

## *David Earnshaw*

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re. Kathy Sinnott MEP versus David Earnshaw

I understand that Kathy Sinnott MEP has submitted a complaint to EPACA about me, in connection with a report I produced for Parliament about the European Commission's proposal on advanced therapies. She suggests that the report should have declared that I work for Burson-Marsteller.

Parliament published my report on advanced therapies on its website and Parliament decided what attribution to make regarding its authorship.

In response to Parliament's call for tender seeking experts on health and pharmaceutical policy I submitted a comprehensive CV and full biographical details including, of course, details about my relationship with Burson-Marsteller. Indeed, my CV refers explicitly to me "directing and providing EU healthcare and pharmaceutical-related policy consultancy" with Burson-Marsteller. I work part-time for Burson-Marsteller and I responded to the call for tender as an individual expert, not as Burson-Marsteller. I was paid by Parliament for the report I produced for it on advanced therapies.

I have previously worked for a Chair of the European Parliament's Environment Committee, a pharmaceutical company, a leading NGO active on development and health issues, a national government, have co-authored a book on the European Parliament and am a visiting Professor at the College of Europe, Bruges. It is this broad experience that would, I assume, have led Parliament to appoint me as an independent expert.

The framework contract I have with Parliament as an independent expert on health and pharmaceutical policies is separate from the work I do with Burson-Marsteller. It is not lobbying - the Parliament was my client for this work - and I consulted no-one in Burson-Marsteller or among its clients about the content of the report. I simply sought to give Parliament my perspective on the Commission's proposal on advanced therapies, on the basis of my wide experience.

Kathy Sinnott's complaint to EPACA is politically motivated. She is a member of the Independence and Democracy Group of the European Parliament whose largest constituent party is the UK Independence Party. I am a long-standing pro-European, Labour Party member and founder of [www.ukipwatch.org](http://www.ukipwatch.org). She is also opposed to stem cell research, an important part of advanced therapies, and the subject of my report for Parliament. This report argues, inter alia, that there is a "risk of opening new social divisions, and of undermining the idea of social solidarity in access to healthcare", as result of limiting patient access to the products of such medical research. Moreover, I have known for some time that some of Ms Sinnott's colleagues in UKIP have been contacting members of the press corps in Brussels to attack me on this. The political motivation for her complaint to EPACA is obvious. There has been no breach by me or by Burson-Marsteller in transparency.

A letter I sent to Kathy Sinnott when she raised this issue in Parliament's Environment Committee is attached.

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Ms Kathy Sinnott, MEP,  
European Parliament  
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13 September 2006

Dear Ms Sinnott,

Several Members have contacted me today to let me know that you referred to me and the report I drafted for Parliament on the advanced therapies proposal during this morning's meeting of the Environment Committee. I understand that you inferred that this was some kind of clandestine lobbying.

These are the facts:

I was appointed as an expert health and pharmaceutical policy adviser to the Environment committee earlier this year. This followed an open call for tenders (on the internet) and the submission of my full curriculum vitae, list of publications, and other details about my professional experience, including my current working commitments. I would be delighted to provide you with a copy of my credentials as submitted to Parliament. Alternatively, you or any Member can ask Parliament's secretariat for this.

My report on the advanced therapies proposal was completed at the end of March 2006, and appeared on the committee website subsequently. It is available for anyone to read, as is a second report on the same proposal produced by another expert.

You will note, should you read my report, that it argues the following points, among others (for your convenience I have emphasized in bold the key aspects):

Parliament should “**ensure that the privacy of patients receiving gene, cell and tissue therapy products has been sufficiently taken into account** by the Commission and that the planned Commission guidelines, once adopted, will do the same.” (p. 16, para 39)

“it is surprising that the explanatory memorandum for the proposal says remarkably little (one short paragraph) about traceability and privacy. **It is also remarkable that there is only one passing reference (at the end of recital 20) in the Commission’s proposal to the requirements of directive 95/46 on the protection of individuals with regard to the processing of personal data and the free movement of such data.**” (p. 16, para 40)

“Parliament should consider whether it is realistic and/or desirable to establish such a **publicly-run and possibly pan-European traceability system for gene, cell and tissue therapy products rather than the potentially fragmented compromise that the Commission has proposed.**” (p.16, para 42)

“The proposal does not refer to what **would happen to traceability data in the eventuality of a hospital, institution or private practice where the product is used closing. This should be rectified.**” (p. 17, para 43)

Crucially, the report argues that “Parliament will no doubt wish to consider whether it is appropriate for access to medicinal products developed for patients with at best intractable and most often incurable illnesses to be denied in parts of the European Union, despite those products having been authorized by the EMEA and being in use elsewhere in the Union. **It is one thing to enshrine this kind of restriction in the context of legislation on the quality and safety of cells (as in directive 2004/23); allowing patients in Europe to be denied access to products resulting from such technologies, whilst others benefit, is going a step further**” (p. 18, para 45)

Associated with the foregoing, the report also points out that:

“Neither is it sufficient to suggest that patients may travel from one member state to another to gain access to treatment: ethically restrictive member states would presumably prevent reimbursement of such treatment also. Hence, access would be limited to those patients who were able to afford treatment themselves, those with supportive families and friends, and those able to travel. **The non-Europe in bio-ethics therefore runs the risk of opening new social divisions, and of undermining the idea of social solidarity in access to healthcare.**” (p. 18, para 46)

And, in paragraph 47 it is argued that

“It will be important for Parliament and Council to debate this issue again as in this case the non-Europe in ethics will cut directly across patient access to authorized medicinal products. **At the very least, Parliament and Council should take political responsibility for confirming that the logic of non-Europe should apply in the case of this legislation** as it does for the human cells and tissues directive.”

On xenogeneic products, the report points out that: “Some religious organizations have suggested excluding xenogeneic products entirely from this proposal. Were xenogeneic products to be excluded the current fragmentation of regulatory approaches in Europe would be perpetuated and the shared scientific and assessment resources of the EMEA would be prevented from contributing to patient safety. Nobody doubts that risks exist in the use of xenogeneic cell and tissue products. However, **excluding such products from this proposal would succeed only in making their regulation and assessment less stringent and most likely lead to patients in some member states being exposed to risks that otherwise could be avoided.**” (p. 19, para 51)

The report adds that “it is for Parliament and Council to review the ethical issues surrounding xenogeneic products, in particular with a view to **taking political responsibility for the possibility that access to potentially life-saving therapies could be denied in parts of Europe, on the grounds of ethical unease.**” (p. 19, para 52)

The issues addressed in my report for the committee are important (as demonstrated by the briefest of glances at the extracts above). You and some of your colleagues may disagree with many of the points made. That is in the nature of independent advice – and why Parliament seeks a range of independent experts. I challenge you, however, to identify in my report any of the main issues I have addressed which correspond with the lobbying efforts conducted by the pharmaceutical and biotechnology industries, NGOs or others. In fact, as far as I can tell, industry lobbying has tended to focus on relative detail (the composition of the CAT, incentives, for example) rather than on addressing the main issues involved, namely, those related to stem cell research and the future fragmentation of Europe as a result of member state governments being able to deny patients in Europe access to new cures and treatments.

Indeed, within Parliament, it appears that the needs of European patients suffering from often incurable and intractable illnesses are being sacrificed due to an exaggerated and ultimately religious obsession to oppose stem cell and other medical research. I freely admit that I disagree with the view that religious and other transient beliefs should override the needs of European patients for new treatments and new cures. My position corresponds, I believe, with the view of the large number of European patients, whose voice is frequently not heard.

While the proposal’s legal base has quite rightly been questioned, partly as a result of the issues raised in my report, neither the rapporteur nor the Environment Committee has questioned significantly the logic – or political implications - of a Europe within which some patients will have access to new cures and treatments, and others will not. This is unfortunate, to say the least.

I understand that today you also referred to Burson-Marsteller, with whom I work three days per week in addition to my other work, such as teaching at the College of Europe, Bruges. Burson-Marsteller is a leading public affairs consultancy in Brussels which

complies entirely with relevant codes of conduct as well as having extremely strict internal rules which require absolute transparency in all communications with the institutions and others. In every communication Burson-Marsteller consultants make with the institutions on behalf of a client (whether face to face, in letter, e:mail or by phone), it is always declared who is the client, and the client is acknowledged in all Burson-Marsteller work.

The report I drafted for the Environment Committee is not connected with my work for Burson Marsteller. Neither is it lobbying. The report I drafted was produced for the Committee and sought to take account (as you will see when you read it) of the committee's likely concerns (it addresses in detail, for example, commitology) based on my knowledge of the Committee, and its work on pharmaceutical policy, over the last 20 years. It is worth adding that I have never lobbied on behalf of a pharmaceutical company or other interest on this legislation and neither has Burson-Marsteller advised clients on it either.

Finally, no-one is "independent": people work for businesses, NGOs, governments, political parties, etc. That is why it is important to be transparent, as I was, about credentials and experience, and why Members may either accept or reject my arguments, on their merits. Again, that is the reason Parliament has a range of experts to provide advice that the committee may either accept or ignore. Also, ultimately, politicians decide, not experts.

In future, I would be obliged if you would have the courtesy to contact me directly, preferably before attacking me, should you have any questions about my work.

Yours sincerely,

David Earnshaw

cc. ENVI Committee chair and Vice chairs  
ENVI Coordinators  
ENVI Committee Secretariat  
M Mikolasik, D Roth Behrendt, F Ries, H Breyer