Special Article

Ethical Concerns of Congresses and Joint Winter Meetings of the Spanish Society of Pneumology and Thoracic Surgery∗

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ABSTRACT

The pharmaceutical industry contributes to the development of new drugs, provides funding for research and collaborates in continuing medical education. Although this relationship with medical practice is beneficial and desirable, commercial interests could potentially eclipse patient benefits and compromise professional integrity. Congresses and meetings of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR) agglutinate different spheres of knowledge, including aspects such as bioethics, management and communication, always centered on patient and their well-being. SEPAR congresses and meetings should provide sufficient economic benefits to be reinvested in research and other purposes which are reflected in SEPAR statutes in order to ensure the solvency, sustainability and economic independence of the Society. SEPAR has developed strict regulations governing the sponsorship and accreditation of training activities while striving for a balance between the interests of the industry and its own necessary independence, which results from the constant concern for maintaining good medical practice and complying with ethical aspects. This regulation is useful from an organizational and logistical standpoint, and it is necessary to prevent or resolve any possible conflicts of interest. Scientific societies should regulate common practices that could potentially result in conflicts of interest.

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Aspectos éticos de los congresos y reuniones de invierno conjuntas de las áreas de la Sociedad Española de Neumología y Cirugía Torácica

RESUMEN

La industria farmacéutica contribuye al desarrollo de nuevos medicamentos, promueve ayudas a la investigación y colabora en la formación médica continuada. Aunque esta relación con la práctica médica es beneficia y deseable, podrían anteponerse así intereses comerciales al beneficio de los pacientes y comprometer la integridad profesional. Los congresos y reuniones de la Sociedad Española de Neumología y Cirugía Torácica (SEPAR) aglutinan distintas parcelas del conocimiento, incluyendo aspectos como la bioética, la gestión y la comunicación, centrados en el paciente. Los congresos y reuniones de la SEPAR deben proporcionar beneficios económicos suficientes para reinvertirlos en investigación y demás fines que quedan reflejados en los Estatutos de la SEPAR, para garantizar la solvencia, la sostenibilidad y la independencia económica de la Sociedad. La SEPAR ha desarrollado un estricto reglamento que regula el patrocinio y la acreditación de las actividades formativas, buscando armonizar los intereses de la industria con la necesaria independencia, en línea con la preocupación constante por mantener la buena práctica médica y cumplir todos los aspectos éticos. Este reglamento es útil desde el punto de vista organizativo y logístico, y necesario para prevenir o resolver eventuales conflictos de intereses. Las sociedades científicas deberían regular algunas prácticas comunes que puedan originarlos.

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Introduction

The influence of the pharmaceutical industry on medical practices is an undeniable reality. This relationship embraces desirable beneficial aspects, such as the industry’s contribution to the development of new drugs, research grants and collaboration in continuing medical training, as well as other less desirable aspects, such as the possibility of putting commercial interests before the benefit of the patients.1

In addition to contributing a high percentage of the financial support for medical research, in Spain the funding of continuing medical training also falls largely on the pharmaceutical industry. This is due, among other factors, to the scant resources from the healthcare administration for training their professionals and the lower salaries of healthcare professionals, compared to other countries in the European Union. This situation makes continuing medical training practically impossible without the help of the industry. However, it is exactly this type of support that is considered undesirable by some academic sectors, since, it is argued, the investment in research by the industry and its influence on publications could lead to a distortion of the scientific evidence and hinder the objective evaluation of data.2,3

The involvement of the pharmaceutical industry in medical education is precisely one of the areas in which conflicts of interest may be generated, so a strict separation is required to achieve critical, unbiased training, based exclusively on scientific evidence. This objectivity is even more important when clinical practice guidelines or consensus documents which directly influence patient care are being drawn up. A recent survey showed that relationships between the executive staff of scientific societies and the industry were common, and that members had participated in decisions about protocols sponsored by companies with which they had a financial relationship. The conclusion was that the guidelines for the appropriate handling of conflicts of interest needed revision.4

In recent years, various prestigious publications have made a critical examination of these issues,5-11 and the debate on the strictness of the ethical guidelines established for relations between healthcare professionals and the industry remains open and is constantly evolving.12-14

In 2006 and 2009, the American Board of Internal Medicine Foundation (ABIM) and the Institute on Medicine as a Profession (IMAP) published joint recommendations on conflicts of interest.15,16 The American Medical Association (AMA) also has a committee specifically dedicated to issues concerning medical ethics, bioethics and legal and professional matters.17 It basically addresses all issues concerning the current influence of market incentives which could challenge the first principle of the medical profession, i.e., the commitment to place the interests of the patient first, with no interference in decision making.

The AMA defines conflict of interest in the relationship between the physician and the industry as the situation “when the financial interest of a physician enters into or threatens to enter into conflict with the best interests of his/her patient”.18 Other definitions proposed include “a set of conditions in which a judgment or action which should be determined by a primary value, defined by professional or ethical reasons, may be or appear to be influenced by a second interest”.7

To remedy the current situation and to prevent professional integrity being compromised in the future, academic institutions and scientific societies must regulate or take a position regarding some common practices which constitute conflicts of interests with pharmaceutical or electro-medical device companies and service suppliers. Although some international societies have produced guidelines in this respect,15,16,19 very few Spanish scientific societies have addressed these general issues, and much less in a detailed manner.20-23

In accordance with the above-mentioned premises, the aim of this paper was to analyze and publish how the Spanish Society for Pneumology and Thoracic Surgery (SEPAR) has addressed possible conflicts of interests and the ethical aspects of SEPAR congresses and scientific meetings, to determine a middle ground between the need for educational activities and updating medical knowledge and the interests of the pharmaceutical industry, within the context of the current situation.

Regulatory Framework of the Spanish Society of Pneumology and Thoracic Surgery

The SEPAR Statutes, in Article 4, specify that the activities of the Society will be to promote research in the areas of respiratory and thoracic medicine and health; to organize an annual National Congress, with the aim, among others, of presenting and discussing medical and surgical issues related with respiratory and thoracic medicine and health, scientific debate on findings, results and data in these areas; to pursue agreements and consensus positions of interest for the scientific community related with respiratory and thoracic physiology, epidemiology and pathology; to exchange opinions on scientific and professional matters regarding respiratory and thoracic medicine and health; to develop educational and continuing training activities; and to discuss and analyze any professional, educational, patient care, training or research matters that may be of interest to the Society.24

These statutes also state that, to achieve these objectives, the Society will be responsible for ensuring, by any means it considers appropriate, that the scientific level of this Congress is sufficiently high and that its structure and organization are optimal.24

In accordance with these statutes, in addition to the annual Congress, SEPAR will be responsible for organizing courses, meetings, conferences, symposia, short courses, workshops, seminars or any other scientific or professional event on matters relating to respiratory and thoracic medicine and health, as determined by the governing body of the Society or, by delegation, its organizational or management structures. SEPAR works with members of the Society who may require collaboration in the organization, management, sponsoring or supervision of courses, seminars, meetings or any type of scientific or professional event which is sponsored by those members, if help is requested. This will be provided that it is in accordance with the established regulations and the dissemination of the activities organized by the Society, as well as how much scientific and professional information is considered necessary, both for the scientific community and the healthcare administration, and for the patients and general population, in relation with the above-mentioned aims and objectives.

In 2008, the Regulations for SEPAR Congresses and Joint Winter Meetings were drawn up and updated in 2011 and 2012.25 The scope of these regulations is wide and the approach is detailed. Most of the issues are covered, including organizational aspects, such as the composition and functions of the Congress Committee (CCO), the functions of the Chairman of the Local Organizing Committee, the CCO’s relationship with the Board of Directors, and with the various Advisory Committees, as well as matters relating to the payment of speakers, relations with the industry, the media, publicizing the Congress and relations with service providers. These regulations address certain ethical aspects, so a large amount of the material discussed here has been reworked from this document, in addition to our consultation of specific bibliographical sources.

Ethical Aspects of the National Congress of the Spanish Society of Pneumology and Thoracic Surgery

The National Congress, together with the Joint Winter Meeting of the various areas, is SEPAR’s most important scientific event.
The Congress is a forum for the dissemination of scientific advances and technological innovations, designed for the exchange of knowledge between specialists in respiratory and thoracic medicine (pneumologists, thoracic surgeons, nursing staff and respiratory physiotherapists), and also with physicians from other specialties and different related professions, as well as specialists from other countries.

The Congress is the natural framework for disseminating the institutional image of SEPAR and raising awareness of the Society's activities among the non-scientific community, particularly regarding patient and media-directed activities. The Congress offers an opportunity for the participation of activities involving SEPAR-Solidarity and SEPAR-Patients.

The Congress provides a fusion of various areas of knowledge, including areas such as bioethics, management and communication, which are fundamental in current patient-centered medical practice, in which the patients' beliefs and expectations must of necessity be respected. The structure of the Congress, in addition, encourages and promotes relations between the various areas of SEPAR. Its objective is to develop and promote respiratory medicine in Spain and the exchange of knowledge among its members. This Congress is the instrument of dissemination of medical knowledge within our specialty, and participants are informed and trained in courses, scientific sessions, symposia, workshops and the trade show (Fig. 1).

The regulations already mentioned indicate that SEPAR should organize its annual Congress with a strongly ethical sense and content. The presence of the industry in the Congress is essential, as the industry represents an important factor in development and innovation in the field of respiratory therapeutics and diagnostics. However, on occasions, the primary scientific interest can be distorted by diverting attention towards considerations that are more commercial than medical, thus diminishing its intrinsic professional character and damaging the essential objectives of the organization.

For these basic reasons, the organization of the SEPAR National Congress is subject to strict regulations regarding the sponsorship and accreditation of educational activities, with the aim of achieving a balance between the legitimate interests of the participating companies and industry exhibitors and the necessary independence of judgment of SEPAR.

**Educational Activities**

The SEPAR National Congress and the joint area meetings, as an important forum for continuing and post-graduate training, will organize a wide-ranging program and up-to-date contents to allow the participant to achieve the best level of training in the respiratory field. The selected subjects will be directed at pneumologists and thoracic surgeons who are currently on specialist residency programs, and fully qualified pneumologists, thoracic surgeons, university-certified nurses and physiotherapists working in the field of respiratory medicine, primary care physicians and other professionals from similar specialties who are interested in receiving respiratory training.

The criteria for selecting the host city, which in no case will be chosen for its possible tourist attractions, and the hotels for the activities of the SEPAR congress, will be subject to the Pharmaindustry Ethics Unit regulations applicable at the time of holding the event. Currently, the applicable regulations are those set down in the Spanish Code for Good Practices for the Promotion of Medicines and Interaction of the Pharmaceutical Industry with Healthcare Professionals (Código Español de Buenas Prácticas de Promoción de Medicamento y de Interrelación de la Industria Farmacéutica con los Profesionales Sanitarios), October 2010 edition, as follows:

"It is generally considered that four-star hotels offer the appropriate standards for holding professional scientific meetings. Notwithstanding the above, the use of a five-star hotel may be permitted, under the following circumstances:

- High attendance of healthcare professionals (at least 200).
- Unostentatious business hotel located within the defined urban center, and
- It is the main site of the event."

The scientific program of the SEPAR Congress consists of a main block which includes the principal program, the assigned institutional sessions and the program for areas and courses, and a second section in which other industry-sponsored activities are listed, but under the strict supervision of the CCO.

**Congress Program**

This includes the Institutional Sessions, organized at the request of the Chairman or the SEPAR Board of Directors or proposed by the CCO and accepted by the Board of Directors. Sessions carried out jointly with other scientific societies from the same or associated specialties, whether Spanish or international, and others that are considered of interest to the strategic policy of SEPAR are considered institutional, as are the Manuel Tapia Formal Address, the Young Teaching Lecture and others which encourage integration between SEPAR members. These may be sessions with clinical, teaching, research or management content, preferably multidisciplinary or general, or others, as considered appropriate, proposed by the Board of Directors, the technical consultancy committees or the various SEPAR platforms.

Another important educational aspect of the SEPAR Congress are the Congress courses which are carried out at the proposal of the working areas or at the recommendation of the CCO, for reasons of demand and interest, and the resident training forums which are currently held on the first day of the Congress, under the tutelage of senior experts, coordinated by the CCO and the Continuing Training Committee.

The third aspect of the SEPAR congress program is the SEPAR working areas, consisting of symposia, conferences and scientific communications, in various formats, which are assigned time every year.

On the basis of the philosophy that in the current conception of the Congress, all these activities and their content are educational, they must be programmed exclusively by the SEPAR CCO, in conjunction with the SEPAR Board of Directors, the area coordinators and other advisory committees involved, such as the Teaching
and Continuing Training Committee, the International Relations Committee, the Press Office and any collaborations considered necessary.

Section 2 of the CCO regulations states that the coordination, organization, planning and financial management of all the activities related with the Society’s annual congresses and the joint winter meetings, and the supervision, control and inspection of any external service provider which may be contracted for the purposes mentioned in this section will be the responsibility and function of the CCO. In addition, the CCO will be responsible for managing any relations with the pharmaceutical industry in all matters pertaining to the annual congresses and winter meetings of the Society, without prejudice to the responsibilities of the working areas.

In the specific section referring to the Director of the CCO, in addition to the Director’s responsibility for organizational aspects, it will be his/her responsibility to supervise the Congress site and the sites of the Joint Winter Meetings and to represent the SEPAR Board of Directors in the presentations to the industry before the Congress is organized, to contact and meet the professional congress organizer (PCO) for the coordination of all activities, to propose satellite symposia requested by the industry to the Board of Directors for approval, checking that they meet the necessary requirements for scientific quality, to ensure that the official Congress documents contain the correct information according to the directives of the Board of Directors, and to present a financial budget before the Congress takes place, and a financial report after it is completed.

These Congress activities, particularly those involving courses, specialist medical training forums, symposia, conferences, “Lunch with the Professor” seminars, round tables, etc., must always meet the following requirements:

a. The medical information must always be presented objectively; this is the responsibility of the continuing medical training providers and of SEPAR.

b. The education provided by SEPAR through congresses and meetings must offer training based on 2 premises: transmission of knowledge by experts and information backed up by the best scientific evidence available.

c. The information must always be objective and impartial, and the teaching staff or speakers must not accept any type of sponsorship which gives the sponsor the right to influence the programs.

d. If the teaching staff and speakers have to use trade names in a presentation, the products or similar services of several companies must be mentioned generically.

e. The teaching staff and speakers must make the participants aware of the source of the documentation and iconographic material provided by the industry.

f. SEPAR does not consider acceptable any type of assistance that enables industry, in return, to select moderators, speakers, subject matter, content or documentation.

g. Intellectual property rights concerning the training material will correspond to the authors of the material, to SEPAR or at most, to co-ownership with the sponsor.

Sponsored Scientific Symposia

This section on congresses refers to the organization of scientific symposia sponsored by pharmaceutical or commercial companies. The so-called parallel or satellite symposia, the recently introduced debate sessions, and promotional sessions which may be included in the future are addressed here. SEPAR agrees that this type of industry-sponsored symposia or meetings may be organized, but it reserves the right to inspect the scientific and technical content of these events before they are accepted. These meetings are continuing training tools that have been traditionally designed by the industry itself, since the industry needs to transmit information on the results of studies which, in one way or another, are related with the products they provide.

However, the regulations at the current time are strict, and holding these symposia is subject to the following rules:

a. The commercial company that wishes to carry out a sponsored scientific symposium must send a request in writing to the CCO, which includes the title, subject matter and participants. The CCO will forward this request to the Board of Directors for their approval.

b. The complete plan for the symposium must be in possession of the CCO on the day on which acceptance of papers ends, so that it can be included in the subsequently-issued Congress programs with mention of the sponsorship of the company in question.

c. The symposium will be held during the period of the Congress, including the opening day, but outside the Congress timetable. The day on which it is to be held will be negotiated between the CCO and the sponsor company, and its priority will be set according to the date of receipt of the request in writing.

d. The parallel symposium will be held, subject to a financial payment which will be determined by the Board of Directors.

e. Expenses deriving from the symposium infrastructure (simultaneous translation, event stewards, technical resources, etc.) will be covered by the sponsor company. For setting up this infrastructure, the sponsor company will contact SEPAR’s PCO, which will inform them about the resources provided by the Congress and those which must be provided by the sponsor company.

f. In addition, the sponsor company will cover all expenses related with speakers.

g. The Congress Organizing Committee will assign the room where the symposium is to be held.

h. The sponsor company of a parallel symposium is entitled to announce the symposium in the official Congress documentation and to obtain the list of registered Congress attendees. Any other symposium advertising will be negotiated with the CCO.

In order to handle sometimes opposing conflicts of interests appropriately, and to avoid the possibility that the information is presented from a one-sided or incomplete point of view, these training activities must be governed by a series of regulations. In this respect, it is recommended that the program and contents are designed with the scientific collaboration of the various SEPAR areas, although this does not rule out the participation of experts from the industry who are involved in these areas of technological research and development. In this way, conflicts of interest can be handled appropriately and the possibility that the information could be presented from a one-sided or incomplete point of view can be avoided.

Certain ethical aspects, other than the purely organizational aspects mentioned above, must be taken into account:

a. Industry sponsorship will be expressly stated on all documents associated with the session (programs, books or any other form of documentation supplied, regardless of technical support: mechanical, optical, electronic, etc.).

b. The use of the SEPAR logotype or the Congress anagram will be avoided, except in those cases previously agreed and authorized.

c. The teaching staff and speakers may be susceptible to possible influences. For this reason, they must provide specific information in their presentation to help the participants make a critical analysis of the content and the scope of the messages provided.

d. The CCO must inform external suppliers (industry) that their training programs must have a balanced content with no bias
in the information, either in favor or against any product or service.
e. It is acceptable to pay reasonable fees to the moderators and speakers of these sessions, and to reimburse reasonable personal expenses, including travel and accommodation.
f. Promotional material given to the participants will be related exclusively with the content of the session.
g. Companies in the healthcare sector may pay Congress inscription fees for participants. In line with the transparency policy followed by SEPAR, any particular financing of attendees must be fully audible.
h. The RESPIRA Foundation (RESPIRA Spanish Lung Foundation, SEPAR) in all cases carries the maximum responsibility for the financial and economic organization of the Congress and the Joint Winter Area Meetings.

Grants and Assistance Sponsored by Industry

One significant and important way of using industry sponsorship is by way of specific grants for attending the annual SEPAR Congress. This support is essential for obtaining the participation of interested professionals. This type of grant, which includes the inscription, travel and accommodation during the annual Congress, has traditionally been aimed at pneumology and thoracic surgery residents, university-certified nurses and respiratory physiotherapists with at least 10 years of experience. Although this financial support originates in the industry, the logistical structure is the responsibility of the SEPAR and the CCO, working together with the corresponding PCO or, if applicable, external agencies considered appropriate for most efficiently managing this type of assistance.

In recent years, the sponsorship of grants for attending international congresses has been considered for residents in their final year of specialist training, who, as first authors of papers presented at the annual Congress, have deserved to be candidates for this type of assistance, due to their merits and according to the evaluation of an expert tribunal nominated for this purpose. This tribunal will be fully independent in their allocation of these grants, and the call for applications must always appear under the heading of SEPAR Grants, followed by the mention of the sponsorship of the corresponding company.

Ethical Code for Congress Financing and External Relations

The members of the CCO and the local organizing committee may not receive financial payment from the industry for belonging to these committees.

Financing of Speakers and Moderators at the Congress and Joint Area Meetings
- Speakers and moderators who are SEPAR members will not be financed by the Congress organization.
- The financing of speakers who are not SEPAR members and are invited by the areas will be covered by the working areas, except if the speaker also participates in an institutional event or in activities in more than one area, in which case the expenses will be shared with the Congress organization and/or corresponding areas.
- Institutional speakers invited by SEPAR (who are not SEPAR members), the board of directors, former chairmen, advisory committee chairmen and speakers at the Manuel Tapia Formal Address and Young Teaching Lecture will be financed by the Congress organization.

Relationships With Trustees and Patrons of the RESPIRA Foundation

These will be governed at all times by the provisions of the SEPAR Congress Regulations, notwithstanding the Spanish Code of Good Practice in the Promotion of Medicines and Interaction of the Pharmaceutical Industry with Healthcare Professionals (Código Español de Buenas Prácticas de Promoción de Medicamentos y de Interrelación de la Industria Farmacéutica con los Profesionales Sanitarios), 2010 edition, 26–28 which establishes that agreements with institutions, foundations, scientific societies, organizations or associations made up of healthcare professionals for the provision of any type of service to a pharmaceutical company, will only be permitted if those services:

- Are provided with the aim of collaborating in patient care, research, teaching/training or the organization of professional or scientific events;
- Are formally documented, and the contracting company keeps a copy of those documents; and
- They do not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of certain medications.

A clear distinction will be made within the Congress between product promotion (trade show and the industry-sponsored symposium program) and medical training and information within the official program. The SEPAR Congress cannot accept any sponsorship that confers a right to influence the official congress program or the official information provided to the public. SEPAR will evaluate the information provided by the industry in its annual Congress program.

The Congress organization will avoid the promotion of specific products or services from a company, either in the name of the Congress or in the name of SEPAR itself, and will also avoid the inappropriate use of the image and logotypes of SEPAR, the RESPIRA Foundation and the Congress.

The sessions sponsored by the industry must appear clearly as a sponsored session in all Congress publications and in the corresponding conference room, with a full list of the sponsoring companies. Information published by the sponsors must not be confused with the official Congress publications. The existence of sponsorship in the official sessions of the Congress can be acceptable provided that this is expressly stated, the objective nature of the information provided is ensured, SEPAR has complete liberty in the choice of contents, speakers, moderators and documentation to be provided, and finally, strict compliance with these regulations is enforced.

The Congress organization, with the aim of ensuring a training program of the highest quality and objectivity, will obtain the certificates of accreditation in continuing medical training and will inform the attendees of the mechanisms for obtaining them.

The Congress organization must ensure that the financial expenses are reasonable. In all cases, both social events and the documents produced for the attendees must be reasonable and rational. Cultural and social aspects must not only come second to the scientific aspect, but they also must not impact on or interfere with the scientific program. In particular, the social program of the participants must not coincide with the timetable of the scientific timetable.

The Congress organization must weigh up the cost of each sponsorship option offered by industry against the advantages obtained by SEPAR and the participants and must push for the rational use of resources.

The Congress organization agrees that inscription fees, and travel and accommodation expenses of the speakers
and moderators of the official program, whether they are members of SEPAR or not, may be financed by sponsors. This financial assistance will be paid via the PCO or the RESPIRA Foundation, but will never be settled directly between the sponsor company and the professional in question.

The financing of participants who are not qualified to prescribe or dispense medications, but who are considered healthcare professionals by Act 44/2003 of 21 November 2003 on Healthcare Professionals, is permitted, provided the same criteria are applied as to healthcare professionals who are qualified to prescribe or dispense medications according to the provisions of the Spanish Code of Good Practices for the Promotion of Medicines. Similarly, Article 7 of Act 44/2003 recognizes that university-certified nursing staff and physiotherapists are healthcare professionals. Consequently, psychologists, physiotherapists and nursing staff are healthcare professionals as set down in this Act, and as such, invitations addressed to them are permitted, provided the provisions of the Code are respected.

Only sponsors offering products or services for the prevention, diagnosis, treatment or rehabilitation of patients with respiratory disease or for the professional practice of the participants will be accepted.

Sponsorship options must be in line with the informative and professional nature of the Congress, and those which could damage the Congress’s good image must be avoided. In general, sponsored activities which create the impression of a lack of objectivity or which might imply an involvement of the participants with the sponsor will be avoided.

SEPAR will observe and enforce the regulations that are in effect regarding the advertising of medications and healthcare products at their Congress.

SEPAR must set up appropriate and effective mechanisms for achieving the effective compliance with this Code and the regulations derived from it, without damaging the interest and courtesy due to all members of SEPAR.

Conclusions

The annual Congress and the Joint Winter Meetings are the most important aspects of the scientific and educational activity of SEPAR, but they must also generate sufficient financial benefits for reinvestment in research and other objectives reflected in the SEPAR statutes, in order to ensure the solvency, sustainability and financial independence of the Society.

SEPAR has constantly strived to uphold good medical practice and to fulfill all ethical requirements in their relationships with the patrons and trustees of RESPIRA and the industry in general, and particularly in their most direct communications, such as their congresses and winter meetings, extending to all types of meetings organized or supported by SEPAR. Developing regulations in this area is useful from an organizational and logistic point of view, and is necessary to avoid or resolve any possible conflict of interest.

Conflict of Interests

The authors declare that they do not have any conflict of interests.

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