

Medical societies, patient education initiatives, public debate and marketing of unproven stem cell interventions

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Abstract

Businesses marketing unproven stem cell interventions proliferate within the U.S. and in the larger global marketplace. There have been global efforts by scientists, patient advocacy groups, bioethicists, and public policy experts to counteract the uncontrolled and premature commercialization of stem cell interventions. In this commentary, we posit that medical societies and associations of health care professionals have a particular responsibility to be an active partner in such efforts. We review the role medical societies can and should play in this area through patient advocacy and awareness initiatives

Key Words: *medical societies, health care professionals, unproven stem cell interventions, “stem cell” clinics, patients*

Introduction

As businesses marketing unproven stem cell interventions proliferate within the USA and in the larger global marketplace, researchers from a variety of academic disciplines and clinical specialties are calling for more robust regulatory oversight, patient education initiatives and public policy debate concerning ethically and scientifically justifiable governance standards for cell-based therapeutics. A recent publication by Sipp *et al.* [1] is an important and timely contribution to global efforts to counteract the rapid increase in businesses selling unproven and unlicensed “stem cell” interventions. The authors rightly emphasize the need for mobilization of various stakeholders and coordinated actions at multiple levels of governance. Building upon their critical analysis and “call to action,” along with recent Food and Drug Administration (FDA) actions sanctioning specific outfits offering unproven cell-based therapies [2,3], we propose that medical societies have a particular responsibility to the patient communities they serve to participate in the struggle to counter the widespread promotion of unproven stem cell interventions. In this perspective, we review the role medical societies can and should play in pursuing

this objective through patient advocacy, education, awareness and engagement initiatives.

As the authors note, medical specialties ranging from respiratory medicine to sports medicine and ophthalmology have issued cautionary statements alerting patients to risks associated with undergoing unproven stem cell interventions [4–6]. These important documents articulate the considered positions of societies representing thousands of medical professionals and provide insight into how such organizations are trying to protect patients from risk of avoidable injuries and even possibility of fatal outcomes, significant financial harm and psychological harms associated with dashed hopes. Such statements also help to clarify what distinguishes carefully designed and properly conducted clinical research involving administration of stem cells or their derivatives as investigational agents from predatory marketing schemes based on little or no credible scientific evidence. However, both the strategies used by businesses marketing unproven stem cell interventions and the global regulatory landscape are in constant flux. Medical societies and associations of health care professionals need to respond to these challenges in a dynamic and sustained manner.

First, education efforts organized by medical societies should be multifaceted and directed at both patients and their loved ones and practicing physicians and other related caregivers. Physicians, nurses and other health care professionals are in the unique position of actively participating in the care and decision-making processes of patients. They play a crucial role in providing information to patients and their family members and helping them make informed decisions about medical interventions. Given their role in helping patients weigh options, gather information and make difficult health-related decisions, it is essential that physicians and other caregivers play an active and engaged role in educating and counseling patients who are considering unproven stem cell interventions [7,8]. For a number of medical conditions, there are promising regenerative medicine-based approaches at various stages of development, extending from basic research to pre-clinical studies and clinical trials [9]. Unfortunately, due to time constraints and challenges associated with tracking the often substantial number of clinical studies associated with particular diseases and other medical conditions, many medical professionals are ill-equipped to discuss the current status of stem cell-based interventions in their clinical specialty. Medical societies have a vital role to play in keeping clinicians informed of such developments and helping patients better understand the current state of clinical research, whether related to stem cells or other possible therapies [10].

Medical societies are well-positioned to distribute to their members and to patients specialty-specific information about developments in stem cell research. Dedicated stem cell-related sessions at medical conferences, literature reviews in specialty and society journals, webinars, patient education guides, succinct summaries of the current state of stem cell research related to particular diseases and other medical problems and regular updates concerning relevant regulatory developments can all be used to keep physicians informed, current and able to respond to their patients' questions and concerns. Similarly, medical societies need to develop, regularly update and widely distribute patient information sheets on the current status of stem cell treatments and clinical research, written using accessible language [11,12]. Patients and their advocates should be encouraged to participate in the development of such guides.

There are currently volunteer physician/scientist organizations, such as ALSUntangled, that publish scientific reports critically evaluating the therapeutic claims of particular "stem cell" clinics [13–15]. These reports appear to have an impact within patient communities and help promote informed, evidence-based decision-making. The ALSUntangled model of paying

attention to businesses marketing unproven stem cell interventions and critically assessing their marketing claims and clinical activities provides insight into how medical societies might better educate and inform physicians and patients. Caution would need to be exercised when producing such reports because some businesses selling unproven stem cell interventions have displayed a willingness to threaten and attempt to intimidate critics. Medical societies, therefore, need to decide whether to address the problem of widespread marketing of unproven stem cell interventions in general terms or grapple with the promotional claims of specific businesses. Acknowledging the importance of engaging in such work in a careful manner that minimizes the threat of litigation, we suggest that the ALSUntangled approach to examining the claims of businesses selling unproven stem cell interventions has lessons that extend beyond the amyotrophic lateral sclerosis community to other groups of patients and clinicians. For example, medical societies can help patients identify marketing claims that are unsupported by scientific evidence. Medical societies can also play a role in bringing particular businesses and clinicians to the attention of regulatory authorities. In some instances, it will be prudent for medical societies to seek the advice of legal counsel before deciding how best to report to authorities clinical and commercial practices that do not appear to comply with applicable regulatory standards.

Next, medical associations should take steps to ensure that they are not endorsing or otherwise enabling clinicians and businesses advertising unproven stem cell-based interventions. Sipp *et al.* summarize the many tokens of scientific legitimacy that have been co-opted by clinics selling unproven "stem cell" interventions [1]. Medical specialties have an important role to play in exposing such tokens. For instance, presentation of data originating from pay-to-participate stem-cell "studies," when such studies have not been properly subject to review by institutional review boards and national regulatory authorities such as the FDA or Health Canada, should not be permitted at medical conferences [16]. The pledges required for members of the International Society for Cellular Therapy (ISCT) [17] and the International Society for Stem Cell Research (ISSCR) may serve as models for medical associations that wish to deter their members from engaging in unethical and unprofessional cell-based interventions. Such pledges can be tied to expectations regarding professional conduct associated with membership in particular medical societies. For example, individuals interested in becoming members of medical societies could first be required to read key resources on ethical, legal and scientific issues related to unproven stem cell interventions and to pledge that they will not be involved in stem

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