

Sir

We have read your feature on Medical Devices with considerable interest and some concern. The various articles raise issues in three broad areas: individual products, the current regulatory system and ethical behaviour in the industry. The industry associations for the medical technology sector in the UK (ABHI) and Europe (Eucomed) are not in a position to comment on criticism of individual products, but we wish to respond on matters concerning device regulation and industry ethics.

It is of paramount importance that patients and consumers have the assurance of a high level of safety and quality of medical devices with clear and predictable safety requirements. In addition, European citizens should also be ensured timely patient access and choice to the best in medical technology that enables them to live healthy lives.

Europe is approaching almost 20 years of proven effectiveness of the Medical Devices Directive in regulating the safe introduction of new medical technology. The EU system is ahead in terms of patient access as European patients benefit from the latest in safe technology nearly 2 years ahead of their US counterparts and up to 5 years ahead of Japanese patients. Recent research published by Dr. Josh Makower\* shows that the regulatory process in Europe is more efficient than in the US while not compromising patient safety.

It is important to note that industry has consistently supported the need for regulation of medical technology and has itself argued in favour of the reforms currently proposed by the Commission and some Member states. The anticipated reforms address the criticism you raise with regards to the regulatory framework: overall management and coordination of the system by Member States' Competent Authorities, the designation and control of Notified Bodies, the availability of information (transparency), requirements for premarket testing and post-market surveillance.

With regards to industry behavior we would like point out that ABHI has for many years operated a Code of Business Practice, which was comprehensively revised in 2008 in conjunction with the revision of a similar Code of Practice operated by Eucomed. These codes lay down, in strict terms, the way in which manufacturers and suppliers should interrelate with health professionals and purchasers of medical technology. It is a condition of membership of both ABHI and Eucomed that members adhere to these Codes which are aimed at establishing and maintaining high standards of business ethics.

Alongside the ABHI Code of Business Practice, we now also have the UK Bribery Act which will be fully in force by July this year. ABHI has long been engaged in a dialogue with the authorities responsible for enforcement of the Act, and they have endorsed our industry Code of Practice as meeting the broad principles enshrined in the new legislation.

In conclusion, we think that much of your criticism of the regulatory system and of industry behaviour is alarmist and fails to take account of both the strong positive track record of the medical technology industry and the regulatory controls applying to it, as well as recent developments and reforms which are in the process of being made both by the authorities and by industry.

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John Wilkinson, Chief Executive  
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*\* 'FDA Impact on U.S. medical technology innovation', Josh Makower MD, Consulting Professor of Medicine, Stanford University, November 2010*