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David Earnshaw Sprl david.earnshaw@skypro.be

Brussels, 13th December 2006

Dear Mr. Earnshaw,

On behalf of Friends of the Earth Europe, I would like to respond to your e-mail from December 5th and the letter you have sent to Mr. Florenz, Chair of the Committee on Environment, Public Health and Food Safety of the European Parliament.

Contrary to what you stated, Friends of the Earth Europe did not subject you to defamation. We submitted a complaint to EPACA on the basis of their existing Code of Conduct. EPACA has previously stated that the complaint procedure is open to NGOs and we are simply making use of that possibility. We have argued in the complaint, and we will continue to argue until we are convinced of the opposite, that we believe that there is a conflict of interest or the appearance of a conflict of interest between your work for the European Parliament and your advisory work for pharmaceutical companies. According to article 11 of EPACA's Internal Regulations, this is exactly the basis for a complaint. Article 11 mentions explicitly that there is such appearance of conflict 'if a company was hired by an EU institution to do a study or survey, or supply advice, on a key policy issue in which important PA clients have an interest'. That is what is at stake here. Earnshaw SprI is selected (hired) for a panel of experts by the European Parliament to advice the ENVI Committee on public health issues. Earnshaw SprI is also hired by Burson Marsteller to advise - among others - pharmaceutical companies, who do have a clear interest in the public health issues the ENVI Committee is dealing with. This constitutes a clear and obvious conflict of interest.

The main point of our complaint is not whether you have or have not taken a different position from that suggested by industry in the specific briefing paper that you wrote. Our main point is that in our view a lobbyist or advisor for the pharmaceutical industry can not at the same time be an independent health expert for the European Parliament. Being a health expert of the ENVI Committee, you have offered your services on a wide range of environmental and health related issues, going beyond the specific topic of the briefing note that you submitted. You have thus offered your services on policy issues where several of your clients have an interest.

You might not be happy with that complaint, but that doesn't qualify our act as defamation.

You mention in your letter to Mr. Florenz that you have been entirely transparent in your application to the parliament and that you thought that 'any fair minded person would recognise that'. You might have noticed that Friends of the Earth Europe did not submit the complaint to EPACA on the basis of the argument that you did not declare the interests represented (article 6 of the Regulation). We do acknowledge that you mentioned in your CV your work for Burson Marsteller and your consultancy for pharmaceutical companies and therefore did not base the complaint on that argument. We even mentioned in our complaint to EPACA that you stated in your own CV that you advise pharmaceutical companies. So your statement that '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' is completely ungrounded.

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Friends of the Earth believes that all lobbyists targeting the EU institutions should provide full transparency on:

- the clients/organisations/companies lobbied for;
- the issues on which the lobby took place;
- the related budgets.

Although you have mentioned in your CV that you worked at Burson Marsteller for companies such as Novartis, Pfizer and Chiron, both Earnshaw Sprl and Burson Marsteller have so far failed to make public a full list of their pharmaceutical and biotechnology clients, the issues lobbied on and the fees for lobby/consultancy/advisory work.

You mentioned in your letter to Mrs. Sinnot that you have never lobbied on behalf of a pharmaceutical company or other interest on the advanced therapy medicinal products legislation and neither has Burson Marsteller advised clients on the legislation that was the subject of your briefing note. As long as the precise information about the clients of Burson Marsteller and Earnshaw SprI is not available, it is impossible for Friends of the Earth Europe, decision makers, the general public and any other interested stakeholder to check if that statement is valid. The declaration of impartiality and availability that you signed is not sufficient for us as long as the necessary information to check the validity of this statement is also not available. Again, I would like to point to EPACA's Code of Conduct, which speaks explicitly of avoiding a conflict or appearance of a conflict of interest. It should have been clear to you that such conflict of interest would exist.

In the complaint submitted to EPACA Friends of the Earth Europe mentioned the example of the German Pharmaceutical Industry Association (BPI) to illustrate that the pharmaceutical industry did argue for avoiding national bans. You pointed out that this statement is not correct and that several pharmaceutical and biotechnology companies have underlined the authority of member states to decide on ethical issues. You are right in that. The example we provided does not prove that pharmaceutical companies have lobbied against national bans. We acknowledge that and we apologize for it.

Nevertheless, that does not imply that your advice against national bans does not correspond with the interests of parts of the pharmaceutical and biotechnology industry to have as few bans as possible. Some of the companies have taken a very pragmatic approach. A position paper of the European Biopharmaceutical Enterprises (EBE, which you refer to in your letter) implies that they rather accept national bans instead of an EU-wide ban when they state 'We urge MEPs to let Member States decide for themselves on which products will be allowed and which not and to not attempt to use this Regulation to force EU-wide bans which run contrary to national law in several Member States' and 'Proposed amendments attempt to create EU-wide bans - even in countries that currently allow such research - and would to deprive patients of benefiting from potential treatments that could be developed in the future. Consequently, EBE members request MEPs to reject the list of unnecessary amendments that seek to ban or restrict future research across the EU ^d.

http://www.ebe-biopharma.org/index.php?option=com_news&task=view&id=66&Itemid=28&lang=en

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Also EuropaBio takes a very pragmatic approach. EuropaBio Secretary General Johan Vanhemelrijkck, in his closing statement at EuropaBio Industry Hearing on Tissue Engineering and Advanced Therapies, Radisson SAS Brussels, 9 Nov 2005: 'The European Parliament will question stem cells, and the Commission's solution to that is Member States subsidiarity. Some of the discussion that went on was about confidence in the competence of the competent authorities of the Member States. Now, are we going to have a single market of patients and not of products? That's a question. On the other hand I understand fully how the Commission comes to that, because if they don't, then legislation will not go through and we will loose another couple of years. So there will be geographical jealousy. In Euro-speak we call that best practice. That means that patients from a certain country will be able to get treatment and others in other countries will have a problem. Best practice then would be: let's also treat those patients.'

So also EuropaBio rather accepts national bans instead of the risk of having EU-wide bans. Furthermore, EuropaBio proposes a public register that will help patients to get around national bans: 'Additionally, we believe it would be in the interest of European citizens if the Commission created and maintained a public register of such prohibitions or restrictions by Member States, updating it on an annual basis. This would ensure transparency, enable patients to know where they may or may not find certain types of treatments and facilitate business planning for companies².

Altogether, when in your briefing note you argue against bans (including national bans), that seems to correspond with the interests of parts of the pharmaceutical and biotechnology industry.

In your letter to Mr. Florenz you accuse Friends of the Earth Europe of being judge and jury and proclaiming your guilt. This is incorrect. We submitted the complaint and of course we believe that our arguments are justified, otherwise we wouldn't submit the complaint. And indeed, we do accuse you of a conflict of interest. But that is a fully normal procedure. A plaintiff filing a complaint in a (semi) legal procedure usually accuses the other party of not adhering to the rules. That is very different from defamation and being the judge and jury.

Furthermore you suggest that Friends of the Earth Europe accuses you because you have a different opinion as we do on advanced therapies. However, you are missing the point of our complaint. It is irrelevant what our position is. We are not arguing that your position is right or wrong. Many of us might even agree with your position. The point is that we are claiming that your participation in the expert panel of the ENVI Committee constitutes a conflict of interest.

Friends of the Earth Europe does acknowledge that there is also a responsibility for the European Parliament in this case. We believe that your application for the expert panel should not have been approved by the Parliament. For that reason we have addressed this issue to Mr. Florenz. We have asked him to reconsider the decision to appoint you as an expert to the ENVI Committee. We also asked him to review the selection process for external experts, e.g. by adopting criteria that would exclude candidates that may have a conflict of interest or the appearance of a conflict of interest.

At the end of your letter to Mr. Florenz, you raise some important questions that need to be addressed by the European Parliament. Friends of the Earth Europe believes that this conflict of interest could have been avoided if the ENVI Committee would restrict its experts to those who do not have ongoing close relationships with parties that have a direct interest in what the ENVI Committee is deciding on. We believe that the EPACA Code of Conduct does give a good description of the kind

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of cases that should be avoided. Full transparency of lobbyists (including a full overview of clients, issues lobbied on and fees) is another important condition to avoid conflicts of interest as the one discussed here.

You requested Friends of the Earth Europe to put your letter to Mr. Florenz on our website. We value transparency highly and will publish your letter as well as our response to that on our website.

Finally, I would like to mention that there has been no involvement of Friends of the Earth England, Wales and Northern Ireland in the submission of the complaint to EPACA.

Yours sincerely,

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Paul de Clerck

Corporate Campaigner Friends of the Earth Europe

CC.

Karl Heinz Lorenz, Chair of the Committee on Environment, Public Health and Food Safety

Tony Juniper, Director, Friends of the Earth England, Wales and Norhern Ireland

EPACA