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This radiant type of strength and youth!
Glowing eternally!

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Stepped forth and never missed his place!
He steps forth the splendor of the sky the wide!
Seeing, far-shining, the shining wanderer!
-Rig Veda, vii, 65

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BIOSIMILARS

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law 111-148) on 23 March 2010. The BPCI Act amends the PHS Act and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with a Food and Drug Administration (FDA)-licensed reference product[1]. Section 351(k) of the PHS Act, added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. To meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHS Act). In 1983, generic drugs accounted for only 13%, while in 2018, they account for about 90% of US prescriptions, indicating a decline in innovative branded new drugs due to generic drugs reaching the market more quickly - thanks to Reagan's Hatch-Waxman Act of 1984[2]. The field of biologics represented 70% of the growth in drug spending from 2010 to 2015 and expected to be the fastest growing segment of drug spending in the coming years[3]. Estimated savings from expected biosimilar competition are range from $54 billion from 2017 to 2026 according to a study by RAND, to as much as $250 billion from 2014 to 2024 from just 11 biosimilars expected to be approved and marketed according to a survey by Express Scripts.

In July 2018, Guidance for Industry for Labeling for Biosimilar Products[4] was published. Also, the FDA has announced a public hearing for 4 September 2018 to gather stakeholder input on FDA's approach to enhancing competition and innovation in the biological products marketplace and facilitating greater availability of biosimilar and interchangeable products, and the Biosimilar Action Plan announced recently[5]. Maintaining the balance between innovation and access to cheap drugs requires a mix of statutory and regulatory measures, such as

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creating scientific processes for drug review to reduce the time, uncertainty, and cost of drug development; and address unmet medical needs. After patents or other exclusivities expire on these novel biologic products, prices can fall dramatically once follow-on products are available, lowering costs for patients and payors and expanding access to the biosimilars, similar to the access cheap pharmaceuticals due to small molecule generics after 1984 that saved the US more than $1 trillion in the last decade[6].

The BPCI Act describes an interchangeable product as a product that may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. A biosimilar product will be specifically prescribed by the healthcare provider and cannot be substituted for a reference product at the pharmacy level using the Purple Book that lists biological products, including any biosimilar and interchangeable biological products, licensed by FDA under the Public Health Service Act (the PHS Act), and includes the date a biological product was licensed under 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act and whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product)[7].

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CANNABIS

Cannabis offers an unparalleled opportunity for businesses.

An estimated 1.4 million Ontarians have driven while under the influence of cannabis, and about one-third of those surveyed have used marijuana before driving in the past three months. According to a Canadian Automobile Association study about 72% perceived that cannabis users drove worse than sober drivers[8]. However, alarmingly, a vast majority of Ontarians were not aware of cannabis impairment, and the Canadian federal government is poised to legalize the use of marijuana (Bill C-45[9]) on October 16, 2018. After the royal assent to the Cannabis Act on 21 June 2018, Canada published the Cannabis Regulations, SOR/2018-144 and new Industrial Hemp Regulations, SOR/2018-145, on 11 July 2018, affecting producers and others within the thriving industry having impact on a variety of areas of production, distribution and licensing of cannabis products, and drugs containing cannabis, and industrial hemp; including packaging and labelling, advertising, cultivation, processing, analytical testing, sale, research, and rules pertaining to investors[10].

Cannabis edible products and concentrates will be legal for sale after 17 October 2019. It is hoped that the Act:

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- keeps cannabis out of the hands of youth
- keeps profits out of the hands of criminals
- protects public health and safety by allowing adults access to safe, legal cannabis

The definition of cannabis under the Act is broad, referring not only to parts of the cannabis plant, but also to the phyto-cannabinoids produced by or found in the plant, including any identical sub- stance regardless of how the substance was obtained. Adults who are 18 years of age or older would be able to possess up to 30 grams of legal cannabis, dried or equivalent in non-dried form in public share up to 30 grams of legal cannabis with other adults buy dried or fresh cannabis and cannabis oil from a provincially-licensed retailer in provinces and territories without a regulated retail framework, and would be able to purchase cannabis online from federally-licensed producers grow, from licensed seed or seedlings, up to 4 cannabis plants per residence for personal use make cannabis products, such as food and drinks, at home as long as organic solvents are not used to create concentrated products. Canada hopes that the Act protects public health through creating strict safety and quality regulations and raising awareness about safety measures and any potential health risks through public education efforts.

Meanwhile, EPIDIOLEX, the first prescription plant-derived cannabinoid medicine in the United States and the first in a new class of anti-epileptic medications, is a pharmaceutical formulation of pure cannabidiol (CBD) approved for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older, and is currently under review by the European Medicines Agency (EMA) for the treatment of seizures associated with LGS and Dravet Syndrome. An EMA decision on whether to recommend approval is expected in the first quarter of 2019[11].

When Mexico legalizes marijuana, recreational cannabis becomes legal along the entire length of North America's Pacific Coast, with Canada, California, Washington, Oregon, and Alaska[12]. Connecticut, Michigan, and Ohio are

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expected to vote on similar legalization programs in November[13]. Dozens of other states have decriminalized the substance or permitted it for medicinal use.

State and federal tax revenues from drug legalization, billions of dollars, 2016

	Total	Marijuana	Cocaine	Heroin	Other
Federal revenues	39.21	8.04	17.28	10.18	3.71
State revenues	19.60	4.02	8.64	5.09	1.86

Capitalism and greed prevail as the state and local governments spend $29 billion on drug prohibition annually and the federal government spends an additional $18 billion, meanwhile full drug legalization would yield $19 billion in state and local tax revenue and $39 billion in federal tax revenue[14], keeping the masses happy and docile with opium, opioids, cocaine, marijuana, alcohol, and other addictions.

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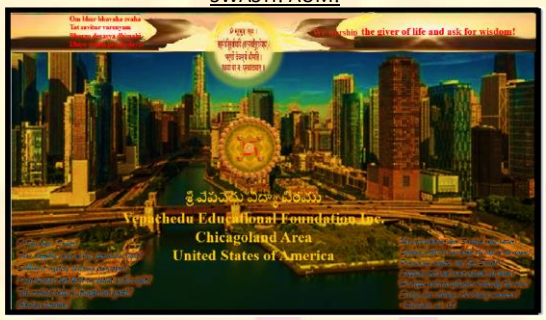
"Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls." Rabindranath Tagore (1861-1941), Gitanjali, 1912.

One World One Family

AUM! SWASTI!

Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

SWASTI! AUM!



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