

COMBATTING UNLICENSED STEM CELL INTERVENTIONS THROUGH TRUTHFUL ADVERTISING LAW: A SURVEY OF REGULATORY TRENDS

*Ubaka Ogbogu**

This paper proposes the adoption and application of consumer protection legal frameworks, specifically truthful advertising laws and enforcement strategies, as a means of combatting the proliferation of clinics offering and providing unproven and unlicensed stem cell interventions to the public. The paper provides a very preliminary and generalized overview of truthful advertising laws in several countries implicated in the marketing and provision of these interventions. The paper aims to identify main trends and to show that truthful advertising laws, compared to other forms of regulation, can provide strong national and extra-national regulation to counter the marketing and pro-

Cet article propose l'adoption et l'application de cadres juridiques visant la protection des consommateurs, en particulier des lois en matière de publicité mensongère et de leurs stratégies d'application, afin de lutter contre la prolifération de cliniques offrant et fournissant au public des interventions non prouvées et non autorisées utilisant des cellules souches. L'article fournit un aperçu très préliminaire et généralisé des lois en matière de publicité mensongère dans plusieurs pays impliqués dans la commercialisation et la prestation de ces interventions. L'article vise à identifier les principales tendances et à démontrer que les lois en matière de publicité mensongère, comparative-

* Ubaka Ogbogu, Assistant Professor and Katz Research Fellow in Health Law and Science Policy, Faculties of Law and Pharmacy & Pharmaceutical Sciences, University of Alberta. The author would like to thank Michael Ginevsky and Carina Chiu for research assistance. The author is also grateful to the anonymous peer reviewers for their helpful comments and suggestions. The preparation of this paper was made possible through grants from the Canadian Stem Cell Network, the Canadian Stem Cell Foundation, and the University of Alberta Endowment Fund for the Future Advancement of Scholarship. Lastly, the author would like to thank Robyn Hyde-Lay, Candice Kozak, and his colleagues at the Health Law Institute for general research and collegial support.

© Ubaka Ogbogu 2016

Citation: Ubaka Ogbogu, "Combating Unlicensed Stem Cell Interventions through Truthful Advertising Law: A Survey of Regulatory Trends" (2016) 9:2 McGill JL & Health 311.

Référence : Ubaka Ogbogu, « Combating Unlicensed Stem Cell Interventions through Truthful Advertising Law: A Survey of Regulatory Trends » (2016) 9 : 2 RD & santé McGill 311.

vision of unproven and unlicensed stem cell interventions. This is mainly because truthful advertising laws and enforcement systems impose legally enforceable obligations on clinics operating within national boundaries, and can also be effectively enforced against extra-territorial clinics and providers through existing bilateral, regional, and international consumer protection enforcement networks.

ment à d'autres formes de réglementation, peuvent fournir une forte réglementation nationale et extranationale pour contrer la commercialisation et la prestation d'interventions non prouvées et non autorisées utilisant des cellules souches. Cela s'explique principalement par le fait que les lois en matière de publicité mensongère et leurs stratégies d'application imposent des obligations juridiquement contraignantes aux cliniques actives à l'intérieur de leurs frontières et peuvent également être appliqués de façon efficace contre les cliniques et les prestataires de services extraterritoriaux par le biais de réseaux de protection des consommateurs bilatéraux, régionaux et internationaux.

INTRODUCTION	313
I. REGULATORY APPROACHES	318
A. <i>Direct regulation of false, misleading, or deceptive advertisements of stem cells and cell-based interventions</i>	319
B. <i>Regulation of advertisements relating to medicinal products and medical treatments</i>	322
C. <i>Online representations</i>	327
II. ENFORCEMENT MECHANISMS	328
III. A MODEL OF CO-OPERATIVE ENFORCEMENT: THE INTERNATIONAL CONSUMER PROTECTION AND ENFORCEMENT NETWORK	332
CONCLUSION	334

INTRODUCTION

It has been almost a decade since the publication of the first studies on “stem cell tourism,” a term that refers to the phenomenon whereby clinics market and provide unproven and unlicensed stem cell interventions to medical tourists or offshore patients.¹ Since then, the phenomenon, which was limited to a handful of clinics mostly in Asia, Eastern Europe, and South America,² has expanded into a global market.³ In April 2015, the *Boston Globe* reported that as many as 170 clinics were operating in the United States.⁴ Clinics offering unproven and unlicensed stem cell interventions are distinguishable from those that provide approved stem cell treatments such as hematopoietic stem cell transplants from bone marrow, umbilical cord blood, and peripheral blood for treatment of solid tumour cancers, blood-based cancers, and other blood disorders.⁵ It should also be noted that there

¹ Darren Lau et al, “Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine” (2008) 3:6 Cell Stem Cell 591; Kirsten A Ryan et al, “Tracking the Rise of Stem Cell Tourism” (2010) 5:1 Regen Med 27; Aaron D Levine, “Stem Cell Tourism: Assessing the State of Knowledge” (2010) 7:2 SCRIPTed 274.

² Lau et al, *supra* note 1 at 591; Ubaka Ogbogu, Christen Rachul & Timothy Caulfield, “Reassessing Direct-to-Consumer Portrayals of Unproven Stem Cell Therapies: Is It Getting Better?” (2013) 8:3 Regen Med 361.

³ See generally Sorapop Kiatpongsan & Douglas Sipp, “Monitoring and Regulating Offshore Stem Cell Clinics” (2009) 323:5921 Science at 1564 (on stem cell tourism); Douglas Sipp, “The Unregulated Commercialization of Stem Cell Treatments: A Global Perspective” (2011) 5:4 Front Med 348 at 349 (on the rapid international growth of the unregulated commercialization of stem cell treatments) [Sipp, “Unregulated Commercialization”]; Leigh Turner, “US Stem Cell Clinics, Patient Safety, and the FDA” (2015) 21:5 Trends Mol Med 271 at 271 (on the proliferation of stem cell treatments across the US).

⁴ Matthew Perrone, “With Few Regulations, Stem Cell Clinics Booming”, *The Boston Globe* (18 May 2015), online: <www.bostonglobe.com/business/2015/05/17/stem-cell-wild-west-takes-root-amid-lack-regulation/IeYHoQc4IZF2ysAgWbCT1I/story.html>.

⁵ The Canadian Stem Cell Foundation maintains an authoritative online resource for approved stem cell therapies and ongoing clinical trials of stem cell-based therapies and products. See Canadian Stem Cell Foundation, “Toward Treatments”, online: <www.stemcellfoundation.ca/en/toward-treatments/>. See also Matthew D Li, Harold Atkins & Tania Bubela, “The Global Landscape of Stem Cell Clinical Trials” (2014) 9:1 Regen Med 27.

are ongoing debates in countries such as the US, China, and India regarding clinical uses of autologous stem cells and “national home-keeping” policies that enable local stem cell applications in the “grey area” between dominant international scientific standards and providers of bogus stem cell therapies.⁶

The proliferation of clinics worldwide has increased attendant risks and harms to treatment seekers and patrons. These include severe medical complications following treatment,⁷ death,⁸ financial losses,⁹ and risks associated with lack of proper clinical disclosure and follow-up.¹⁰ The phenomenon

⁶ See Margaret Sleeboom-Faulkner et al, “Comparing National Home-Keeping and the Regulation of Translational Stem Cell Applications: An International Perspective” (2016) 153 Soc Sci Med 240.

⁷ Duangpen Thirabanjasak, Kavirach Tantiwongse & Paul Scott Thorner, “Angiomyeloproliferative Lesions Following Autologous Stem Cell Therapy” (2010) 21:7 J Am Soc Nephrol 1218; Ninette Amariglio et al, “Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient” (2009) 6:2 PLoS Med e1000029; Ferris Jabr, “In the Flesh: The Embedded Dangers of Untested Stem Cell Cosmetics”, *Scientific American* (17 December 2012), online: <<https://www.scientificamerican.com/article/stem-cell-cosmetics/>>; Nick Miller, “Stem Cell Therapy Sees Man ‘Infected’ with Cancer”, *WA Today* (22 November 2009), online: <www.watoday.com.au/national/stem-cell-therapy-sees-man-infected-with-cancer-20091122-itch>.

⁸ David Cyranoski, “Korean Deaths Spark Inquiry” (2010) 468:7323 Nature 485; Robert Mendick & Alasdair Palmer, “Baby Death Scandal at Stem Cell Clinic Which Treats Hundreds of British Patients a Year”, *The Telegraph* (23 October 2010), online: <www.telegraph.co.uk/news/worldnews/europe/germany/8082935/Baby-death-scandal-at-stem-cell-clinic-which-treats-hundreds-of-British-patients-a-year.html>; Gretchen Vogel, “Authorities Shut Controversial German Stem Cell Clinic”, *Science Insider* (10 May 2011), online: <news.sciencemag.org/2011/05/authorities-shut-controversial-german-stem-cell-clinic>.

⁹ Robert Mendick & Patrick Sawyer, “Patients Threaten to Sue Doctor over Exploitative Stem Cell Treatments That Did Not Work”, *The Telegraph* (5 September 2010), online: <www.telegraph.co.uk/news/health/news/7981700/Patients-threaten-to-sue-doctor-over-exploitative-stem-cell-treatments-that-did-not-work.html>; David Cyranoski, “Patients Seek Stem Cell Compensation” (6 July 2012), *Nature Newsblog*, online: <blogs.nature.com/news/2012/07/patients-seek-stem-cell-compensation.html>; Alan Zarembo, “A Desperate Injection of Stem Cells and Hope”, *Los Angeles Times* (20 February 2005), online: <www.latimes.com/nation/la-sci-stemcells20feb20-story.html>.

¹⁰ See David Cyranoski, “Stem Cells in Texas: Cowboy Culture” (2013) 494:7436 Nature 166 at 166, 168.

has also proved an intractable regulatory challenge. Efforts to protect patients have been hindered by a lack of effective domestic and extra-territorial enforcement options¹¹ and “heavy” reliance on “soft law” measures that neither generate legal consequences nor serve as effective deterrents against providers.¹² The emergence of clinics in the US, one of several countries (including Canada, the UK, and Australia) that are generally regarded as target markets for treatment providers,¹³ suggests an alarming normalization of the phenomenon in countries with advanced systems for regulating clinical testing and utilization of medical products and interventions. It also signals that it may be time for these countries to strengthen, intensify, and increase the scope of regulatory measures within their national boundaries.

The suggested change in emphasis is already underway in several countries, where authorities have shut down clinics, instituted criminal proceedings against operators, or enacted bans on clinical uses of unlicensed stem cell interventions.¹⁴ In the US, operators of clinics offering unlicensed

¹¹ Carmel Shalev, “Stem Cell Tourism – A Challenge for Trans-National Governance” (2010) 10:5 *Am J Bioeth* 40; Sipp, “Unregulated Commercialization”, *supra* note 3 at 352.

¹² Leigh G Turner, “Federal Regulatory Oversight of US Clinics Marketing Adipose-Derived Autologous Stem Cell Interventions: Insights from 3 New FDA Draft Guidance Documents”, *Commentary*, (2015) 90:5 *Mayo Clin Proc* 567 [Turner, “Federal Regulatory Oversight”]; Cynthia B Cohen & Peter J Cohen, “International Stem Cell Tourism and the Need for Effective Regulation – Part II: Developing Sound Oversight Measures and Effective Patient Support” (2010) 20:3 *Kennedy Inst Ethics J* 207.

¹³ Ogbogu, Rachul & Caulfield, *supra* note 2 at 366.

¹⁴ Sipp, “Unregulated Commercialization”, *supra* note 3 at 349; Douglas Sipp, “Direct-to-Consumer Stem Cell Marketing and Regulatory Responses” (2013) 2:9 *Stem Cells Transl Med* 638 [Sipp, “Direct-to-Consumer”]; Rory Carroll, “Costa Rican Health Ministry Bans Experimental Stem Cell Treatment”, *The Guardian* (7 June 2010), online: <www.theguardian.com/world/2010/jun/07/costa-rica-stem-cell-treatment>; Susan Carroll, “Feds Bust Alleged Scam to Sell Stem Cells to the Dying”, *Chron* (28 December 2015), online: <www.chron.com/news/houston-texas/article/Feds-bust-alleged-scheme-to-sell-stem-cells-2429836.php>; Tony Sheldon, “Dutch Clinic Is Ordered to Stop Giving Stem Cell Therapy” (2006) 333:7572 *Brit Med J* 770; Tony Sheldon, “Holland Bans Private Stem Cell Clinic” (2007) 334:7583 *Brit Med J* 12; Ned Stafford, “Germany Tightens Law on Stem Cell Treatments” (2009) 339:7 *Brit Med J* 2967; Krisztina Than, “Hungary Detains 4 Over Illegal Stem Cell Treatment”,

stem cell interventions to the public have faced criminal charges,¹⁵ and in a recent case, one operator was sentenced to 78 months in a federal prison on a charge of conspiracy to introduce unapproved drugs into interstate commerce.¹⁶ The US Food and Drug Administration (FDA) has issued a number of guidelines to clarify when human cells, tissues, and cellular and tissue-based products may be used in clinical procedures,¹⁷ and has also successfully obtained a judicial order to close loopholes relied on by treatment providers to evade regulatory scrutiny.¹⁸ However, FDA actions have had limited impact on the growing US market, mainly because the guidelines are not legally enforceable.¹⁹ Moreover, enforcement gains and successes have not prevented new providers from entering the market, nor deterred existing ones, as they simply relocate to more accommodating

Reuters (29 July 2009), online: <www.reuters.com/article/us-hungary-stem-cell-idUSTRE56S4PR20090729>.

¹⁵ S Carroll, *supra* note 14; US, Food and Drug Administration, Consumer Update, “FDA Warns About Stem Cell Claims”, part 3: “Thwarting a Stem Cell Scheme” (6 January 2012), online: <www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm#Thwarting>; US, Federal Bureau of Investigation [FBI], “Illegal Sale of Stem Cell Case Lands Engineer to Federal Prison” (2 May 2014), online: <www.fbi.gov/houston/press-releases/2014/illegal-sale-of-stem-cell-case-lands-engineer-to-federal-prison>; “Stem Cell Fraud: A 60 Minutes Investigation”, *CBS News 60 Minutes* (9 January 2012), online: <www.cbsnews.com/news/stem-cell-fraud-a-60-minutes-investigation-09-01-2012/>.

¹⁶ FBI, *supra* note 15.

¹⁷ Turner, “Federal Regulatory Oversight”, *supra* note 12 at 568; Philippines, Food and Drug Administration, *Advisory No 2013-12 – Public Health Warning Against Receiving Unapproved Stem Cell Preparations in Non-Health Facilities* (15 May 2013), online: <www.fda.gov.ph/advisories/pharmaceutical/70146-fda-advisory-no-2013-012>.

¹⁸ *US v Regenerative Sciences, LLC*, 878 F Supp (2d) 248 (DDC 2012). The order was affirmed on appeal: *US v Regenerative Sciences, LLC*, 741 F (3d) 1314 (DC Cir 2014). See also David Cyranoski, “FDA’s Claims over Stem Cells Upheld” (2012) 488:7409 *Nature* 14; Tamra Lysaght & Alastair V Campbell, “Regulating Autologous Adult Stem Cells: The FDA Steps Up” (2011) 9:5 *Cell Stem Cell* 393; Barbara von Tigerstrom, “The Food and Drug Administration, Regenerative Sciences, and the Regulation of Autologous Stem Cell Therapies” (2011) 66:4 *Food & Drug LJ*, 479; Douglas Sipp & Leigh Turner, “US Regulation of Stem Cells as Medical Products” (2012) 338:6112 *Science* 1296.

¹⁹ Turner, “Federal Regulatory Oversight”, *supra* note 12 at 568, 570.

legal environments while maintaining their ability to reach potential clients through internet-based, direct-to-consumer advertising practices.²⁰ Regulators in the US and other jurisdictions have also had little or no success in monitoring or regulating the online presence of clinics and providers,²¹ despite increasing evidence to suggest that the internet is a primary means of patient or consumer recruitment by clinics and that online claims and representations are largely unsubstantiated and possibly fraudulent.²²

This article proposes the adoption and application of consumer protection legal frameworks, specifically truthful advertising laws and enforcement strategies, as one more tool in the regulatory arsenal. In particular, the article provides a very preliminary and generalized overview of truthful advertising laws in several countries implicated in the marketing and provision of unproven and unlicensed stem cell interventions. The article aims to identify main trends and to show that truthful advertising laws, compared to other forms of regulation, can provide strong national and extra-national regulation to counter the marketing and provision of unproven and unlicensed stem cell interventions. This is mainly because truthful advertising laws and enforcement systems impose legally enforceable obligations on clinics operating within national boundaries and can also be effectively enforced against extra-territorial clinics and providers through existing bilateral, regional, and international consumer protection enforcement networks.

The article begins with a section that explores the two current approaches to truthful advertising regulation that are most applicable to clinics and providers who advertise or market unproven and unlicensed stem cell interventions, namely (1) direct regulation of false, misleading, or deceptive advertisements of stem cell or cell-based interventions and (2) general regulation of advertisements relating to medicinal products and medical treatments. The section highlights some strengths and shortcomings of each approach, and examines how online representations are regulated under

²⁰ Ogbogu, Rachul & Caulfield, *supra* note 2; Sipp, "Unregulated Commercialization", *supra* note 3 at 352; Sipp, "Direct-to-Consumer", *supra* note 14; Bryan A Liang & Tim K Mackey, "Stem Cells, Dot-Com", Commentary, (2012) 4:151 *Sci Transl Med* 151cm9.

²¹ Sipp, "Unregulated Commercialization", *supra* note 3 at 349; David Cyranski, "China's Stem-Cell Rules Go Unheeded" (2012) 484:7393 *Nature* 149.

²² Lau et al, *supra* note 1 at 591; Ogbogu, Rachul & Caulfield, *supra* note 2 at 367; Liang & Mackey, *supra* note 20; Christen Rachul, "'What Have I Got to Lose?': An Analysis of Stem Cell Therapy Patient Blogs" (2011) 20:1 *Health L Rev* 5.

both. The next section examines enforcement mechanisms, particularly the role that regional and international co-operative consumer protection networks can play in addressing false, misleading, or deceptive advertising and marketing of unproven and unlicensed stem cell interventions. The final section deals with the potential enforcement role of the International Consumer Protection and Enforcement Network, the largest and most active global co-operative enforcement initiative.

I. REGULATORY APPROACHES

Many countries around the world regulate truthfulness in advertising, mainly as a component of consumer protection or competition laws and policies. Generally speaking, regulatory approaches are diverse, ranging from “soft” governmental or non-governmental mechanisms that promote voluntary compliance with advertising standards to “hard” approaches based on formal, legally binding rules. Enforcement activities also differ among jurisdictions: some countries rely mainly on a process whereby enforcement actions are initiated by consumer complaints, while others adopt a more direct approach whereby government agencies identify and combat breaches of consumer protection laws. Cross-border governance and enforcement is also a feature of consumer protection regulation in many countries, mainly through participation in regional, international, and co-operative consumer protection networks such as the International Consumer Protection and Enforcement Network, the Organisation for Economic Co-operation and Development (OECD) Committee on Consumer Policy, the European Union Consumer Protection Cooperation Network, the Central American Council of Consumer Protection, the Consumer Forum of East Asia Nations, and the African Consumer Protection Dialogue.²³

²³ See e.g. Debra A Valentine, “Cross-Border Canada/US Cooperation in Investigations and Enforcement Actions” (2000) 26 Can-USLJ 271; Carlos Di Ponio, “Competition, Cooperation, and Conflict: An Assessment of the Extraterritorial Application and Enforcement of Competition Laws in Canada and the United States” (2005) 13:3 MSU-DCL J Intl L & Prac 283 at 283; Fabrizio Cafaggi, “The Great Transformation. Administrative and Judicial Enforcement in Consumer Protection: A Remedial Perspective” (2009) 21:4 Loyola Consumer L Rev 496 at 496, 498–500, 505–07; Competition Bureau, “International Efforts” (5 November 2015), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/h_00128.html>; *Competition Act*, RSC 1985, c C-34, Part III; US, Federal Trade Commission, “Consumer Sentinel Network” (nd), online: <<https://www.ftc.gov/enforcement/consumer-sentinel-network>>; Organisation

Substantive rules and standards addressing truthful advertising are equally diverse. As noted later in this article, truthful advertising laws in most jurisdictions are designed to govern representations made in relation to goods and services broadly rather than specific products or services. However, there are two notable exceptions to this general trend that are especially relevant to the marketing of unproven and unlicensed stem cell interventions. These include laws that directly regulate representations regarding stem cells and cell-based products and therapies, and laws that regulate advertising or representations of health products or treatments.

A. Direct regulation of false, misleading, or deceptive advertisements of stem cells and cell-based interventions

The Philippines is the only country that utilizes the direct regulation approach. Rules and regulations pertaining to the advertising and provision of stem cell therapies and other cell-based therapies and products are contained in an administrative directive issued in March 2013 by the Philippines Department of Health.²⁴ The main objectives of the directive are to establish a governance framework for the accreditation and monitoring of health facilities that provide human stem cell therapies and other cell-based therapies and to ensure that such therapies are “safe and effective for their intended use.”²⁵ In line with both objectives, the directive addresses the growing societal concern over the proliferation of stem cell treatments for diverse conditions, including “the latest passion for skin rejuvenation or aesthetic purposes”²⁶ and claims of success in treating patients that are not

for Economic Cooperation and Development [OECD], “Consumer Policy”, online: <www.oecd.org/sti/consumer/>.

²⁴ Philippines, Department of Health [DOH], Office of the Secretary [OS], *Administrative Order No 2013-0012 – Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell-Based or Cellular Therapies in the Philippines* (18 March 2013), online: Philippines FDA <www.fda.gov.ph/attachments/article/38686/STEM%20CELL%20AO.pdf> [Philippines DOH Administrative Order]; Melnie Ragasa-Jimena, “DoH Firms Up Stem Cell Therapy Control”, *People’s Journal* (21 March 2013), online: Philippines, DOH <portal.doh.gov.ph/sites/default/files/032113-0003.pdf>.

²⁵ Philippines DOH Administrative Order, *supra* note 24 at 2.

²⁶ *Ibid* at 1.

well supported by “published data from controlled clinical trials.”²⁷ The directive applies to all public and private institutions and facilities “involved in the use of human stem cell and cell-based or cellular therapies.”²⁸

Under the directive, “[p]lant parts labeled as stem cells”²⁹ and stem cell therapies derived from human embryonic sources and aborted human fetuses are prohibited by law and cannot be promoted or marketed to consumers or used in clinical procedures.³⁰ The Philippines Food and Drug Administration (PFDA) must approve stem cell preparations and therapies that are not prohibited by law prior to importation, promotion, marketing, or use in humans.³¹ Applications for approval of stem cell products and therapies may be accompanied, where available, with a proof of market authorization issued by the country of origin.³² However, the PFDA conducts its own independent review of stem cell products and therapies prior to registration and approval.³³ Approved products and therapies can only be administered in accredited health facilities.³⁴ Product claims relating to “cell-based” preparations and therapies must also be submitted to the PFDA for review and verification of the claims.³⁵ Making false product claims, including through advertisements, marketing, or related activities, constitutes a violation of the directive and could result in the suspension or revocation of accreditation.³⁶ Violators could also face criminal prosecution.³⁷

²⁷ *Ibid.*

²⁸ *Ibid* at 2.

²⁹ *Ibid* at 6.

³⁰ *Ibid.*

³¹ Philippines, DOH, Food and Drug Administration, *FDA Circular 2013-017 – Registration of Human Stem Cell-Based Products* (8 July 2013), online: <www.fda.gov.ph/attachments/article/80416/FC2013-017.pdf> [PFDA Circular].

³² *Ibid* at 1.

³³ See generally *ibid.*

³⁴ Philippines DOH Administrative Order, *supra* note 24 at 5.

³⁵ *Ibid* at 14.

³⁶ *Ibid.*

³⁷ *Ibid.*

The provisions relating to product claims discussed in the preceding paragraph are noteworthy in three main respects. Firstly, they facilitate proactive monitoring and verification of claims before they are disseminated to the public. Secondly, the verification of product claims is handled by the PFDA, and is conducted in a process separate from the accreditation of health facilities that provide stem cell interventions, which is handled by several agencies, including the Bureau of Health Facilities and Services, the National Kidney and Transplant Institute, the National Transplant Ethics Committee, the Department of Health, the PFDA itself, and the national Bioethics Advisory Board.³⁸ This ensures that product claims are subject to dedicated scrutiny, and that the assessment of product claims is not subsumed into the complex and extensive procedures and considerations that govern accreditation. Lastly, the provisions appear to govern product claims originating from or imported into the Philippines, and could therefore provide a basis for enforcement actions against web-based dissemination of false, deceptive, or misleading claims within the Philippines.

Conversely, the directive is lacking in a few important respects. One drawback is that it lacks many features found in standard consumer protection and product advertising legislation. For instance, the directive does not specify the criteria for assessing product claims or thresholds that claims have to meet to pass regulatory scrutiny. It is therefore unclear, for example, if a product that is simply promoted as a “cell-based therapy” will pass scrutiny if no claims are made as to its safety or efficacy. The directive has also been criticized for providing a basis for accreditation of stem cell clinics, despite the fact that no stem cell therapies had been approved for clinical use in the Philippines at the time of its release.³⁹ To date, the PFDA has not approved any stem cell interventions for clinical use, but has issued a statement acknowledging the use of stem cells in hematopoietic transplantation, corneal resurfacing with limbal stem cells, and skin regeneration with epidermal stem cells as “acceptable or standard healthcare procedures.”⁴⁰

³⁸ *Ibid* at 13.

³⁹ Kim Luces, “DOH Stem Cell Treatment Regulations ‘Flawed,’ Says Former Adviser”, *GMA News Online* (19 August 2013), online: <www.gmanetwork.com/news/story/322708/scitech/science/doh-stem-cell-treatment-regulations-flawed-says-former-adviser>.

⁴⁰ Philippines, DOH, Food and Drug Administration, *FDA Advisory No 2014-033 – Update of FDA Registration of Stem Cells or Human Cells, Tissues, and Cellular and Tissue-Based Products* (2 May 2014), online: <www.fda.gov.ph/advisories-2/pharmaceutical-2/153578-fda-advisory-2014-033>. For a more

Three health facilities – the Medical City, Asian Stem Cell Institute, and Makati Medical Center – have been accredited by the PFDA to provide the latter treatments.⁴¹

Despite these drawbacks, the directive highlights and responds to the unique regulatory challenges associated with representations of putative stem cell interventions and represents the first attempt by any country to tackle the issue directly.

B. Regulation of advertisements relating to medicinal products and medical treatments

An approach focused on medical advertising is a standard feature of consumer protection legislation in several countries (see Table 1 for a list of relevant legislation, by country). One or a combination of two regulatory strategies are employed: (1) a general ban on false, misleading, or deceptive advertising of medical products, devices, and treatments; and (2) provisions specifying the information that must be included in or excluded from advertising or promotional materials. Canada and the US are among the countries that employ the former strategy, while China, the Philippines, India, Ukraine, and the United Kingdom utilize both. Chinese legislation, for example, provides that advertisements for pharmaceuticals or medical apparatuses and instruments should not contain an “[a]ssertion or guarantee on efficacy or safety” nor any statements regarding efficacy or cure rates.⁴² The use of testimonials solicited from patients and clients to promote pharmaceutical products or medical services, either of which would

recent advisory, see Philippines, DOH, Food and Drug Administration, *Joint FDA-HFSRB Advisory No 2015-001 – Accredited Health Facilities for Human Stem Cell and Cell-Based or Cellular Therapies and Approved Indications* (1 July 2015), online: <www.fda.gov.ph/attachments/article/266694/FDA-HFSRB%20Advisory%20No.%202015-001.pdf> [PFDA, 2015 Advisory]. The 2015 Advisory omits mention of “acceptable or standard healthcare procedures.”

⁴¹ PFDA, 2015 Advisory, *supra* note 40 at 1.

⁴² *Advertisement Law of the People's Republic of China* (promulgated by Order No 34 of the President 27 October 1994, effective 1 February 1995; amended by Order No 22 of the President 24 April 2015, effective 1 September 2015), art 16, online: World Intellectual Property Organization <www.wipo.int/wipolex/en/text.jsp?file_id=374499> (unofficial English translation reflecting amendments up to 2015).

TABLE 1. TRUTHFUL ADVERTISING LEGISLATION, BY COUNTRY

Country	Main Legislation
Australia	• <i>Competition and Consumer Act</i> , 2010
Barbados	• <i>Consumer Protection Act</i> , 2002
Canada	• <i>Competition Act</i> , 1985 • <i>Food and Drugs Act</i> , 1985
China	• <i>Advertisement Law of the People's Republic of China</i> , 1994 • <i>Law of September 2, 1993, of the People's Republic of China Against Unfair Competition</i> (promulgated by Presidential Order No 10) • <i>Law of the People's Republic of China on Protection of Consumer Rights and Interests</i> , 1993
India	• <i>Consumer Protection Act</i> , 1986 • <i>Competition Act</i> , 2002 • <i>Drug and Magic Remedies (Objectionable Advertisements) Act</i> , 1954
Mexico	• <i>Federal Law on Consumer Protection</i> , 1992
Panama	• <i>Law No. 29 of 1 February 1996 Enacting Rules to Protect Competition and Adopting Other Measures</i> • <i>Consumer Protection and Defence of Competition Law Law No. 45 of 2007</i>
Philippines	• <i>Consumer Protection Act of the Philippines</i> , 1992
Seychelles	• <i>Consumer Protection Act</i> , 2010
Ukraine	• <i>Law on Advertising</i> , 2014
UK	• <i>Consumer Protection from Unfair Trading Regulations 2008</i> • <i>Medicines (Advertising) Regulation 1994</i> • <i>Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999</i> • <i>Business Protection from Misleading Marketing Regulations 2008</i>
US	• <i>Federal Trade Commission Act</i> , 1914

presumably include stem cell cures, is also considered deceptive advertising in China.⁴³ Ukrainian law forbids advertisements of medicinal products, medical devices, and “methods of prevention, diagnostics, treatment and rehabilitation” that “contain references to therapeutic effects with regard to

⁴³ Zhihong Gao, “Controlling Deceptive Advertising in China: An Overview” (2008) 27:2 J Public Policy & Marketing 165 at 169.

diseases which are not or hardly curable.”⁴⁴ The latter provision is pertinent to the marketing of unproven stem cell therapies that are promoted as complete cures for a variety of diseases that have not been shown to be curable through any scientifically validated means.⁴⁵

As noted above, most jurisdictions maintain a general ban on false and misleading advertising. However, what is considered “false” or “misleading” varies by country. In Canada, the relevant test is that the offending representation must be “false or misleading in a material respect.”⁴⁶ A representation is material if its literal meaning or the general impression it conveys could influence the ordinary consumer to buy or use the advertised product or service.⁴⁷ Representations that include a performance claim (i.e., a claim or statement regarding the performance of the advertised product or service) must be “based on an adequate and proper test” that objectively establishes that the effect claimed is significant, meaningful, reproducible,⁴⁸ and not a chance result.⁴⁹ Testimonials would generally not meet this standard,⁵⁰ but the testing required “need not be as exacting as would be required to publish the test in a scholarly journal.”⁵¹ Canadian health regulations also forbid marketing and advertising practices that make claims that are not included in a product’s market authorization, misrepresent the product’s licensing

⁴⁴ Ukraine, *Law on Advertising*, OJVR 1996 No 39, at 181, art 21.5, online: World Intellectual Property Organization <www.wipo.int/wipolex/en/text.jsp?file_id=187714> (unofficial English translation reflecting amendments up to 2006).

⁴⁵ See generally Lau et al, *supra* note 1.

⁴⁶ *Competition Act*, *supra* note 23, s 52(1). See also Competition Bureau, “False or Misleading Representations and Deceptive Marketing Practices under the *Competition Act*” (5 November 2015), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03133.html> [Competition Bureau, “False or Misleading Representations”].

⁴⁷ *Competition Act*, *supra* note 23, s 52(3); Competition Bureau, “False or Misleading Representations”, *supra* note 46.

⁴⁸ *Competition Act*, *supra* note 23, s 74.01(1)(b); Competition Bureau, “False or Misleading Representations”, *supra* note 46.

⁴⁹ *Canada (Competition Bureau) v Chatr Wireless Inc*, 2013 ONSC 5315 at para 295, 288 CRR (2d) 297 [Chatr].

⁵⁰ Competition Bureau, “False or Misleading Representations”, *supra* note 46.

⁵¹ Chatr, *supra* note 49 at para 295.

approval category, provide therapeutic guarantees of a general nature, or exaggerate the benefits and merits of or degree of relief provided by the advertised or marketed product or service.⁵²

In Barbados, China, and Australia, the term “false and misleading” covers, respectively, representations that “omit pertinent information which will allow the consumer to make an informed decision,”⁵³ are “unfair,”⁵⁴ or have a “real and not remote possibility” of conveying factual errors to persons at whom they are directed.⁵⁵ In China, advertisements based on subjective or circumstantial claims, or which do not reflect the “absolute truth” or actual effects, are considered misleading.⁵⁶ Also in China, claims based on statistical analysis are deemed misleading, as “statistical differences may reflect differences in research design rather than real differences in the actual effect.”⁵⁷ Advertisements using “cure rates, testimonials, guarantees, and comparisons” are also considered misleading.⁵⁸ In the US, claims regarding health, safety, and product efficacy are false or misleading unless substantiated or supported with “competent and reliable scientific evidence.”⁵⁹ The latter standard means “tests, analyses, research, or studies

⁵² Health Canada, Health Products and Food Branch, Guidance Document, *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs Including Natural Health Products)* (18 October 2006), paras 1.1–1.4, 2.8, online: <www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/guide-ldir_consom_consum-eng.pdf>

⁵³ Barbados, Fair Trading Commission, “Understanding Consumer Law and Treating Consumers Fairly” (11 June 2012), online: <www.ftc.gov.bb/index.php?option=com_content&task=view&id=240&Itemid=27>.

⁵⁴ Gao, *supra* note 43 at 171.

⁵⁵ *Noone (Director of Consumer Affairs Victoria) v Operation Smile (Australia) Inc & Ors*, [2012] VSCA 91.

⁵⁶ Gao, *supra* note 43 at 169.

⁵⁷ *Ibid.*

⁵⁸ *Ibid.*

⁵⁹ *In the matter of NBTY, Inc, Naturesmart LLC and Rexall Sundown, Inc*, US Federal Trade Commission, Docket No C-4318, FTC File No 102 3080 at 3, online: <<https://www.ftc.gov/sites/default/files/documents/cases/2011/03/110329nbttydo.pdf>> [NBTY]. See also Federal Trade Commission, “Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill: In the Matter of GeneLink, Inc. and foru International Corporation” (7 Janu-

that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.”⁶⁰ In practice, the Federal Trade Commission, which enforces the standard, requires “at least two adequate and well-controlled human clinical trials” as proof of compliance.⁶¹

Given that regulation of advertisements relating to medicinal products and medical treatments is common across countries, this approach provides the strongest legal basis for cross-border or international co-operation on non-compliance issues arising from the advertising or marketing of unlicensed and unproven stem cell treatments. However, variations among jurisdictions in what is considered “false or misleading” may render it difficult to find common ground for co-operative enforcement. For example, a representation that is deemed circumstantial and therefore misleading in China may not necessarily be seen as false and misleading in a material respect in Canada. Applications of regulatory standards in some countries may also be untenable in others due to differences in legal, political, and constitutional arrangements. Thus, for instance, regulators in China have imposed fines for deceptive advertising on content determined to be non-compliant with government-approved advertising standards⁶² and which

ary 2014) at 2–3, online: <<https://www.ftc.gov/public-statements/2014/01/statement-chairwoman-edith-ramirez-commissioner-julie-brill>>; *In the Matter of L'Oréal, USA, Inc.*, US Federal Trade Commission, FTC File No 122 3016 (2014), online: <<https://www.ftc.gov/system/files/documents/cases/140627lorealcmpt.pdf>> [*L'Oréal*].

⁶⁰ *NBTY*, *supra* note 59 at 3.

⁶¹ *In the matter of Nestle Healthcare Nutrition, Inc.*, US Federal Trade Commission, Docket No C-4312, FTC File No 092 3087 at 3, online: <<https://www.ftc.gov/sites/default/files/documents/cases/2011/01/110118nestledo.pdf>>; *In the matter of Genelink, Inc.*, US Federal Trade Commission, Docket No C-4456, FTC File No 112 3095 at 4, online: <https://www.ftc.gov/system/files/documents/cases/140512genelinkdo_0.pdf>; Randal Shaheen & Amy Ralph Mudge, “Has the FTC Changed the Game on Advertising Substantiation?” (2010) 25:1 Antitrust 65 at 66; Latham & Watkins Corporate Department, Client Alert No 1407, “*POM Wonderful* Opinion Provides Limited Clarification on FTC Substantiation Requirements” (1 October 2012), online: <www.lw.com/thoughtLeadership/pom-opinion-clarifies-FTC-substantiation-requirements>.

⁶² Gao, *supra* note 43 at 168.

contained “puffery” and terms such as “award-winning.”⁶³ The application of similar standards for assessing deceptiveness in jurisdictions such as Canada and the US could be perceived as violating constitutionally protected free speech or expression laws.

C. Online representations

Consumer protection legislation in most of the jurisdictions covered in this article is designed to apply to false and misleading representations regardless of the medium of dissemination. While some countries specifically address online or electronic representations in their policies, others simply stipulate rules that apply to representations by any means. False or misleading advertising through the internet will typically attract legal sanctions both in the jurisdiction where the content originated and in the jurisdiction where it is disseminated or viewed by consumers. However, it may be difficult or impossible to prosecute persons responsible for the creation or dissemination of false or misleading content who do not have assets in, reside in, or carry on business within the prosecuting state.⁶⁴ Thus, for example, a clinic domiciled in China that controls or causes the dissemination of false or misleading content via the internet to Canadian consumers would be subject to prosecution both in China and Canada. However, regulators in Canada will generally not be able to commence prosecution against the Chinese clinic as their legal powers and jurisdiction do not extend beyond Canada’s territorial borders.

In general, legal liability for a false and misleading online representation is attributed to a “controlling mind,” i.e. the person who caused the representation to be made or who is in control of the creation and dissemination of the representation. Persons other than the controlling mind who are involved in creating or disseminating a false and misleading online representation, such as webpage designers and providers of web hosting or internet services, are typically exempt from liability. In Canada, for example, persons other than the controlling mind who “print or publish or otherwise disseminate” a false or misleading representation will not face any legal

⁶³ *Ibid.*

⁶⁴ See generally I Glenn Cohen, “Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument” (2010) 95 Iowa L Rev 1467.

consequences.⁶⁵ However, this rule is subject to a proviso that the representation be accepted “in good faith and in the ordinary course of business” and on behalf of a controlling mind who is resident in Canada and whose name and address were recorded.⁶⁶ It follows from the latter rule that persons who act on behalf of non-resident controlling minds may be held legally responsible in Canada.

II. ENFORCEMENT MECHANISMS

In most jurisdictions, the contravention of truthful advertising regulations will attract both civil and criminal liability. A government regulator is typically charged with enforcing both forms of liability and with imposing penalties. The penalties for violation of truthful advertising regulations include fines, imprisonment, and confiscation of advertising income and earnings from the advertised product. Regulators can also issue warnings and compliance directives and obtain judicial remedies such as injunctions, declarations, and damages to enforce compliance.⁶⁷

While regulators in most jurisdictions are authorized to initiate enforcement actions through direct monitoring and investigative powers, the majority of enforcement activities tend to arise from consumer complaints. For example, Canada’s federal regulator, the Competition Bureau, handled near-

⁶⁵ Competition Bureau, “Application of the Competition Act to Representation on the Internet” (16 October 2009), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03134.html> [Competition Bureau, “Application of the Competition Act”].

⁶⁶ *Ibid.*

⁶⁷ See generally Michael Faure, Anthony Ogus & Niels Philipsen, “Enforcement Practices for Breaches of Consumer Protection Legislation” (2008) 20:4 *Loyola Consumer L Rev* 361 at 375–98. See also *Competition Act*, *supra* note 23, ss 7, 74.01–74.09; Competition Bureau, “The Competition Bureau”, online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03336.html>; *False advertisements; injunctions and restraining orders*, 15 USC § 53; Competition and Consumer Act 2010 (Cth), Schedule 2, chs 4–5 (generally); *The Australian Consumer Law: A Framework Overview* (Commonwealth of Australia, July 2013) at 6–8, online: <consumerlaw.gov.au/files/2015/06/ACL_framework_overview.pdf>; Mexico, *Federal Consumer Protection Law*, arts 99–134, online: Procuraduría Federal del Consumidor <www.profeco.gob.mx/juridico/pdf/1_lfpc_06062006_ingles.pdf> (unofficial English translation as amended up to 2006).

ly 11 000 consumer complaints and information requests in the 2015–2016 reporting period⁶⁸ while its Chinese counterpart handled over a million complaints in the same period, including 131 800 cases involving infringements of consumer rights.⁶⁹

An aspect of enforcement that is especially pertinent to the regulation of unlicensed and unapproved stem cell therapies and products is cross-border and international enforcement activity. A good number of bilateral, regional, and international co-operation agreements between countries implicated in stem cell advertising and marketing activities are currently in place (see Figure 1 for a mapping of bilateral agreements), and can be harnessed to tackle the challenges posed by evasive relocation and online advertising by clinics and providers. It is also noteworthy that many of these countries belong to the International Consumer Protection and Enforcement Network,⁷⁰ the largest and most active international consumer protection enforcement body worldwide. (See the next section for a full discussion of the Network and its activities.)

Co-operative enforcement arrangements have yielded some success in addressing cross-border violations. In one illustrative case that occurred between 1996 and 2005, the Mexico, US, Canada Health Fraud Work Group (MUCH), which was established in 1994 to strengthen the partner countries' ability to deal with cross-border health fraud, successfully undertook coordinated enforcement actions against CSCT Inc., a Canadian company based in Ontario and British Columbia.⁷¹ CSCT used its website and other

⁶⁸ Competition Bureau, *Quarterly Statistics Report for the Period Ending September 30, 2016* (2 September 2016), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04129.html>.

⁶⁹ “Consumer Complaints Surge in China”, *China Daily USA* (14 March 2014), online: <usa.chinadaily.com.cn/business/2014-03/14/content_17347239.htm>.

⁷⁰ International Consumer Protection and Enforcement Network, “Participants” (nd), online: <www.icpen.org/for-consumer-experts/who-we-are/participants>.

⁷¹ See US, Federal Trade Commission, Press Release, “FTC, Canada, and Mexico Officials Crack Down on Foreign Companies that Offer Bogus Cancer Treatment” (20 February 2003), online: <<https://www.ftc.gov/news-events/press-releases/2003/02/ftc-canada-and-mexico-officials-crack-down-foreign-companies>> [FTC, 2003 Press Release]; Innovation, Science and Economic Development Canada [ISED], News Release, “Criminal Charges Laid in Cancer Treatment Scam Following Competition Bureau Investigation” (2 August 2005), online: Government of Canada <news.gc.ca/web/article-en.do?crrt>.

**FIGURE 1. BILATERAL CONSUMER PROTECTION/TRUTHFUL ADVERTISING
ENFORCEMENT AGREEMENTS**

Legend: Each black cell indicates that a bilateral consumer protection agreement exists between the two jurisdictions or countries in the corresponding row and column. For example, Canada has bilateral consumer protection agreements with the European Union, Mexico, the US, Australia, and the UK.

	Canada	China	European Union	Mexico	United States	Australia	United Kingdom
Canada							
China							
European Union							
Mexico							
United States							
Australia							
United Kingdom							

promotional materials to disseminate false and misleading representations and claims regarding a bogus cancer therapy called “Zoetron Therapy” or “Cell Specific Cancer Therapy.” CSCT claimed that Zoetron, a proprietary electromagnetic device it had developed, could selectively kill cancer cells without affecting healthy cells. CSCT also operated outpatient cancer clinics in Mexico, Spain, Switzerland, and the Dominican Republic, and claimed to have successfully treated over 850 patients worldwide.⁷² Treatment costs ranged from US\$15 000 to \$20 000.⁷³ This amount did not include travel and accommodation expenses for patients who received the “treatment” outside their home countries.⁷⁴

sj1D=&mthd=advSrch&crtr.mnthndVI=&nid=162269&crtr.dpt1D=&crtr.tp1D=&crtr.lc1D=&crtr.yrStrtVI=&crtr.kw=kitchener&crtr.dyStrtVI=&crtr.aud1D=&crtr.mnthStrtVI=&crtr.yrndVI=&crtr.dyndVI=>; US, Federal Trade Commission, Press Release, “Canadian Company Settles FTC Charges that It Offered Bogus Cancer Therapy to US Citizens” (25 February 2004), online: <<https://www.ftc.gov/news-events/press-releases>>.

⁷² FTC, 2003 Press Release, *supra* note 71.

⁷³ ISED, *supra* note 71.

⁷⁴ FTC, 2003 Press Release, *supra* note 71.

In 2003, seven years after CSCT began operations, MUCH, which includes officials from the partner countries' consumer protection and health agencies, commenced separate but coordinated enforcement actions against the company and its principal officers, including execution of search warrants on the company's offices in Ontario and British Columbia, suspension of the company's domain name, and closure of its clinics. The Federal Trade Commission (FTC) also successfully obtained a court order that prohibited CSCT from making false and misleading treatment claims and from advertising, promoting, selling, or distributing its Zoetron Therapy.⁷⁵ The court also ordered that the company shut down its website and that the assets of its principal officers be frozen.⁷⁶

Details of the FTC indictment against the company are reminiscent of the dangers reportedly faced by patients engaged in stem cell tourism. The company preyed on its clients' conditions and fears by promoting Zoetron Therapy as a more effective and less aggressive alternative to established cancer therapies such as chemotherapy and radiation. Promotional materials claimed that unlike chemotherapy, Zoetron did not target or harm healthy cells, but simply attacked the cancer cells. Swayed by the false claims and CSCT's slick marketing activities, many of its clients abandoned chemotherapy and radiation to pursue Zoetron exclusively. Following "treatment" with Zoetron Therapy, clients were informed that tests showed that they had been completely cured, only to learn upon their return home and consultation with their health care providers that their condition had deteriorated and, in some cases, could no longer be effectively treated by established means.⁷⁷

Co-operative enforcement activities have benefited greatly from increased alignment and harmonization of consumer protection rules among regional and international partners. For example, recent amendments to Canadian consumer protection law that expand its scope to cover false and misleading representations made outside Canada were influenced by international model guidelines and best practices, as well as by OECD peer re-

⁷⁵ *Ibid*; ISED, *supra* note 71.

⁷⁶ *Federal Trade Commission v CSCT, Inc*, Docket No 03 C 00880, FTC File No X030027 (ND Ill, 17 February 2004), online: FTC <<https://www.ftc.gov/enforcement/cases-proceedings/012-3056-x030027/csct-inc-et-al>>.

⁷⁷ FTC, 2003 Press Release, *supra* note 71.

views of Canada's competition law and policy.⁷⁸ Similarly, Mexico has integrated OECD model guidelines on advertisements made through electronic or optical means into its consumer protection law.⁷⁹

III. A MODEL OF CO-OPERATIVE ENFORCEMENT: THE INTERNATIONAL CONSUMER PROTECTION AND ENFORCEMENT NETWORK

The International Consumer Protection and Enforcement Network is an informal network comprising consumer protection authorities from over 50 countries.⁸⁰ The Network was established in 1992 to promote and encourage international co-operation among member countries on consumer protection issues. The goals of the Network are to combat cross-border violations of consumer protection laws; facilitate cross-border enforcement; promote measures for effective enforcement; and share information, intelligence, and best regulatory and enforcement practices.⁸¹ Members of the Network include countries where treatment centres for unlicensed stem cell therapies are located, as well as countries from which the majority of the centres' clients come (see Table 2 for a list of member countries). Many of the countries in both categories, including Australia, Canada, China, Mexico, the UK, and the US, are very active within the Network. The US FTC, for example, provides support for *econsumer.gov*, a project of the Network designed to gather and share cross-border complaints and to help consumers resolve such complaints. Generally, to remain a member, a participating country must actively participate in a minimum of three Network projects.⁸²

⁷⁸ Competition Bureau, "Competition Law in a Global and Innovative Economy – A Canadian Perspective" (Presentation delivered at the 3rd BRICS International Competition Conference, New Delhi, India, 21 November 2013), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03631.html>.

⁷⁹ OECD, *Mexico: Annual Report on Consumer Policy Developments* (2001), online: <www.oecd.org/internet/consumer/1955364.pdf>.

⁸⁰ See the Network's website at icpen.org.

⁸¹ International Consumer Protection and Enforcement Network [ICPEN], "Memorandum on the Establishment and Operation of the International Consumer Protection and Enforcement Network (ICPEN)" (last updated March 2016), s 4, online: <https://www.icpen.org/files/icpenSites/Memorandum_on_the_Establishment_and_Operation_of_ICPEN_2016_1.pdf> [ICPEN Memorandum].

⁸² *Ibid*, s 6(e).

The Network supports a number of enforcement initiatives that aim to address false and misleading advertising, including consumer education campaigns, a “Fraud Prevention” month, and collection and sharing of consumer complaints with consumer protection authorities through the econsumer.gov website.⁸³ One of its enforcement activities, namely the Internet Sweep Program, has the greatest potential to impact directly on the marketing of unlicensed stem cell interventions. The Internet Sweep is an annual event designed to identify websites and other forms of electronic communication that contain false, misleading, or fraudulent representations and advertising. The stated objective of the Sweep is “to improve consumer confidence in e-commerce by demonstrating a global law enforcement presence online.”⁸⁴ During the Sweep, consumer protection agencies, including non-Network member agencies, carry out intensive internet searches on a chosen theme. Past Internet Sweeps have focused on misleading and incomplete content in children’s online games and applications;⁸⁵ fraudulent and deceptive advertising in online and mobile markets⁸⁶ and social networking sites;⁸⁷ cyber scams, including “get rich quick,” “work at home,” and “free offer” schemes;⁸⁸ and “deceptive marketing practices aimed at vulnerable consumers.”⁸⁹ Websites identified during the Sweep are targeted for enforcement action or consumer education by consumer protection agencies.

⁸³ International Consumer Protection and Enforcement Network, “Network Activities”, online: <www.icpen.org/for-consumer-experts/what-we-do/network-activities-1>.

⁸⁴ *Ibid.*

⁸⁵ Competition Bureau, News Release, “Competition Bureau Coordinates Joint International Internet Sweep” (30 September 2013), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03612.html>.

⁸⁶ Competition Bureau, News Release, “Competition Bureau Coordinates Worldwide Sweep for Online and Mobile Fraud” (28 September 2012), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03502.html>.

⁸⁷ Competition Bureau, “Social Media Sites Targeted by Competition Bureau in International Sweep” (24 September 2010), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03291.html>.

⁸⁸ Danish Consumer Ombudsman, Media Release, “International Network Sweeps the Internet for Fast Money” (12 April 2004), online: <www.consumerombudsman.dk/Nyheder-fra-FO/Media-releases/sweep>.

⁸⁹ Competition Bureau, News Release, “Competition Bureau Coordinates Joint

**TABLE 2. INTERNATIONAL CONSUMER PROTECTION AND ENFORCEMENT
NETWORK MEMBER COUNTRIES AND PARTNER ORGANIZATIONS**

Founding members	Australia, Austria, Belgium, Canada, Denmark, France, Finland, Germany, Hungary, Ireland, Japan, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, the United States
Other members	Angola, Azerbaijan, Barbados, Bulgaria, Chile, China, Colombia, Costa Rica, Cyprus, the Czech Republic, the Dominican Republic, Egypt, El Salvador, Estonia, Greece, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Mexico, Mongolia, Nigeria, Panama, Papua New Guinea, the Philippines, Poland, the Republic of Korea, Seychelles, Slovakia, Suriname, Turkey, Vietnam, Zambia
Partner organizations and observers	Competition Authority of Kenya, Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (IN-DECOPI) (Peru), Ministria e Tregtisë Dhe Industrisë (Kosovo), European Commission, Iberoamerican Forum of Consumer Protection Agencies (FIAGC), OECD, UNCTAD

An “Internet Sweep” focused on false and misleading advertising of unlicensed stem cell therapies and procedures may not fully address the complexities of the phenomenon or guarantee follow-up enforcement action against clinics. However, it would serve to highlight the problem on a global scale and to put it on the regulatory radar of consumer protection agencies worldwide. This may in turn affect providers’ advertising behaviour. Past research suggests that regulatory action and increased scrutiny can result in changes in providers’ advertising behaviour, such as the introduction of legal disclaimers stating that treatments offered are unlicensed or experimental.⁹⁰

CONCLUSION

The worldwide proliferation of clinics offering unproven and unlicensed stem cell interventions creates a host of regulatory, clinical, and ethical problems that require governance solutions that address local and cross-border markets and impacts. While more than one governance strategy is needed, truthful advertising laws and enforcement strategies offer a handy solution

International Internet Sweep” (30 September 2014), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03821.html>.

⁹⁰ Ogbogu, Rachul & Caulfield, *supra* note 2 at 367.

to meet this governance objective. Approaches to truthful advertising regulation also offer distinct advantages over existing regulatory mechanisms in that they are legally binding, can be proactively implemented to target client recruitment by clinics, and can be robustly enforced both within and outside territorial borders. While differences in political contexts and thresholds for assessing the veracity of product claims may pose some challenges for collaborative enforcement, current regulatory harmonization efforts and past instances of co-operative enforcement suggest that these challenges can be overcome and that the regulatory gains are likely to be significant.

