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Karl Heinz Florenz,
Chair,
Committee on Environment, Public Health and Food Safety,
European Parliament,
Brussels.

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Dear Mr Florenz,

As you know, a member of your Committee raised my role as an independent expert to the Committee and, in particular, the report I submitted at Parliament's request in March 2006 on advanced therapies, during the meeting of 13-14 September 2006. Though I responded to her unfounded claims in writing and at length the same day, Ms Sinnott and the press attaché of her group have subsequently pursued the allegations, including by submitting a complaint to the European Public Affairs Consultancies Association (EPACA) - which was subsequently rejected - and also through briefing journalists. At no point still has Ms Sinnott had the courtesy to discuss this issue with me herself or even reply to my letter.

I had hoped that my long and detailed response to Ms Sinnott would clarify any outstanding concerns over whether I had been completely transparent about my other professional commitments and also any concerns over potential conflicts of interest. Inevitably, my letter to her found its way immediately to an anti-European website, becoming readily available for all to read.

You will recall that I also challenged Ms Sinnott to identify "any of the main issues I have addressed which correspond with the lobbying efforts conducted by the pharmaceutical and biotechnology industry, NGOs or others". Though I expect she and other Members have been lobbied by many different interests on this proposal, I have yet to hear from her or any other Member of a single example where the important concerns I raised correspond with industry or other lobbying. Indeed, having checked my text carefully, it is obvious that where I do raise issues also addressed by industry I have invariably taken a different position from that suggested by industry in the ways forward I propose for Parliament.

Despite the events in Committee during September, some occasional journalistic interest since, and some rather silly campaigning about my role by minor NGOs, I had thought that any fair minded person would recognise that I had actually been entirely transparent at all times about my experience, professional commitments and expertise. And, as my report is available to be read on the internet, as is much of the lobbying material submitted by affected interests of all kinds, I had also thought it a relatively straightforward task for anyone with even the most basic of research skills to be able to compare my approach with that of industrial, NGO or other interests, thereby confirming that any allegation of conflict of interest was unfounded in practice. I was wrong.

Last Thursday a major European environmental NGO launched a high profile public attack on me with the title “Lobby Scandal: David Earnshaw accused of conflicting interests”. As usual, the first I heard of the allegations was when it was launched publicly by press release. This personal and vindictive campaign against me (at <http://www.foeeurope.org/>) involves another complaint to EPACA, this time by the NGO concerned and makes further allegations that a conflict of interest exists between my role as an independent expert to your Committee and my other professional commitments (namely, working part time with Burson-Marsteller). The dossier disseminated by the NGO as part of its campaign also includes photocopies of material (my cv and details of my publications and other experience) which I submitted to Parliament in response to its call for tender for independent experts in 2005 – and which is now on the NGO’s website. Interestingly, the NGO fails to point out that the cv they attach to their press release was the very one that I included in my response to Parliament’s tender and which fully and transparently discloses all my interests.

The campaign launched against me last week is based on either ignorance, willful distortion or is simply duplicitous. Friends of the Earth Europe has set itself up as judge and jury – and proclaimed my guilt. It is claimed that a one paragraph descriptive reference on the Burson-Marsteller website about the advanced therapies proposal (along with information and updates about many other European affairs issues), published four months after my report was submitted to Parliament, constitutes a conflict of interest and demonstrates that the conclusions drawn in my report to Parliament are “in line with the broad agenda of the pharmaceutical industry of avoiding national bans in order to ensure the sale, use or supply of products.” This is blatant nonsense which obviously demonstrates nothing of the kind. A one paragraph marketing piece on a website can hardly constitute a conflict of interest.

Friends of the Earth Europe also claims that a quote from a German Pharmaceutical Industry Association (BPI) submission to the Commission on advanced therapies demonstrates that “both Mr. Earnshaw and the pharmaceutical industry argue for a similar position to avoid national bans and promote harmonized regulation and that the industry did lobby in favour of such a position.” This is also blatant nonsense. Hardly anyone is opposed to a European regulatory framework to license advanced therapy medicines – and it is that which the BPI is supporting. That is very different, however, from challenging – as did my report – the possibility of member states being able, under

European law, to ban to patients the sale, supply or use of medicines licensed by the EMEA/Commission – a possibility so far only available to member states in the case of contraceptives and abortifacients.

Moreover, the BPI submission was made in connection with a May 2005 pre-draft of the Commission's eventual proposal. If the NGO had bothered to check it would have discovered that this pre-draft did not even include the provision enabling member states to deny the sale, supply or use of medicines!

It might be useful of me, for the record, to demonstrate the very different position to mine which is held by the pharmaceutical and biotechnology industries. Firstly, the EFPIA – Emerging Biopharmaceutical Enterprises position paper (at http://www.ebe-biopharma.org/index.php?option=com_news&task=view&id=66&Itemid=28&lang=en, dated 2006) states the following:

“EBE members believe that such decisions of an ethical nature should be dealt with at the national, Member State level, to respect the sovereignty of those countries and to allow individual groups of EU citizens to reach their own ethical and moral decisions. Individual Member States that wish to ban such products from their territory would be allowed to do so under the provisions of the amendments proposed in ENVI 109 and ITRE 39.”

Secondly, the EuropaBio Policy Brief on the advanced therapies Regulation (at <http://www.europabio.org/relatedinfo/Advancedtherapiesregulation.pdf>, dated June 2006) states:

This is “an important piece of legislation that should be supported. It seeks to solve several problems caused by the lack of European law in this field. It will be a positive step forward, because:...Member States that are opposed to certain cell technologies on ethical grounds may continue to prohibit them in their national markets.”

The report I submitted to Parliament takes a diametrically opposed position to that of the organizations quoted above, which are the trade associations representing in this case the relevant parts of the pharmaceutical and biotechnology industries. I hope this confirms once and for all that far from having a similar position to that of the pharmaceutical industry, I have actually set out an approach which is independent and in line with what I regard as the policy preferences of the Environment Committee. I assume my position is also different from that of those NGOs questioning my motives – but they do not tell us what their position on advanced therapies is. Perhaps they are just comfortable attacking anything European in the interests of cheap publicity!

It might be useful, however, with a view to further dispelling any outstanding doubt there might be about the rationale underlying the approach I adopted in my report for your Committee, for me to set out three over-riding influences on my thinking on advanced

therapies, and in particular on article 28 of the Commission's proposal. These have nothing to do with the interests of the pharmaceutical industry or other interested parties.

Firstly, your Committee has a long history of addressing what are ultimately ethical issues. Halting the slaughter of baby seals in Alaska in the early days of the Environment Committee, the consideration of what EU role there could be regarding aid to the terminally ill (with Leon Schwartzberg's hearing on that subject in 1991), bringing an end to the testing of cosmetics on animals, and halting the suffering caused by leg-hold traps, are all ethical questions on which the position of the Committee has been absolutely clear. As you know, there are many more examples. Even in the area of biotechnology, it was an amendment tabled in your Committee by Ian White that found the compromise necessary in Parliament to allow adoption of the biotechnology patenting directive, by inserting an oversight role for the European Group of Ethics into the directive, at Article 7 – an approach that was also used on the GMO legislation later. While Council has objected frequently that “Europe doesn't do ethics”, the simple fact is that the regulation of economic activity falling within the competences of your Committee inevitably takes EU law frequently into the area of ethics – if it didn't there would be no EU law banning the animal testing of cosmetics for example, and French law on animal testing would over-ride European law now banning such practices! In the past, the Environment Committee has had an important and remarkable record in confronting the thinking of national governments on such issues, to the benefit of Europe's citizens.

I considered that the Commission's proposal on advanced therapies, which seeks to legitimize in European law the idea that for some member states access to new medicines and other treatments would be limited to patients who are able to afford treatment themselves, those with supportive families and friends, and those able to travel, was likely to be politically unacceptable to the majority of Members of your Committee. It is that position as you know which is put forward in my report. I stand by that position. I also continue to oppose the potential to open up new social divisions, and of undermining the idea of social solidarity in access to healthcare, which could result from the Commission's proposal. Over the years, that has always, I believe, been the position taken by a majority of members of the Environment Committee. Indeed, hardly a month passes without the Committee arguing for equity in access to healthcare for Europeans.

Secondly, as I pointed out to Ms Sinnott previously, I regard it as important that religious beliefs should not over-ride the needs of countless European patients for new treatments and new cures. Again, this is a position which corresponds, I believe, with the view of the vast majority of European patients organisations, whose voice is frequently not heard and, as pointed out above, here contrasts starkly with that of the pharmaceutical industry. The real problem, as we all know, is that on the issue of stem cell research in Europe the coalition of convenience of green, religious and anti-European campaigners coalesces, frequently drowning out the interests of patients and the voice of reason.

Finally, we all have family members and friends who would not be alive today but for having benefited from the fruits of medical research. Having lived through a partner's

fight with cancer for three years, a fight which was ultimately unsuccessful, in a member state other than her own, I am only too aware of the need for barriers to treatment in Europe to be removed, not new ones raised. It is outrageous that the personal attacks now being made on me ascribe to me shallow commercial motives when my experience is that of having lost a wife – and mother of a young child - to cancer. The vested economic interests that I am supposed to represent are truly insignificant in comparison with this profound and personal experience, an experience which unfortunately is so similar to that faced by so many other Europeans.

In these circumstances, and in view of the vindictive, personal, ignorant and stupid attacks on me, I shall be writing separately to Friends of the Earth Europe to seek a formal apology for the defamation to which I have been subject and to gain their acknowledgment that the research they conducted simply failed to set out the correct industry position and quoted from an industry position paper commenting on a pre-draft of the Commission's eventual proposal. I shall also, of course, be writing to the Director of Friends of the Earth (England and Wales) to resign as a paying supporter of that organization, which I have been for nearly twenty years. While I continue to support the objectives, inter alia, of confronting climate change, promoting sustainable development and strictly controlling the effects of human activity on the environment, I will have no part in an organization which indulges in personal attack and which so obviously propagates bogus claims and lies.

This case also raises questions, however, which need to be addressed by Parliament. How can Parliament have available to it the widest possible range of expertise when one set of interests will quite naturally seek to discredit the views of those they oppose? Where does the concept of conflict of interest start and finish, when anyone opposed to a particular view or individual can allege that a conflict of interest exists? How should Parliament respond when expertise provided to Parliament becomes part of the political discourse - including that about Europe – thereby distracting attention from the real issues? What responsibility does Parliament have to ensure that independent experts are not subject to personal attack and defamation – including by Members and their staff? After all, if independent advice is worth having, it is highly likely to be uncomfortable for some of the interests involved. Should personal data submitted to Parliament as part of the process for recruiting experts be made available to vested interests outside Parliament and, if so, which personal data? I have no objection in this case and have nothing to hide - but this does raise further interesting questions about Parliament's protection of individuals with regard to the processing of personal data, privacy, and the ownership of personal data under Community law. Is signature of a declaration of impartiality and availability (in this case conveniently overlooked by Friends of the Earth and others) undertaking to execute responsibilities in full independence of other commitments, sufficient to guard against victimization by outside interests? How can Parliament - and its committees - ensure that its choice of independent experts, made transparently following open calls for tender and in full knowledge of personal commitments, is not undermined by smear campaigns such as the one which has met the decision of Parliament to appoint me as an independent expert? There are many more questions that could be raised.

In my case I had assumed, as apparently did Parliament, that the breadth of my experience – including uniquely NGO, business and political experience, including on healthcare and pharmaceutical policy and legislative issues with the Committee over many years – would be valuable to Members. I consider that still to be the case. Over the course of more than twenty years working on this and related issues I have had to critically assess all sides of the argument on most healthcare (and environmental) issues, and I have always sought to do so with integrity and frankness. This incident, however, is now starting to undermine the valuable role played by your Committee and by Parliament. The unwarranted and continuing personal attacks on me mean that I shall not be responding to the new call for tender for external expertise currently in progress. Also, the interests of Parliament would not be served through a perpetuation or a repeat of the unwarranted attacks to which I have been subject.

I apologize for writing at such length. I remain proud of the contribution I have been able to make to the work of your Committee over many years and in different ways. I will be writing separately to Friends of the Earth Europe and I shall be asking them to place this letter on their website with the same prominence as that given to their attack on me. I have copied also the political group coordinators on the Environment Committee and the rapporteur and shadow rapporteurs on the advanced therapies proposal.

Best wishes

David Earnshaw