Consumer protection, advertising and unapproved stem cell treatments

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Regulating the advertising and promotion of stem cell therapies
Author:
Barbara von Tigerstrom

Clinics that offer unapproved stem cell treatments are growing in number around the world. These unproven therapies are often advertised by clinics directly to potential customers with advertisements and information that many people consider misleading. Consumer protection laws could assist in addressing and restricting how unproven stem cell therapies are marketed, but also face limitations due to the international scope of the stem cell market.

What questions & challenges are raised?

Around the globe, the number of clinics offering unapproved stem cell (SC) treatments is increasing. Many of these clinics make claims on websites, advertisements and social media about the safety and effectiveness of treatments, which are not supported by scientific evidence. These clinics also commonly omit or downplay treatment risks and use scientific publications, testimonials, and even clinical trial registrations to make their therapies appear credible. There are concerns that these marketing practices sell expensive and unproven SC treatments by promoting unrealistic expectations in patients and carers. In her recent publication, Dr Barbara von Tigerstrom from the University of Saskatchewan discusses how consumer protection laws could offer some assistance to curtail misleading marketing practices of clinics offering unproven treatments. Dr von Tigerstrom explains how laws that regulate advertising in the United States, Canada and Australia apply to many common concerns about websites and advertisements marketing SC therapies, but also notes several limitations of enforcing these laws.

What background and point are discussed?

Dr von Tigerstrom begins by explaining consumer protection laws, pointing out that most countries have laws of some form that prohibit businesses from using false, misleading or deceptive claims or information to advertise products and services. These laws apply to all types of communication, including websites, blogs, social media and television. Determining what marketing and other information is deemed 'misleading' is often based on the overall impression it makes on the advertisement's target audience. In the United States (US), Canada and Australia, general consumer protection laws are overseen and enforced by government bodies on the national and regional level. A notable difference between these three countries is that Canada and Australia have stricter laws that specifically apply to medical products. While the US allows advertising of prescription drugs to be marketed directly at consumers, Canada and Australia (and most other countries in the world) limit or fully prohibit this. Furthermore, in all three countries the marketing of services offered by medical professionals, such as surgical operations, must follow specific ethical codes of conduct and governmental regulations. These ethical codes are established by medical boards, colleges and other professional bodies and forbid medical practitioners to provide patients with misleading or inaccurate information. Australia and parts of Canada have additional laws limiting (or banning) promotions for services that use testimonials or claims that promote unrealistic expectations. Testimonials are also subject to standard consumer protection laws in most countries, which require them to be genuine and fully disclose any sponsorship, compensation or financial affiliation. However, these laws do not regulate independent (unaffiliated) testimonials. Nor do they prohibit independent news reports that build excitement about treatments by over-enthusiastically describing research.

What insight & direction does this give for research policies?

Dr von Tigerstrom points out that many of the marketing practices of SC clinics causing concern appear to violate general consumer protection laws that require claims about products to be accurate and adequately supported. Dr von Tigerstrom supports this claim by pointing to a recent ruling by the US Federal Trade Commission that stated claims of therapeutic effects must be backed by "valid studies using current scientific methods". Therefore, it appears clinics cannot make claims about the safety and effectiveness of SC therapies without being proven scientifically, such as in clinical trials. Even if unsupported claims are not made and all the information in advertisements is accurate, it could still be deemed 'misleading' information depending on the impression it gives consumers. Even 'fine print' and disclaimers written elsewhere on websites or advertisements may not be sufficient to prevent content from being labelled as misleading. Other practices, such as testimonials, also clearly violate medical advertisement laws in Australia and Canada. Dr von Tigerstrom states that enforcing consumer protection laws could potentially make advertisements for SC treatments less attractive and protect individuals from physical and financial harm. However, the enforcement of consumer protection laws is not simple and raises many issues. First of all, reporting or complaining about SC clinics to government authorities may only result in limited enforcement of laws because of restricted amounts of time, resources and understanding of SC therapies. Also, many types of advertising can appear to be independent news stories or testimonials, which are particularly difficult to prove as advertisements. Additionally, countries only have the ability to enforce laws within their own borders, making it difficult to enforce consumer protection laws on businesses promoting themselves from other countries. The size and international scope of unapproved SC clinics and SC tourism (traveling internationally for treatments) would require international agreements to enable cooperative enforcement of consumer protection laws. While such collaboration may be possible, enforcing regulations internationally would still be complicated because laws in each country or jurisdiction are somewhat different. Enforcement is also complicated by legislation in some countries that exempts specific products from being regulated as medical treatments. This is particularly true for treatments using autologous cells (cells that are collected from a patient and then used for a medical procedure in the same patient). These exclusions can change the advertising laws that apply to the unapproved therapies. For example, exemptions for autologous SC treatments in Australia have consequently opened debate about whether clinics should be allowed to advertise unproven treatments directly to consumers – which currently is allowed. Dr von Tigerstrom points out that even clear regulations that ban direct-to-consumer advertising for regulated medicines will only protect consumers if they are enforced, which may not happen.