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The European Society of Intensive Care Medicine (ESICM) and the Surviving Sepsis Campaign (SSC)

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Sir: During the annual congress of the European Society of Intensive Care Medicine (ESICM) in Barcelona (September 2002), several hundred participants signed a declaration giving birth to the Surviving Sepsis Campaign (SSC) [1]. This declaration called on health care professionals and their organizations, governments, health agencies and public to support an initiative to reduce the mortality from sepsis by 25% within 5 years. This process involved a number of leading international societies coming together to develop an evidenced-based set of guidelines [2] for the management of severe sepsis that could then be implemented into clinical practice with beneficial effects for patient outcome. In recent months, however, this process has been strongly criticized by a number of authors [3, 4, 5]. These criticisms include the following issues:

1. The sponsors of the SSC were too closely aligned with the process.
2. This closeness allows the integrity of the guidelines to be questioned.
3. The implementation process of the guidelines has become part of a marketing strategy for one of the sponsors.

Although ESICM is not synonymous with the SSC, it is one of the founding societies of the campaign and by association is therefore criticized in these papers.

The integration of recent research findings into routine clinical practice is often slow, and this delay is part of the reason why patient outcomes do not always improve as quickly as the underlying data suggest they should [6, 7]. The production of evidence-based guidelines that aim to change current clinical practice to improve patient outcomes should therefore be actively encouraged as they can help accelerate this process. The SSC is therefore an example whereby research data are incorporated into a set of guidelines with the aim of producing recommendations that accelerate the change in clinical practice to a new and theoretically superior standard of care. All of the recommendations included in the SSC guidelines reflect an evidence-based appraisal of available data. Unfortunately the processes involved with the SSC have become entangled in a web of controversy despite the good will, best intentions and integrity of the leading experts involved in the development of the SSC guidelines.

The major issue that has been raised surrounds the need for industrial money to support the process. The fact that the SSC had a single sponsor that provided almost 80% of the financial support certainly amplified the consequences of such limitations and potentially led to the perception that biased behavior may have affected the process. It must be remembered that although there is the general perception that industry and one company in particular funded the guidelines, the relative contributions of the involved societies has never been either quantified or taken into account. When we consider the number of society officers and members that have worked on this process without reimbursement, we can begin to recognize that the relative contributions from industry are not perhaps as significant as we may be led to believe.

At the onset of this process ESICM recognized the limits that industrial support of this type of process change project may bring. The utilization of sponsors to support the process was not considered ideal; however, other streams of funding were not readily available and it was felt that careful handling of the situation would enable a clear and transparent method for supporting the process. The debate within ESICM bodies came to the conclusion that appropriate distancing between the sponsors and the guidelines writing committees would ensure that direct influence was kept to the minimum. These firewalls were instituted so that there were no industrial representatives present in either the original guideline development meeting in Windsor, U.K., or the revision meeting held in San Francisco in 2006. These firewalls should allow us to be confident that the SSC guidelines document is the considered recommendations from a number of esteemed scientific experts and remains scientifically valid. It should be stressed that the guidelines deserve to be judged only on their scientific merit, which will inevitably change following appropriate open debate and the appreciation and understanding of new data that becomes available. Whether or not

inappropriate industrial influence occurred within the SSC process is difficult to discern; however, it is plain to see that, in general, the interests of the marketing departments are in direct conflict with independent clinician's views.

The relationships between scientific societies and industry are complex and fraught with problems. Although inextricably linked, each society has very different strategies, behaviors, interests and end points. In theory, each group exists to improve the care of patients; however, in practice this is not always the prime motivation for any decision-making process. The primary objective of industry is to sell their products and make money for their owners or shareholders. Societies such as our own should impartially represent their members and should therefore provide advice and support that is in the best interests of patient care irrespective of the implications of that advice for outside parties. There is, therefore, and always has been, a potential for a direct conflict of interest between these groups. These conflicts can take the form of many different guises and can often be difficult to detect. Although economic conflicts can be disclosed and managed, academic issues are less easy to handle. If we take the example of the "New England Journal of Medicine" article about the SSC [3], authors that did not directly contribute to the recent multicentre randomized clinical trials on sepsis, despite their leading position at the National Institutes of Health, one of the most relevant institutions supporting and producing clinical research worldwide, may have had quite obvious academic interests in publishing their points of view. These conflicts have been neither declared nor discussed.

The ESICM now recognizes that the processes used for the development of the SSC have had many shortcomings, and these have led to the open criticism of the process. It is now important that ESICM be both, perceived as being aware of these past shortcomings and also to be dealing with them so that in the future similar conflicts do not arise. The ESICM has therefore developed a number of strategies and mechanisms to better understand these conflicts so that we can improve our relationships with industrial sponsors without impeaching our ultimate aims, and to minimize undue industrial influence:

1. The ESICM has an independent Scientific Committee responsible for all the scientific activities and an independent Education Committee to deal with educational issues and publications. It now insists on compulsory disclosure of potential conflicts of interest for all candidates to all posts in the Society, to officers and to invited faculty.

2. The ESICM facilitates the presentation, analysis and debate of over 1,000 original, scientific abstracts annually as a primary feature of its congress and, in the interest of scientific enquiry, encourages openness at these and all meetings and the stimulation of discussion and debate between speakers and the public.

3. In their article, Eichacker and coworkers [3] report that the journal "Critical Care Medicine" removed mention from an invited editorial [8] that the Infectious Diseases Society of America declined to endorse the SSC guidelines. "Intensive Care Medicine", the ESICM's official journal, has complete editorial and scientific independence, and its publications strongly debated the recommendations of the SSC [9, 10, 11, 12].

4. The ESICM now has a formal task force relating to issues of governance. Any internal or external issues causing concern can be referred to this body. The issue of how industrial relationships are handled, both now and in the future, is being addressed by an ongoing association between ESICM, the American Thoracic Society (ATS) and the Society of Critical Care Medicine (SCCM). The aims of this association are to develop and publish clear and transparent guidelines for ongoing relationships with industry and the handling of any conflicts. The ESICM hopes that these issues will allow an open, fair and honest relationship to continue with industry.

Now that these important issues have been raised, there is a need for us to stop and take stock. We need to reassure ourselves of the facts. If mistakes have been made, then they should be understood and corrected. The SSC is currently re-evaluating the guidelines taking into account studies that have been published since the original version. This process commenced in 2005 well before the recent critiques. This is now being done without financial support from industry. Hopefully this will lead to a document that will be accepted by a wider range of clinicians. We also need to ensure that the implementation of these guidelines occurs in a way that cannot be misconstrued as a marketing vehicle for any individual company. We have to accept that if the process of developing guidelines and recommending therapies continues, similar situations are likely to develop. What happens with the next company or their product? We need to develop a process that allows us to champion a therapy alongside the company that makes it, without being criticized for taking a parallel view. If we fail with this important issue, then we may simply end up encouraging companies to spend their valuable research money on other clinical specialties. This may not ultimately be beneficial for critical care.

We are confident that by openly discussing these issues we can move forward on future projects with our eyes widely open. Rather than decrying our critics, we feel it is important to listen and to learn. We have never doubted the principles of the SSC, or the probity of the leaders of ours and other scientific societies involved in the SSC, since the credibility of scientists and scientific organizations is based on their perceived independence and the reproducibility of any data produced. The ESICM considers it to be extremely important

to maintain this credibility, not just of itself as a society but also of each of its members. To this end it will strive to improve its relationships with its industrial partners with the aim of continuing to produce excellent research, education, recommendations and guidelines that improve the care and outcome for our patients.

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