

Life Sciences & Health Law

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This Article updates selected international legal developments relating to health and life sciences in 2018.

I. African Updates

A. MADAGASCAR

At the beginning of 2018, Madagascar passed the Reproductive Health and Family Planning Law.¹ This law discards colonial era prohibitions on the promotion of contraception and recognizes reproductive health and family planning as basic human rights. This new law updates the legal framework and aligns it with the government's dedication to protect the reproductive well-being of the Malagasy people. It also includes provisions to give health providers the authority to promote family planning and reproductive health in the adolescent population. Currently, one out of three girls become pregnant before their eighteenth birthday. The new law authorizes health providers to offer advice regarding contraception to all patients, regardless of the patient's age. Other aspects of the law promote family planning, outreach campaigns, bolster community lead services, and make contraceptive commodities, including emergency contraception, more widely available. This law marks a change in governmental ideology and realigns it to address a public health concern.

B. SOMALIA

Currently, in Somalia, there is only one health care professional per every 2,500 people. The World Health Organization, on November 8, met with the Somali government to develop a roadmap to attain universal health

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1. Journal officiel de la République démocratique de Madagascar [Official Journal of the Democratic Republic of Madagascar] is not publicly accessible. *See generally* Reproductive Health and Family Planning Law, 04-HCC / D3 (2018) (Madag.); *see also* Madagascar Passes Landmark Reproductive Health and Family Planning Law, HEALTH POLICY PLUS <http://www.healthpolicyplus.com/madagascarHFPLaw.cfm> (last visited Apr. 9, 2019).

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coverage in the country.² The goal of this roadmap is to offer essential and quality healthcare to every Somali citizen without the imposition of a financial burden. Led by the Somali Ministry of Health, the roadmap implements a collaboration between government representatives, United Nations (UN) agencies, and nongovernmental organizations to review the current health situation and host a joint summit to construct a plan to effectively move forward. The Director-General for the Somali Ministry of Health, Dr. Abdullahi Hashi, outlined in a resolution the importance and necessity of developing an effective roadmap with international support.³ The international partners, in developing this roadmap, considered options to finance the universal healthcare system, to enact true government reform, and to deliver essential and important health services. Somalia has reiterated its dedication to furthering the health of its people through new legislation.

C. SOUTH AFRICA

South Africa is proposing a State Liability Amendment Bill, which may have consequences for medical malpractice claimants.⁴ This Bill limits and structures the payment of a victim's damages from a medical malpractice claim against a state hospital. This Amendment was triggered after an increase in medical malpractice claims against the state that have caused budgetary issues.

D. TANZANIA

In the year 2017, there were more than 500,000 "people of concern" in Tanzania, including refugees and "asylum seekers."⁵ Malaria is an ongoing epidemic and accounts for a significant percentage of outpatient visits in refugee camp health facilities.⁶ Additionally, the Ministry of Health and the World Health Organization report that new cases of cholera continue to

2. World Health Organization [WHO], WHO and Somali Government roll out process to deliver quality health services to all Somalis, <http://www.emro.who.int/pdf/som/somalia-news/quality-health-services.pdf?ua=1>.

3. See Qorshaha Qaranka ee lagu heli karo Caymiska Caafimaadka ee Universal [National Plan to Attain Universal Health Coverage], Bolletino ufficiale della Repubblica Democratica Somala [Official Bulletin of the Democratic Republic of Somalia], (Nov. 2018) (Somal); see also *id.*

4. See generally State Liability Amendment Bill 16 of 2018 (S. Afr.) <http://www.justice.gov.za/legislation/bills/2018-B16-StateLiability.pdf>.

5. US Agency for Int'l Dev., *Tanzania: Food Assistance Fact Sheet* (Sept. 30, 2018), <https://reliefweb.int/sites/reliefweb.int/files/resources/FFP%20Fact%20Sheet%20Tanzania%2009.30.18.pdf>; see generally Tanzania Refugee Situation Public Health and Nutrition Strategy 2016–2018, UNHCR (2016), <https://data2.unhcr.org/es/documents/download/52191>.

6. See UNICEF Annual Report 2017 Burundi.

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break out, totaling 32,285 since 2015.⁷ Although public health law enforcement has been bolstered due to environmental health officers and closing vendors not in compliance, issues continue to arise. In addition, to fight the recent outbreak of the Ebola Virus Disease, thermal scanners are at all the ports of entry along the borders of the DRC.

E. ZIMBABWE

In Zimbabwe, the colonial-era public health laws have been cited as not guaranteeing human rights to all and the dignity and equality of everyone. Particularly, Article 35 of the Public Health Act Amendment Bill could put adolescent girls' health at risk, as it denies anyone under eighteen years old to consent to receiving health information and services.⁸ The age of consent is sixteen years old; but, girls seeking access to sexual and reproductive health information and services are denied access until they reach eighteen years old, the prescribed age of capacity in the Bill.⁹

II. Asian Updates

A. PEOPLE'S REPUBLIC OF CHINA

The 2018 Draft Amendment to the "Regulations on the Supervision and Administration of Medical Device" introduced possible changes that will significantly affect all the market players in the medical device industry.¹⁰ These changes aim to improve the Market Authorization Holder (MAH) mechanism, reform the clinical trial management system, and change post-marketing regulatory requirements. This draft was released by the Central Office of the Communist Party of China and the Office of the State Council (f/k/a China Food and Drug Administration).

In Chinese law, a "right to health" has been a negative civil right in civil law, but in 2018, a draft of the Basic Healthcare and Health Promotion Law, has proposed a "right to health" as a positive social right by National People's Congress Education, Science, Culture and Public Health Committee to the National People's Congress.¹¹ If passed, this will create a

7. World Health Organization Tanzania [WHO Tanz.], Working Together to Promote Health, Annual Report (2017), https://afro.who.int/sites/default/files/2018-08/WHO%20Annual%20Report%202017_0.pdf.

8. See Public Health Bill (2017), (Zimb.), <https://www.parlzim.gov.zw/component/k2/public-health-bill-2017>.

9. Amnesty Int'l, "Lost Without Knowledge" Barriers to Sexual and Reproductive Health Information in Zimbabwe, AI Index AFR 46/7700/2018 at 7, Jan. 26, 2018, <https://www.amnesty.org/en/documents/afr46/7700/2018/en/>.

10. See generally Yiliáo qìxiè jiāndu guānli tiáoli xiūzhèng àn cǎo'àn (医疗器械监督管理条例修正案草案) [Draft Amendment to the Medical Device Supervision and Administration Regulations] (promulgated by Ministry of Just., June 25, 2018, effective June 25, 2018) (China).

11. See Jiben yiliáo wèisheng yu jiànkāng cùjìn fǎ cǎogāo (基本医疗卫生与健康促进法 草稿) [Basic Health Care, Medicine and Health Promotion Law (Draft)] (promulgated by Standing

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“right to health” as a basic human right in Chinese law, advancing health care on both institutional and strategic levels. It may even develop into a constitutional right. With epidemiological studies showing that the Chinese population is aging, this right becomes even more central.

B. JAPAN

In Japan, tobacco regulations became stricter as Act No. 103 of 2002 amended the Health Promotion Act.¹² This amendment aims to protect people who want to avoid second-hand smoke when in indoor facilities.¹³ Facilities used by “many people” are obligated to make the indoor area smoke-free, with only a few exceptions.¹⁴ The amended Act will ban smoking indoors at schools, hospitals, and government offices within eighteen months of the implementation date. Smaller establishments, not owned by large corporations, will be given a grace period of execution. Failure of an individual to stop smoking in a smoke-free area is punishable by fine of approximately USD \$2,700.

C. MALAYSIA

The government in Kuala Lumpur enacted an amendment to the law that forces cancer patients to pay high rates for treatment at public hospitals if they are referred there by private or university hospitals. This 2017 amendment to the Fee (Medical) (Amendment) Order is now causing issues in 2018 and is creating financial difficulties for patients seeking treatment.¹⁵ The government has been urged to standardize the fee structure in all government hospitals.

D. SOUTH KOREA

In an effort to fight the overconsumption of caffeine, South Korea will introduce new regulations banning the sale of coffee, and other caffeinated drinks, on all school campuses across the country.¹⁶ The Ministry of Food and Drug Safety (MFDS) advocated for this ban, hoping that students facing intense academic pressure will adopt healthier sleeping and eating habits. South Korean consumption of caffeine has already surpassed all other Asian

Comm. Nat'l People's Cong.), Dec. 29, 2017 (China); see also Zijun Zhao, *Recent Legislative Progress on Healthcare Law in China: Establishing “Right to Health” as a Basic Right*, OXFORD HUMAN RIGHTS HUB (May 18, 2018), <http://ohrh.law.ox.ac.uk/recent-legislative-progress-on-healthcare-law-in-china-establishing-right-to-health-as-a-basic-right/>.

12. See Kenko Zoshin-ho [Health Promotion Act], Law No. 78 of 2018, art. 1, para. 1 (Japan).

13. *Id.*

14. *Id.*

15. See generally Perintah Fi (Perubatan), [Fees (Medical) (Amendment)] 2017 Order, P.U. (A) 47 (Malay.).

16. Eolin-i sigsaenghwal-anjeongwanli teugbyeolbeob [Special Act on Safety of Children's Eating and Living Safety], Act. No. 14263, May 29, 2016, amended by Act. No. 15485, Mar. 13, 2018, (S. Kor.).

countries and continues to increase. Despite being aware of the risks of excessive caffeine intake, according to a MFDS conducted study, more than half of South Korean students consume some sort of caffeinated beverage in an effort to stay awake longer and study more arduously. The law became effective on September 14 and attempts to combat the increasing number of students seeking treatment for caffeine related heart palpitations. Students have also been complaining of caffeine related dizziness, tachycardia, sleep disorders, and debilitating nervousness as other symptoms; however, the MFDS has also linked the increase rate of childhood obesity and diabetes to the increased consumption of sugary and dairy based caffeinated drinks. Earlier this year, South Korea also banned the sale of energy drinks in schools.

In another effort to increase awareness and public health in the youth population, South Korea also prohibited advertisement for fast food restaurants, sugary snacks, and high caffeine beverages during the times that most children's programs air. South Korean childhood obesity has increased more than 13% in the last six years, catalyzing the strict legislative response.

III. Caribbean Updates

A. CAYMAN ISLANDS

On November 14, the Cayman Islands Legislative Assembly voted to amend the Penal Code and introduce into law the Stalking (Civil Jurisdiction) Bill, which clarifies a legal lacuna in this jurisdiction and allows the police to analyze legal patterns of behavior which, when combined, can amount to stalking.¹⁷ The new bill allows for a victim of stalking to petition the courts for a protective order barring all forms of communication and interaction with the stalker either on a temporary or permanent basis.¹⁸ In the Cayman Islands, psychiatric harm can amount to the criminal offenses of either actual bodily harm or grievous bodily harm. Clarifying this lacuna makes the stalker criminally liable for any psychiatric or physical harm caused to the stalked individual. Additionally, as they would be legally protected for the first time ever in this jurisdiction, it is likely that this law will decrease the trauma and mental health detriments endured by victims of stalking. Furthermore, these legislative changes are likely to protect the physical health of the stalked individual because imposing upon the stalker a legal bar of communication and interaction with the stalking victim would likely greatly decrease the victim's risk of assault and battery and the associated subsequent injuries. By ratifying these legislations, the Cayman Islands has taken a huge step forward in its peoples' public health.

17. Stalking (Civil Jurisdiction) Bill 2018, at 1 (Cayman Is.).

18. *Id.* at 2.

IV. European Updates

A. AUSTRIA

In the absence of clear guidance from the European Court of Justice, there has been some uncertainty in Austria – and in many EU Member States – on whether, in pharmaceutical product liability cases turning on “failure to warn,” the information and warnings supplied directly to health care professionals are to be taken into account.¹⁹ In its ruling of 18 February 2018, the Austrian Supreme Court confirmed a decision of the Higher Regional Court of Vienna, which clarified that, with prescription-only medication, the task of assessing the risks, deciding on the suitability of this (type of) medication and warning the patient about side effects, all fall primarily upon the physician.²⁰ The court viewed the manufacturer’s package information leaflet as *additional* information provided to the patient at a later date and secondary to the obligatory, critical, information provided by the prescribing physician.²¹

B. GERMANY

In Germany, as in the rest of the EU, advertising for medicinal products is strictly regulated. Prescription-only medicinal products may be promoted only to healthcare professionals qualified to prescribe or supply them (Sec 10 Advertising of Medicines Act, HWG).²² General advertising of medicinal products to the public is entirely prohibited.²³ The preamble to the Directive clarifies that, in order to safeguard public health, information supplied to users should provide ample consumer protection so that medicinal products may be used correctly on the basis of full and comprehensible information (Recital 40); this public interest justifies the restriction of the principle of freedom of expression.

“Advertising,” is defined in the Directive as “any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products” and is interpreted very broadly by the German and European courts. The term encompasses dissemination on the internet of information relating to medicinal products (ECJ C-421/07, *Damgaard*, in which information was

19. See generally Council Directive 85/374, 1985 O.J. (L 210) 29 (EEC).

20. Oberster Gerichtshof [OGH] [Supreme Court] Feb. 18, 2018, 10 Ob 8/18a, https://rdb.manz.at/document/ris.just.JJT_20180220_OGH0002_0100OB00008_18A0000_000.

21. For more information see generally Katrin Hanschitz, *Austria: “Failure To Warn” In Pharmaceutical Product Liability Cases*, MONDAQ (Nov. 19, 2018), <http://www.mondaq.com/Austria/x/756214/food+drugs+law/Failure+To+Warn+In+Pharmaceutical+Product+Liability+Cases>.

22. Gesetz über die Werbung auf dem Gebiete des Heilwesens [Act on Advertising in the Field of Health Law], Dec. 20, 2016 (Ger.).

23. See Directive 2001/83, of the European Parliament and of the Council of Nov. 6 2001 on the Community Code Relating to Medicinal Products for Human Use, Art. 86 et seq., 2001 O.J. (L 311).

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published by a journalist on his website).” If the message is designed to promote the prescription, supply, sale or consumption of medicinal products, it is advertising for the purposes of that directive. But material that is purely informative, without promotional intent, is not covered by the provisions of that directive relating to advertising of medicinal products.”²⁴

In a recent decision handed down by the Higher Regional Court of Cologne,²⁵ the court was called upon to decide whether public messages pertaining to a prescription-only veterinary product may be permissible if made in reaction to ongoing negative discussions about the product that appeared on social media. While the decision pertains to a veterinary drug, it is more broadly relevant for two reasons. First, under German law, as is reflective of the law in a number of EU member states, veterinary products are subject to the same advertising restrictions as human medicinal products. Secondly, this recent decision further develops the line of jurisprudence introduced by the German Supreme Court in 2009,²⁶ which allowed Pfizer’s public statements in reaction to public discussions on pricing of its (human medicinal) product “Sortis.” Until the European Court of Justice is called upon to address the questions of whether and to what extent manufacturers may make public statements in reaction to negative media, a clear and well-reasoned line of case law in a Member State may help to establish a consistent body of jurisprudence within the EU and provide manufacturers with much-welcome guidance.

In this case, the Appeal Court decided that, when hit by a media “shitstorm” (original phraseology unedited), a pharmaceutical manufacturer may defend its product in publicly disseminated materials. The defendant’s product in the subject case had been massively maligned in social media with incorrect and substantiated allegations about its side effects. In response, the defendant posted several items on Facebook with links to its homepage for “further information.” The competitor’s application for a preliminary injunction was successful in the court of first instance but was largely overturned by the Court of Appeal. The upper court applied an overall assessment of the parties’ constitutional rights, in particular the right to free speech and the freedom to practice a profession on the one hand and the public interests underlying the advertising prohibition on the other hand. To the extent the manufacturer’s Facebook posts and linked information specifically addressed the social media discussions and were, for readers, clearly a response to these, they were held to be permissible, even if the

24. Bundesgerichtshof [BGH][Federal Court of Justice] May 5, 2011, ECJ C-316/09 (Ger.) (discussing the Medicinal products for human use - Directive 2001/83/EC - Prohibition on the advertising to the general public of medicinal products available only on prescription - Definition of ‘advertising’ - Information communicated to the competent authority - Information accessible on the internet, which allowed the literal reproduction of the package leaflet on the manufacturer’s website).

25. Oberlandesgericht Köln [Higher Regional Court of Cologne] Jan. 12, 2018, 6 U 92/17 (Ger.).

26. Bundesgerichtshof [BGH][Federal Court of Justice] March 26, 2009, I Zr 213/06 (Ger.).

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content would otherwise be deemed promotional. To the extent the Facebook post claimed the drug was “safe and effective” and did not sufficiently clearly address the public discussion, the injunction was confirmed.²⁷

C. NORWAY

At the beginning of this year, Norway, which has one of the highest drug overdose mortality rates in Europe, implemented law that no longer punishes individuals suffering from drug addiction, but instead provides help and treatment.²⁸ By doing so, Norway decriminalized drugs and redirected state funding and resources to instead combat the increasing public health risk of drug addiction in the Norwegian jurisdiction. The new legislation focuses on decriminalizing only non-violent drug related offences and promotes investment in treatment programs, after-care facilities, and drug substitution therapies. With the interests of public health at its heart, the aim of this new law is to step away from the relatively ineffective punitive approach to those charged with non-violent drug offences by the criminal justice system and instead offer a curative model. By extending a hand through medical treatment, the Norwegian government hopes to influence societal change with the ratification of this new law. Backed by the majority of the Storting, the Norwegian Parliament, Norway moved to decriminalize the offences of possession, dealing, using illicit drugs. Furthermore, this legislation will test the provision of free heroine, coupled with state regulated education and prevention programs, as a curative therapy for those addicted to heroin.

The Norwegian Parliament’s ultimate goal is to rid drug users of their drug dependency. Policy makers do not advocate the legalization of drugs but, instead, hope to help those struggling with drug use return to a healthy lifestyle. Through these controversial measures, Norway joins Switzerland, the Netherlands, and Denmark in attempting to better the lives of its citizens suffering from drug addiction.

D. UKRAINE

Medical reform is the aim of a new health care financing system in Ukraine. The System will reorganize publicly owned medical institutions, which will obtain more operational and financial autonomy; transition from the mechanism of financing of publicly owned clinics’ infrastructure, payment for the number of hospital beds available at the clinic to

27. For more information, *see generally* Knoetzl, European Union: Are Pharmaceutical Manufacturers Permitted To Publicly Respond To Negative Media?, *mondaq* (Nov. 22, 2018), <http://www.mondaq.com/germany/x/757228/Social+Media/Are+Pharmaceutical+Manufacturers+Permitted+To+Publicly+Respond+To+Negative+Media>.

28. Forskrift om narkotikaprogram med domstolskontroll [Regulations on drug program with judicial review] (Justis-og beredskapsdepartementet) [FOR] (2017) (Nor.).

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reimbursement of cost of medical services actually provided to patients; and procurement of standardized medical services under unified tariffs.²⁹

Private clinics and individual doctors have concluded agreements with National Health Service of Ukraine, a newly created authority playing the key role in the process of financing of healthcare institutions. As a result, the clinics and doctors will receive access to the public funds along with publicly owned medical institutions. The access to public funds should lead to increase of competition, as well as improve the quality of medical services in Ukraine.

Another key element of the reform is the *National essential medicines list (NEML)*. Starting in 2018, medicines included into the NEML have a priority in terms of public procurements. At first, publicly owned medical institutions must cover 100% of their need in medicines included into NEML, and only then may other medicines be procured.

NEML will also play the key role in reimbursement and provision of inpatient medical care, as only medicines included into the NEML will be selected for reimbursement and will be covered for inpatient use.

Additionally, a nation-wide E-health system is currently being implemented to ensure operation of unified and updated registries of patients, clinics, doctors, and medicines in electronic form.

Furthermore, the reform calls for individual licensing of doctors. It is expected that starting in 2020, doctors will have to obtain an individual license for medical practice from the Licensing Council of the Ministry of Health. The Licensing Council of the Ministry of Health consists of 30 doctors, including foreign experts, and is authorized to consider patients' complaints on the doctors' actions, as well as to impose sanctions such as cancelling licenses, or suspending a doctor from practicing. This measure is expected to raise the level of doctors' responsibility when treating the patients.

Finally, the reform requires opening of the transplantology market for private clinics. Currently, only publicly owned healthcare institutions may operate in the sphere of transplantology. New legislation entering into force in 2019 opens the transplantology market to private clinics. Before the Law comes into force, the Cabinet of Ministers should review the Licensing Terms for Conducting Medical Practice in terms of requirements for the material and technical base of the clinics, which will carry out transplantation activities.

29. See generally Про державні фінансові гарантії медичного обслуговування населення [On State Financial Guarantees of Public Health Care], Відомості Верховної Ради [ВВР] [Bulletin of the Verkhovna Rada] No. 2168-VIII dd. Oct. 19, 2017 (Ukr.).

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E. UNITED KINGDOM

In Northern Ireland, the High Court is reviewing a case to have the near-blanket ban on abortion declared unlawful.³⁰ Abortions in Northern Ireland are illegal in all but exceptional medical and mental health circumstances. This comes after the Supreme Court had narrowly dismissed a legal challenge by the Northern Ireland Human Rights Commission regarding the ban, determining that it had no jurisdiction because there was no actual or potential victim of an unlawful act involved in the challenge.

The First Global Ministerial Mental Health Summit took place in the United Kingdom.³¹ It was a widespread event aimed at raising awareness and discussing the future of mental health worldwide, but was criticized for a lack, or very little, involvement of users. In addition, the United Kingdom wanted to present itself as a 'leader' on mental health, but according to the concluding observations from the United Nations Convention on the Rights of Persons with Disabilities (CRPD) Committee, the country is far from being a good example.³² At the summit, the Lancet Commission on Global Mental Health and Sustainable Development launched a report on global mental health in the context of the 2030 Sustainable Development Goals (SDGs), consisting of seventeen universal goals to achieve a better and more sustainable future for all.³³ SDG 3, specifically, seeks to ensure "healthy lives and promote well-being for all at all ages."³⁴ Certain organizations, including Mental Health Europe (MHE), published a critical response to this report.³⁵ MHE's criticism stems from the idea that the Commission's report focuses on the biomedical viewpoint of mental health, instead of recognizing both the psychosocial model of mental health and community services.³⁶ MHE goes on in the report to criticize the of the role of inequalities, violence, and poverty as determinants of mental health.³⁷ MHE argues that these factors need to be addressed in order to overcome both social and structural determinants of mental health.³⁸ Furthermore, MHE

30. See *In the matter of an application by the Northern Ireland Human Rights Commission for Judicial Review* [2018] UKSC 27 (appeal taken from NI).

31. COMMONWEALTH FUND INTERNATIONAL, *World's First Global Ministerial Mental Health Summit*, Commonwealth Fund International Health News Brief: 2019, No. 2 (Feb. 26, 2019), <https://www.commonwealthfund.org/publications/newsletter-article/2019/feb/worlds-first-global-ministerial-mental-health-summit>, at 1.

32. See Jessica Hullinger, *The good, the bad, and the ugly of England's universal health care system*, THE WEEK (Dec. 26, 2018), <https://theweek.com/articles/789287/good-bad-ugly-englands-universal-healthcare-system>.

33. See G.A. Res. 70/1 *Transforming our world: the 2030 Agenda for Sustainable Development* U.N. Doc. A/RES/70/1 (Oct. 21, 2015).

34. *Id.* at 14.

35. See generally MENTAL HEALTH EUROPE, *MHE Response to the Lancet Commission Report on Global Mental Health and Sustainable Development*, <https://mhe-sme.org/mhe-response-to-the-lancet-report-gmh/> (last visited Dec. 6, 2018).

36. *Id.* ¶ 7.

37. *Id.* ¶ 10.

38. *Id.*

argues that the CRPD was not acknowledged strongly enough within the report.³⁹ As the EU, along with most of the world, has ratified the CRPD, there should be a stronger commitment to promote and implement the rights protected within this internationally binding treaty.

F. WORLD HEALTH ORGANIZATION

The World Health Organization (WHO) removed being transgender from the latest edition of the International Classification of Diseases, which lists both mental and physical disorders. Gender incongruence will now be classified as a sexual health condition.⁴⁰ This is a sign of progress and a move away from stigma in the community, promoting inclusivity and acceptance.

However, “gaming disorders” has been added to the International Classification of Diseases.⁴¹ The disorder is characterized by “impaired control” with increasing priority given to gaming and “escalation” despite “negative consequences.” It includes only a clinic description and not prevention or treatment options. Excessive use of the Internet, computers, and other electronic devices have led to health problems.

V. Middle East Updates

A. IRAN

In November, Iranian officials passed a law punishing cosmetic surgeons and their patients who undergo eccentric cosmetic surgery procedures.⁴² The Judicial and Legal Committee of the Islamic Consultative Assembly said “unconventional procedures”⁴³ that grossly alter a person’s appearance, like the current Iranian trend to undergo procedures for “cat eyes” or “donkey ears,”⁴⁴ would be held to have committed offenses against the public moral, a violation of Article 638 of the Islamic Penal Code of Iran. Those convicted of this offense will be punished by either imprisonment from ten to sixty days or subject to seventy-four lashes. This law is in response to what has been described as epidemic plastic surgery. In Iran, a person is seven times more likely to have undergone plastic surgery than in the United States. Rhinoplasties have become so commonplace that a Johns Hopkins study was conducted in conjunction with the Rhinology Research Society of Iran. The study found that each Iranian plastic surgeon performs almost

39. *Id.* ¶ 11.

40. *Gender Incongruence*, ICD-11 for Mortality and Morbidity Statistics, <https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2fcd%2fent%2f411470068>, (last visited Mar. 23, 2019).

41. *Id.* See also *Gaming Disorder*, WORLD HEALTH ORGANIZATION, <https://www.who.int/features/qa/gaming-disorder/en/> (Sept. 2018) for more information.

42. See QANOON-E JAZAI-E ELSAMI [ISLAMIC PENAL CODE] [1990], art. 638 (Iran).

43. Michael Cook, *Iran promises the lash for unconventional cosmetic surgery*, BIOEDGE (Nov. 17, 2018), <https://www.bioedge.org/bioethics/iran-promises-the-lash-for-unconventional-cosmetic-surgery/12899>, ¶ 2.

44. *Id.*

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200 rhinoplasties every year. This law also hopes to combat procedures performed by unlicensed surgeons. Unlicensed surgeons are in demand due to the relatively high cost of plastic surgery in Iran where the average income is a few hundred dollars a month. Although seemingly nonsensical, this law hopes to decrease the number of plastic surgery “horror stories” and regulate an industry, which has become the center point of controversy and malpractice.

B. REPUBLIC OF LEBANON

The Lebanese Medical Association for Sexual Health (LebMASH), a non-governmental organization comprising of mental health professionals, in conjunction with the Lebanese Psychiatric Society, and the Lebanese Psychological Association, publicly denounced the use of conversion therapy on members of the LGBTQ community. LebMASH launched a campaign entitled “Homosexuality is Not a Disease” (HINAD) following multiple endorsements for conversion therapy by local physicians, some of whom advocated the use of shock therapy to reverse homosexual tendencies and perpetuate the belief that homosexuality is a choice or mental illness. This public denunciation follows a 2018 three-judge bench appeals court decision not to prosecute nine homosexual and transgender individuals under Article 534 of the Lebanese Penal Code that states “any sexual intercourse contrary to the order of nature is punishable by up to one year of prison.”⁴⁵ The court questioned the current, strict interpretation of the ninety-eight year old law and found it was discriminatory and against the human rights of individuals in 2018. The court confirmed the lower court’s decision preventing the prosecution of those accused of violating the Penal Code.⁴⁶ Parliament has left the interpretation of Article 534 to the courts, creating an uncertainty that rests when standing bench trial. The Court of Criminal Appeal’s decision and the respected medical bodies’ public condemnation is a modernizing step in the areas of public and mental health which has already affected the nation’s policy and is suggestive of change in the Lebanese attitude toward mental health.⁴⁷

C. SUDAN

In July 2018, Sudanese officials from the Federal Ministry of Health, Ministry of Animal Resources and Fisheries, and Ministry of Agriculture and Forestry in conjunction with the WHO and the United Nations (UN)

45. Legislative Decree 340 of 3 Jan. 1943 (Leb.)

46. Maʿkamat al-Istiʿnaf [Istiʿnaf] [Court of Appeals], Mount Lebanon, 12 July 2018, MAJALLAT AL-ʿADL (ʿADL OR AL-ʿADL), 2018 (Leb.), <http://www.legal-agenda.com/uploads/%D8%A7%D9%84%D8%AD%D9%83%D9%85%202018.pdf>.

47. See generally, *Lebanon: Same-Sex Relations Not Illegal*, Human Rights Watch (July 19, 2019, 12:00 a.m.), <https://www.hrw.org/news/2018/07/19/lebanon-same-sex-relations-not-illegal>.

formulated a national plan to combat antimicrobial resistance (AMR).⁴⁸ The plan is a product of a three-year collaboration where the Federal Ministry of Health worked closely with the WHO and the UN to implement this plan which will become the mainstay in combatting what could become a public health crisis. AMR is a public health threat and has risen to dangerously high levels, undermining the efforts of medical professionals in combatting commonplace infections. The danger of AMR is especially commonplace in developing countries where the population lacks a proper education on the use of antimicrobial agents such as antibiotics. The national plan includes, in its efforts, five objectives it hopes to accomplish. These efforts are education and training aimed at helping the population understand AMR and its associated risks, obtaining greater empirical data through surveillance and research, instilling effective sanitation, hygiene, and prevention measures to reduce the incidence of infection, optimizing the use of antimicrobial medicines in both areas of human and veterinary medicine, and economic support aimed at increasing investment in new medicines, diagnostic tools, vaccines, and other interventions. Working in union with the WHO and the UN, Khartoum hopes to effectively implement the guidelines outlined by the plan with international support.

VI. Northern American Updates

A. CANADA

Canada was the second nation and first G7 nation to legalize marijuana through its Bill C-45, also known as the Cannabis Act.⁴⁹ It aims to keep cannabis out of the hands of youth and keep the profits out of the hands of criminals. Along with this Act, changes to impaired driving laws addressing the repercussions for driving under the influence of cannabis have also been implemented.

B. UNITED STATES

Legalized cannabis use in Oregon is making it harder for those who have a prescription for medical marijuana to obtain the product needed. There are only three medical-only processors left in the entire state of Oregon. In addition, Oregon is currently down to eight medical dispensaries, from 420 dispensaries in 2016, because many of the processors have shifted towards processing recreational product. Sick people, for which the law was originally enacted, are now having to turn to the black market because the recreational dispensaries cap the amount allowed in recreational products, which is far under what is needed for medicinal use. Additionally, these

⁴⁸ *Ministry of Health of Sudan, with WHO and partners, launch AMR national action plan*, WHO, ¶ 1 (July 22, 2018), <http://www.emro.who.int/sdn/sudan-news/ministry-of-health-of-sudan-with-who-and-partners-launch-amr-national-action-plan.html>.

⁴⁹ See Cannabis Act 2018, S.C. 2018, c. 16 (Can.).

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recreational products are quite expensive, leaving those who need the cannabis for medical purposes in a difficult position.

The Federal Circuit cleared up the split decisions from lower courts and found that Congress lawfully withheld funding for the Affordable Care Act (“ACA”) “risk corridor program,” essentially denying health insurance companies billions of dollars in ACA funding. This program was structured to shift money from profitable ACA insurers to money-losing ACA insurers. As profits did not cover losses, Congress did not have to pay the \$12 billion.⁵⁰

The U.S. Supreme Court denied review of the case between Kindred Hospitals East LLC and the Estate of Marianne Klemish, affirming the Florida Appellate Court, which found a patient arbitration agreement unenforceable due to a conflict with state law.⁵¹ The healthcare provider warned that this ruling could render every health care arbitration agreement in Florida unenforceable, but the court found that the healthcare provider’s selective use of Florida’s Medical Malpractice Act in the agreement favoring health care provider and keeping out language favorable to the patient created an invalid agreement.

In California, the superior court overturned a 2016 state law that allows doctors to prescribe lethal drugs to terminally ill adult patients, known as The End of Life Option Act.⁵² But the decision to overturn the Act was stayed, reinstating the Act while litigation is ongoing. The American Academy of Medical Ethics argued that the Act’s purpose was not to give medical aid to the dying. Since the Act’s passage, approximately 504 California adults have received life-ending drugs from their doctors.

The United States surprised the world at the World Health Assembly when they threatened trade restrictions and the removal of military aid in Ecuador if the Ecuadorean government did not drop the Breastfeeding Resolution.⁵³ That Resolution said that mother’s milk is the healthiest for children and countries should strive to limit the inaccurate or misleading marketing of breast milk substitutes.⁵⁴ The United States Department of Health and Human Services wanted to remove the language regarding governments’ duty to “protect, promote and support breast-feeding” and to restrict promotion of food products that had harmful effects on young children. In the end, the final resolution stayed intact. However, in this

50. See *Land of Lincoln Mut. Health Ins. Co. v. U.S.*, 892 F.3d 1184, 1185-86 (Fed. Cir. 2018); *Moda Health Plan Inc. v. U.S.*, 908 F.3d 738, 740 (Fed. Cir. 2018).

51. *Klemish v. Villacastin*, 216 So. 3d 14, 17 (Fla. App. 2016), *cert. denied*, 138 S. Ct. 645 (2018).

52. See generally *People ex rel. Becerra v. Superior Ct.*, 240 Cal. Rptr. 3d 250, (Cal. Ct. App. 2018).

53. Andrew Jacobs, *Opposition to Breast-Feeding Resolution by U.S. Stuns World Health Officials*, N.Y. TIMES (July 8, 2018), <https://www.nytimes.com/2018/07/08/health/world-health-breastfeeding-ecuador-trump.html>, ¶ 3.

54. See WHO Res. EB142/22, Exec. Board 142d Sess. (Jan. 2, 2018).

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same World Health Assembly, the United States also removed statements from documents supporting soda taxes in countries with high obesity rates.

The current U.S. immigration policies are making it more difficult for foreign doctors to continue to work in the U.S. This stems from the “Buy America, Hire America Executive Order.”⁵⁵ Doctors who were already confirmed for visas in past years are being rejected after presenting USCIS with the same information they had in past years. Approximately 25 percent of foreign medical residents rely on H-1B visas. Furthermore, about 8,000 doctors were from countries included in the original travel ban. These visa restrictions are making it more difficult for healthcare facilities to hire foreign doctors because there is no guarantee that they will get the visa even after the facility has paid for it. These restrictions may incline foreign-trained doctors to go elsewhere, adding to the projected 40,800-105,000 shortage of doctors.

The Mexico City policy or global “gag rule,” rebranded as the Protecting Life in Global Health Assistance by the Trump Administration, was aimed at reducing the number of abortions by blocking U.S. federal funding for NGOs that provide abortion counselling or referrals, advocate for decriminalizing abortion, or expand abortion services. But certain communities, like Kiberia in Africa, are reliant on international donors for support, contraceptives, and family planning options. Blocking this funding takes away \$8.8 billion in U.S. global health assistance and, although aimed at lowering abortions, studies have found that where this policy is in place, women were up to 2.73 times more likely to get abortions than in countries without this policy. Without the option to get a medically authorized abortion, the women get botched abortions, which are more affordable to them, but end up costing much more in medical treatment than a medically authorized abortion would.

The “gag rule” affects U.S. citizens as well. President Trump also has plans to cut Planned Parenthood from the federal family planning program, Title X in the Public Health Service Act. The program provides wellness exams and comprehensive contraceptive services, including screenings for cancer and STDs. Planned Parenthood cares for more than 40% of the federal family planning program’s 4 million patients. The Office of Management and Budget would require any facility that receives federal family planning funds to be physically separate from those that perform abortion, eliminate requirement that women be counseled on their full range of reproductive options, and ban abortion referrals. Consequences of this would be widespread, but would affect remote areas most where Planned Parenthood is the only provider that stocks all methods of birth control.

The U.S. Department of Health and Human Services is considering regulatory changes to a rule issued by President Obama that prevented discrimination against transgender people in the Affordable Care Act

55. Exec. Order No. 13,788, 82 Fed. Reg. 18,837 (April 21, 2017), sec. 2(b).

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(ACA).⁵⁶ The Act affected all providers and insurers that received any federal funding and forbid any discrimination based on “gender identity” and “stereotypical notions” about gender. The proposed changes create barriers to healthcare for many LGBT people. The proposed rule broadens existing religious exemptions in healthcare law, allowing insurers, hospitals, and providers to deny service or treatment to patients based on their own religious beliefs. This was brought to the forefront in a decision by the district court Judge O’Connor, who temporarily stopped enforcement of the protections for transgendered patients based on the idea that discrimination based on gender was clearly outlawed by the law but transgender status was not.⁵⁷ This decision follows Judge O’Connor’s previous decision finding that the ACA is lawful and does not contradict the Constitution.⁵⁸

VII. South American Updates

A. ARGENTINE REPUBLIC

Despite strong public support, passing through the lower house (129-125), and the promise of President Mauricio Macri to sign it, the Argentine senate rejected a bill to legalize abortion in the first 14 weeks.⁵⁹ This bill would have ceased to make abortion illegal, but after fifteen hours of debating, the senate voted against the bill thirty-eight to thirty-one.⁶⁰ With the rejected bill, abortion remains legal only in the cases of rape or if the woman’s life is in danger. This is the sixth bill in the last thirteen years to attempt to decriminalize abortion. It is suspected that the Catholic Church’s opposition of the bill was a main factor in its failure. There are 500,000 estimated abortions each year in Argentina, but as it is illegal, there are no official records. The Health Ministry revealed that in 2016, 43 deaths were caused by abortions.

56. See 42 U.S.C. § 18116; Robert Pear, *Trump Plan Would Cut Back Health Care Protection for Transgender People*, N.Y. TIMES (April 21, 2018), <https://www.nytimes.com/2018/04/21/us/politics/trump-transgender-health-care.html>, ¶ 1.

57. *Texas v. United States*, 201 F. Supp. 3d 810, 836 (N.D. Tex. 2016).

58. *Texas v. United States*, 300 F. Supp. 3d 810, (N.D. Tex. 2018).

59. See generally Daniel Politi and Ernesto Londoño, *Argentina’s Senate Narrowly Rejects Legalizing Abortion*, N.Y. TIMES (Aug. 9, 2018), <https://www.nytimes.com/2018/08/09/world/americas/argentina-abortion-vote.html>; also see Emily Stuart, *Argentina’s historic vote to decriminalize abortion, explained*, VOX (Aug. 8, 2018 4:14 PM), <https://www.vox.com/2018/6/13/17460824/argentina-abortion-bill-ni-una-menos>.

60. Proyecto de Ley de Interrupción Voluntaria del Embarazo en Argentina Expte. [Draft Law of Voluntary Interruption of Pregnancy in Argentina] 230-D-2018 (Arg.).

B. FEDERATIVE REPUBLIC OF BRAZIL

A Personal Data Protection Law was enacted in 2018.⁶¹ This law protects a person's fundamental rights of freedom, privacy, and free development of personality as their personal data is processed. Processing of personal data may only be carried out with the consent of the holder and is limited to certain uses, including for the protection of health, in a procedure carried out by health professionals or health entities. This consent must be provided in writing or in other means, which demonstrates the expression of will of the holder.

C. CHILE

At the end of August, the newly elected Chilean President Sebastián Piñera and Chilean Health Minister Emilio Santelices thwarted an attempt by Gilead, the manufacturer of an expensive Hepatitis C drug called Sovaldi, and the International Federation of Pharmaceutical Manufacturers (IFPM) to overturn Resolution 399/2018.⁶² Resolution 399/2018 allowed for the Ministry of Health, in an effort to make Sovaldi more affordable, to adopt measures to obtain compulsory licenses for Hepatitis C drugs. Resolution 399/2018 was enacted to ensure that those infected with Hepatitis C would be able to access this treatment course previously barred due to its high price of 36,000 USD per patient. Up until this past year, the drug was excluded from being publicly funded. Gilead and IFPM's efforts included domestic and international lobbying as well as arguing that Resolution 399/2018 did not have legal merit due to the government's consideration of the drug's price in its decision to include Sovaldi in Resolution 399/2018. The Chilean government argued that Sovaldi was justified in its inclusion of Resolution 399/2018 because of "the freedoms granted by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as well as in the Doha Declaration on TRIPS and Public Health."⁶³ Ultimately, Resolution 399/2018 was upheld and negotiations are underway between Gilead and the Chilean government to grant the government a voluntary license in order to avoid a legal precedent risking further loss of income in the region. This decision grants Chile the right to legally put life and health of its people first and ignore the lobbying and political pressures of big corporations.

61. Lei Geral de Proteção de Dados [LGPD] [Personal Data Protection Law], Law 13,709/2018 (translated by Ronaldo Lemos, Daniel Douek, Sofia Lima Franco, Ramon Alberto dos Santos, and Natalia Langenegger) (Braz.), art. 1.

62. See generally Res. 399/2018 to Require the Ministry of Health to Adopt Measures to Obtain Compulsory License's for Hepatitis C Drugs (Sept. 1, 2018) (Chile).

63. Luis Villarroel, *Inside Views: New Health Ministry Of Chile Reaffirms Path to Compulsory Licence For Hepatitis C Drugs*, INTELLECTUAL PROPERTY WATCH, ¶ 5 (April 9, 2018) <https://www.ip-watch.org/2018/09/04/new-health-ministry-chile-reaffirms-path-compulsory-licence-hepatitis-c-drugs/>.