted legislation to make stem cell therapies more accessible and affordable. New Jersey joins this effort for the health and welfare of its citizens, and the fiscal health of the State;
4. States are not required to enforce federal law or prosecute people for engaging in activities.
prohibited by federal law; therefore, compliance with this act does not put the State of New Jersey in violation of federal law;

(5) The opioid abuse epidemic is both a national emergency and a State emergency that directly impacts the State, its residents, physicians and, businesses, and for which the chronic pain that often precipitates the abuse has few safe, effective treatment options; and

(6) One of the main drivers of the unsustainable increases in government costs in recent years has been the unrelenting rise in the cost of providing generous health benefits coverage to current and retired State employees, as well as the retired teachers and local employees, and, if left unchecked, would significantly erode the State’s ability to address important priorities, including providing critical services to residents in need, making investments that create jobs.
ENDNOTES

24 Song, L., & Tuan, R. S. (2004). Transdifferentiation potential of human mesenchymal stem cells derived from bone marrow. FASEB J. 18(9), 981-982.


Charlie’s Law. TXHB 810 (2017). Relating to the provision of certain investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses and regulating the possession, use, and transfer of adult stem cells; creating a criminal offense. [https://legiscan.com/TX/drafts/HB810/2017](https://legiscan.com/TX/drafts/HB810/2017).


