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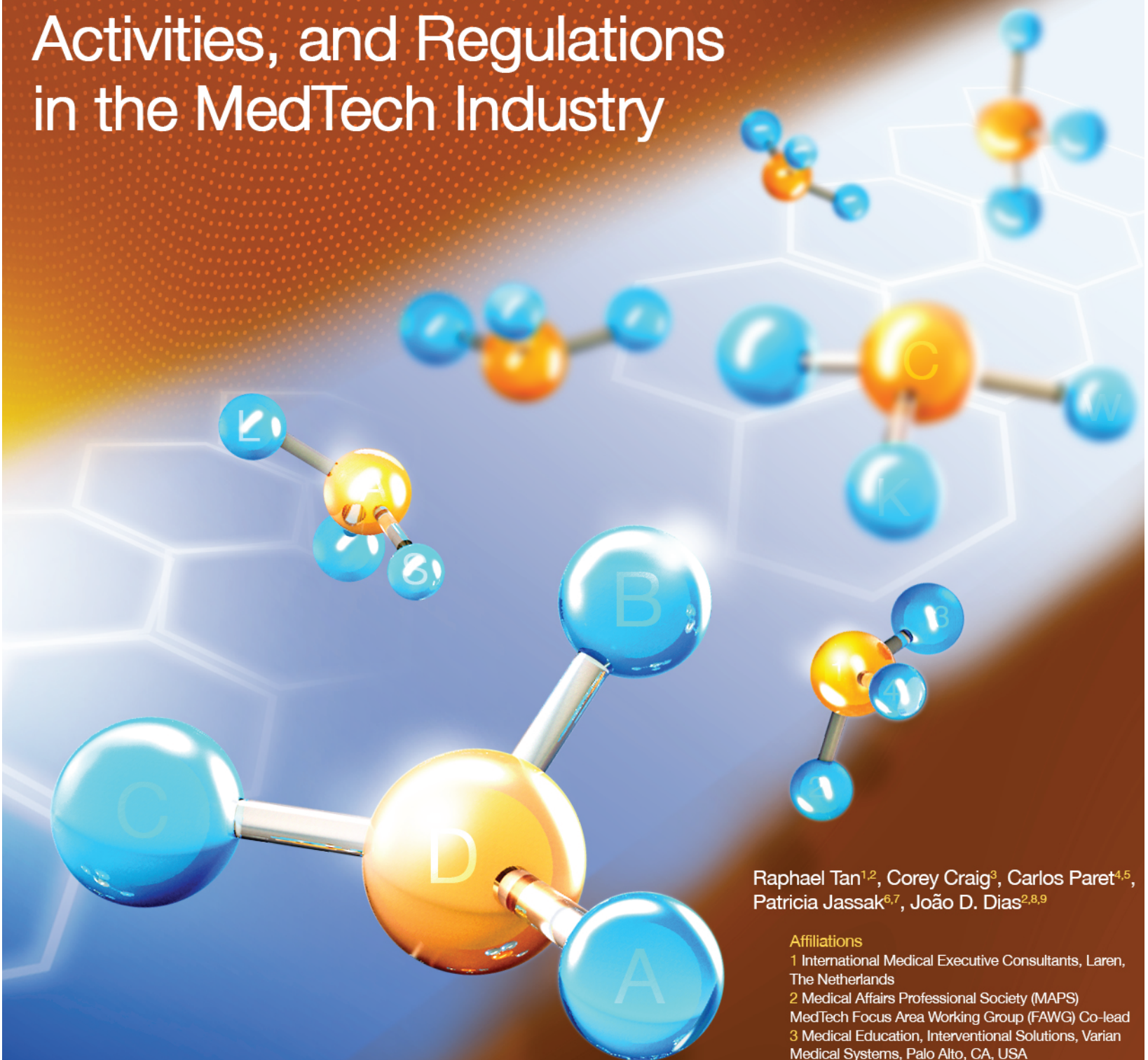
An Overview of External Education Structure, Activities, and Regulations in the MedTech Industry



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This publication represents the consensus opinion of members of the MAPS MedTech and External Education Focus Area Working Groups (FAWGs) but does not represent formal endorsement by the authors' organizations.

KEYWORDS: Devices, training, safety, noncommercial, regulations

ABSTRACT

Medical technologies such as medical devices and diagnostics are set apart from pharmaceuticals in that successful deployment depends on not only equipping health care providers with the theoretical knowledge of best and safest use but also ensuring users' practical competence. Simply, with medical technologies across the spectrum from noninvasive diagnostics to high-risk therapeutics, clinical outcomes and patient safety depend on both proper education and proper training. In fact, this training is often a gatekeeper for use, as governments, trade organizations, and even hospitals may require medical staff to be adequately trained before new medical devices can be used in their settings. External education and training of health care professionals is largely the responsibility of External Education teams within Medical Affairs. This article details the importance of the External Education function and describes best practices for the implementation of External Education related to medical diagnostics/devices within a manufacturer's organization.

INTRODUCTION

Clinical outcomes of medical technologies such as medical devices or diagnostics rather than pharmaceutical agents are dependent on the skills of the user.[1] Various publications on the adoption of new medical technologies have demonstrated that clinical competency in the use of therapeutic and diagnostic medical devices is acquired only after adequate theoretical and practical training and experience.[2] The studied procedures all had a discernable and specific learning curve in order to achieve proficiency, which is reflected in a positive correlation of, for instance, shorter procedure duration and lower complication rates with an increasing number of procedures performed.[3,4] As this is also acknowledged by regulatory bodies and reimbursement authorities, market approval and/or reimbursement are increasingly made contingent upon the availability of adequate user training commensurate to the risk profile of a medical device.[5,6] Competence and confidence in the deployment of medical devices are related to the quality of product and/or procedure training, which is mostly provided and/or sponsored by industry not only because of its obvious vested commercial interest in proper adoption and optimal clinical outcomes but also because they are the experts in the rationale of the design and thus the technical merits and limitations of their device/diagnostic.

REGULATORY REQUIREMENTS FOR MEDICAL TECHNOLOGY USABILITY AND TRAINING

Worldwide regulatory agencies appreciate the fact that medical technology safety depends on factors of human usability, both from the perspective of device design and on the side of training. For example, in the United States, the Food and Drug Administration includes Human Factors/Usability Engineering (HF/UE) review as a routine part of its premarket review process and has published recommendations for the industry guiding the application of HF/UE to medical devices.[7] Likewise, worldwide HF/UE is addressed by the quality standard from the International Electrotechnical Commission, IEC 62366, which specifies usability requirements for medical devices.[8]

In addition to design, quality standards such as ISO13485 address training needs for potential customers, with article 7.2.1 stating that an organization shall determine "any user training needed to ensure specified performance and safe use of the medical device."[9] Likewise, the European Union Medical Device Regulation (EUMDR) states that "manufacturers shall provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users."[10] For implantable devices and Class III devices, EUMDR additionally requires manufacturers to publish a Summary of Safety and Clinical Performance containing a suggested profile and training for users, whether they are laypersons or professional health care providers. For in vitro diagnostics, the EU In Vitro Diagnostic Regulation (IVDR) has similar requirements.[11] Various other country-level requirements for medical device training also exist; for instance, in Germany the Medical Device Act states that health institutions are responsible for adequate training of their staff on the medical devices they use and defines professional requirements for "medical device consultants" appointed by the manufacturer.[12] Recently, some device manufacturers have gone so far as to only supply specific high-risk medical devices exclusively to health care professionals who have successfully completed mandatory training and work in a health care facility that has capabilities to handle potential complications.

More and more other stakeholders such as hospitals and medical-professional authorities provide guidelines for privileging and credentialing qualified health care professionals in the performance of medical procedures with selected medical devices (eg, robotic-assisted gynecologic laparoscopy).

Privileging and credentialing is defined as "the process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care or services in or for a health care organization."[13]

Monitoring the performance during the life cycle of a medical device itself is a given, as it is mandatory for manufacturers to periodically evaluate the safety and clinical performance of marketed devices based on literature, filed complaints, and reported incidents.

THE DEVELOPMENT OF MEDICAL TECHNOLOGIES TRAINING WITH INTERNAL STAKEHOLDERS

In most MedTech organizations, meeting the aforementioned training needs/requirements is accomplished in tandem between Marketing and Medical Affairs functions. Commercial training curricula may include fundamental training programs, didactic sessions, training manuals, device demonstrations, simulations or benchtop models, case observations, or case reviews. Alongside these programs managed by Marketing, Medical Education teams within Medical Affairs create and deliver nonpromotional training programs that provide education on the safe and effective use of new devices in a fair and balanced way. This training can consist of specific product training, procedural training, disease state training, clinical data training, patient selection, or refresher trainings. The latter might include, for example, device and/or procedure updates or training for major changes that directly and broadly impact patient outcomes and warrant mandatory communication to all users. Depending on the device technology, Medical Education trainings may also be developed in partnership with additional internal stakeholders including R&D, Quality Assurance, Clinical Affairs, Regulatory, Global Physician Training, or other Medical Affairs staff.

THE DEVELOPMENT OF MEDICAL DEVICE TRAINING WITH EXTERNAL STAKEHOLDERS

Medical Education may also collaborate with external stakeholders to fulfill training needs. External experts are often identified through existing relationships with an organization's Medical Affairs teams. Alternately, external experts may not have an existing relationship with the organization but may be identified as highly experienced and knowledgeable about a treatment option or a disease state. If the training is directly related to a specific product, then it will be necessary to identify an expert who is a current user. When identifying external experts, Medical Education teams are increasingly prioritizing experts who are well spoken, approachable, and open to questions and discussion, in addition to having experience and expertise with a product or disease. Medical Education teams may also partner with appropriate societies that are already providing a credible platform for training, which may amplify an organization's reach.

EXTERNAL EDUCATION AS A NONCOMMERCIAL ACTIVITY

Regulations exists to ensure as promotional in nature rather than an educational tool.[14] However, regulations exist to ensure nonpromotional content of External Education programs and, in fact, there is significant mutual benefit for the medical community and for medical device manufacturers in ensuring an accurate understanding of the possibilities and limitations of medical devices and diagnostics. For example, MedTech Europe, the European trade organization of medical device manufacturers, explicitly states in its Business Ethics Code "The program must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event. The program must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective."[15] Furthermore, it underlines core principles when it comes to medical training and education such as separation of educational and transactional interactions, transparency, and disclosure of ties between health care professionals and the industry analogous to the US Sunshine Act.

In order to help dilute any potential argument that external education is promotional in nature, Medical Affairs teams need to not only ensure compliance to regulations and guidance, but should also confirm that the education is effective.

CONCLUSIONS

User training and education on medical devices are key for obtaining optimal clinical outcomes and minimizing complications. Local laws, regulations, hospitals, and trade organizations address the obligation of manufacturers to identify the training needs of target audiences and offer fit-for-purpose training and education opportunities. Ideally, the primary responsibility for external education is allocated to a noncommercial business function such as the Medical Education function within Medical Affairs so as to ensure a fair and balanced representation of device properties and supporting clinical evidence. The involvement of carefully selected clinical experts for program design, content review, and practical training increases the validity and credibility of programs offered and/or supported by the medical technology industry.

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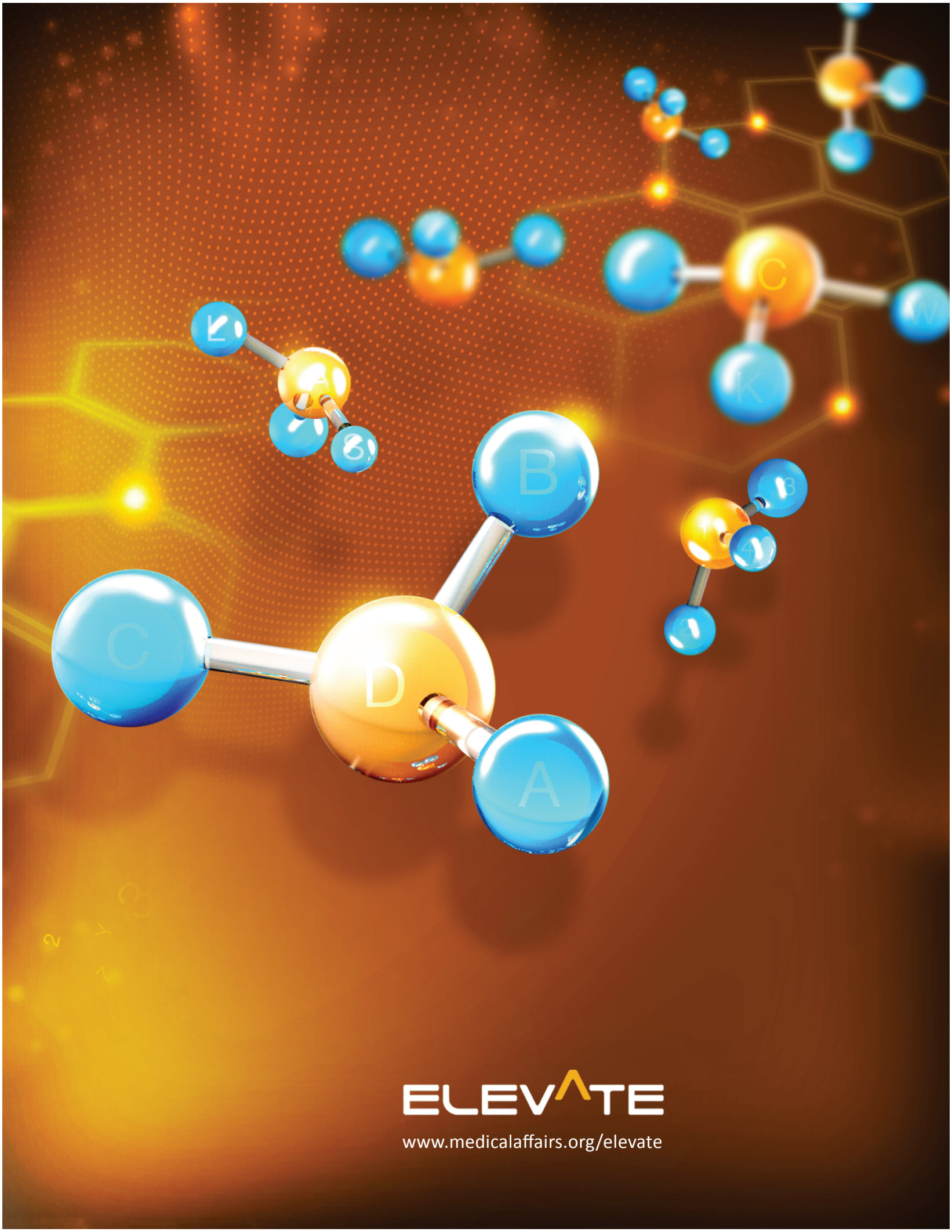

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