COMPLAINT IN RELATION TO EPACA'S CODE OF CONDUCT

'Conflict or appearance of conflict of interest' constituted by Mr. David Earnshaw

The European Parliament's Committee for Environment, Public Health and Food Safety (ENVI) established a panel of 7 public health experts at the end of 2005, following an informal call for interest. A high official from the Committee's secretariat explained their motivation for establishing the panel as follows: 'The idea with the panel of public health experts was to protect the Committee from being too dependent on lobbyists, trade organisations and industry. Often we trust the European Commission's legislative proposals, but we also want to create our own opinion. We want to become independent from the European Commission and can tell them when they are wrong'.

One of the seven experts who was selected to be on the panel is Mr. David Earnshaw. In March of this year, Mr. Earnshaw submitted a briefing note on advanced therapy medicinal products to the ENVI Committee.

Mr. Earnshaw is a well known lobbyist in Brussels. He has worked for several companies and organisations. According to his own CV (see attachment), from 1996 till 2001 he worked for SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline, one of the major pharmaceutical companies). From 2001 to 2002 he was working in the Oxfam EU office and since 2002 he is part-time Managing Director of the Brussels office of Burson Marsteller where he is 'directing and providing EU healthcare and pharmaceutical related policy consultancy for several major pharmaceutical companies'. Mr. Earnhshaw adds in his CV that 'at Burson Marsteller he specialises in EU health and pharmaceutical policy issues, advising companies such as Novartis, Pfizer and Chiron as well as pharmaceutical and vaccine industry bodies'.

Violation of EPACA's Code of Conduct

Friends of the Earth Europe believes that, by becoming a public health expert advising the ENVI Committee, Mr. Earnshaw has violated the EPACA Code of Conduct and the EPACA Internal Regulations.

The relevant article of <u>EPACA's Code of Conduct</u> is the following:

In their dealings with the EU institutions public affairs practitioners shall: (i) avoid any professional conflicts of interest;

The relevant article of EPACA's Internal Regulations is the following:

Conflict of Interest

11. Similarly, they should be careful to avoid any conflict or appearance of conflict of interest between any work for or professional relationships with public sector institutions, and lobbying for private clients (it would for example be open to such appearance of conflict

¹ http://www.corpwatch.org/article.php?id=14119. This article is a translation of an article that appeared in the Swedish magazine VI: www.vi-tidningen.se

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).

Mr. Earnshaw has established a 'conflict or appearance of conflict of interest between any work for or professional relationships with public sector institutions, and lobbying for private clients'.

EPACA's code of conduct clearly does apply to Mr Earnshaw, as Burson Marsteller is a member of EPACA and Mr Earnshaw works for both Burson Marsteller and the ENVI Committee via the company David Earnshaw Sprl.

Conflict of Interest

By performing as a health expert for the ENVI Committee and writing a briefing note for the Committee about advanced therapy medicinal products, David Earnshaw supplied advice on a policy issue (healthcare and pharmaceutics) in which his important public affairs clients have an interest. This is a breach of article 11 of EPACA's Internal Regulations.

In a letter of Mr. Earnshaw to members of the ENVI Committee², he states that he has 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 his briefing note.

Perhaps Mr. Earnshaw has never lobbied personally on this issue. But it is impossible to check if his claim is correct, because neither he nor Burson Marsteller provide a detailed list of pharmaceutical clients and the issues they lobbied on for these clients. However, looking at Burson Marsteller's website on their 'Hot Issues from Brussels' July 2006³, it shows that they do provide information on the Advanced Therapies Regulation. That suggests that some of their clients actually do have an interest in this issue. Furthermore, by being a health expert for the ENVI Committee, Mr. Earnshaw is expected to advise MEPs on environmental and health issues in general, not just on the specific topic of the briefing note he submitted. His pharmaceutical clients definitely have an interest in environmental and health issues in general.

Mr. Earnshaw also challenges MEPs in his letter to the ENVI Committee to identify '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 his briefing paper on advanced therapy medicinal products, Mr. Earnshaw advocates against member states banning some advanced therapy products. In the executive summary he writes: '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, and licensed by the European Commission, to be denied to patients in parts of the European Union. While this approach may be legitimate in the context of legislation on the quality and safety of cells (as in directive 2004/23), denying patients access to medicinal products resulting from such technologies, whilst others in Europe benefit, is

² http://englandexpects.blogspot.com/2006/09/new-labour-lobbyist-caught-in-breach.html

http://www.bmbrussels.be/hotissues/hi 200607.php

going a step further. At the very least Parliament will need to take political responsibility for confirming that the logic of non-Europe should apply in this case, to the likely detriment of some patients'.

The Burson Marsteller 'Hot Issues from Brussels' July 2006 notes in regard to Advanced Therapies Regulation that 'of particular interest is that the proposed Regulation would leave to the individual Member State the decision on the use or prohibition of any type of cells (such as embryonic stem cells) due to the ethical issues raised by some countries on the use of human and/or animal cells in some advanced therapy products. Industry is now recognizing that application of the "subsidiarity" principle in this way will allow some EU countries to prevent the sale, use or supply of these products thereby fragmenting the single market and casting doubt over the integrity of a single European marketing authorization'. This illustrates that the pharmaceutical industry has an interest in the Advanced Therapies Regulation and is being alerted by Burson Marsteller about member states possibly banning some advanced therapy products. It also shows that (one of) the conclusions of Mr. Earnshaw's briefing note is 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.

The suggestion of Mr. Earnshaw that none of the main issues he has addressed correspond with the lobbying efforts conducted by the pharmaceutical and biotechnology industries, NGOs or others, is not correct. In a submission to the European Commission of June 20 2005 the German Pharmaceutical Industry Association (BPI) states the following on the Proposal for a Community Regulatory Framework on Advanced Therapies: 'A European regulatory framework is especially requested in view of national tendencies to regulate the matter in national regulatory framework (e.g. 12th and 14th amendment of the German Federal Drug Act – AMG). However such national unharmonised regulations will hamper the development of advanced therapies within the EC; a common European market under a common regulatory framework is needed for improving the availability of advanced therapies within the community, for ameliorating the competitiveness of European business units, Again we see 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.

Appearance of a Conflict of Interest

Mr. Earnshaw is well known for his work as Managing Director for Burson Marsteller - a company that advises pharmaceutical companies. According to his CV, he provides EU healthcare and pharmaceutical related policy consultancy for several major pharmaceutical companies.

Mr. Earnshaw has argued in his letter to members of the ENVI Committee that his work for the ENVI Committee is not connected with his work for Burson Marsteller. This is not a credible argument. Mr. Earnshaw has a high ranking and very visible position in Burson Marsteller. MEPs, Commission officials, NGOs, public affairs professionals, members of the public and other stakeholders connect him directly with Burson Marsteller. In that light it is critical that the EPACA Code of Conduct does not only speak of a 'conflict of interest' but also of the 'appearance of a conflict of interest'. While one could argue that formally Mr. Earnshaw does not have a conflict of interest because he performs his advisory work to the ENVI Committee on his own capacity, it is obvious that there is the 'appearance of a

⁴ http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/stakehcom2005/industry/bpigerman pharmaceutical industry association-1.pdf

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conflict of interest', due to Mr. Earnshaw's prominent position in Burson Marsteller and the work he does for pharmaceutical companies in his capacity of Managing Director.

Summary

To summarize, we believe that by presenting his services to the ENVI Committee of the European Parliament, Mr. Earnshaw has constituted a 'conflict or appearance of conflict of interest between any work for or professional relationships with public sector institutions, and lobbying for private clients'. As a health expert of the ENVI Committee, Mr. Earnshaw offered his services on a wide range of environmental and health related issues, going beyond the specific topic of the briefing note that he submitted. Mr. Earnshaw thus offered his services on policy issues where several of his clients have an interest. Also on the specific topic of advanced therapy medicinal products, Mr Earnshaw advised the ENVI Committee on the issue whilst Burson Marsteller conveyed a similar position to their clients.

Mr. Earnshaw has also made statements that can either not be checked (specifically the claim that Burson Marsteller did not provide actual services to pharmaceutical companies on the legislation at stake in his briefing note) or statements that appear to be incorrect (specifically the claim that Burson Marsteller did not advise clients on the legislation that was the subject of his briefing note and the claim that none of the main issues he has addressed in his briefing note correspond with the lobbying efforts conducted by the pharmaceutical industries). This combination of lack of transparency and incorrect statements further contributes to the appearance of conflict of interest.

We would like to note that, while we do believe that the European Parliament has the responsibility to carefully assess the independence of the experts appointed for expert panels, we are convinced that lobbyists have the responsibility to avoid a conflict of interest such as the one apparent in this case. From EPACA's Code of Conduct we understand that this belief is shared by EPACA.

Therefore, we request EPACA to investigate this complaint and take the necessary steps to prevent any further conflict of interest in relation to Mr. Earnshaw's services to the ENVI Committee of the European Parliament.

Friends of the Earth Europe Paul de Clerck Transparency Campaigner November 30 2006

Attatchment:

1) CV Mr. David Earnshaw

164 rue Victor Hugo Brussels B-1030 Tel: 02 734 4474

Fax: 02 732 8534
GSM: 0475 654854
david.earnshaw@skypro.be
david.earnshaw@compagnet.be

David EARNSHAW

Date of Birth: 02 August 1958

Education:

1980 : BA (Hons) Political science, University of Hull, England

1993 : Master of Business Administration (Hons), Solvay Business School,

Université Libre de Bruxelles, Belgium

Career and appointments

2004- College of Europe, Bruges - Visiting Professor,

2002- Burson Marsteller, Brussels (part-time) - Managing Director,

directing and providing EU healthcare and pharmaceutical-related policy consultancy for several major pharmaceutical companies, trade

associations and professional/medical organisations

2002-2004 European Commission, DG-Development, Unit for Human and

Social Development - technical assistance via UK DFID Health

Systems Resource Centre. Consultancy support relating to

implementation of the European Commission's Programme for Action on HIV/AIDS, TB and malaria, and Commission participation in the

Global Fund for AIDS, TB and malaria

2001-2005 Open University - Associate Lecturer for course: "Governing Europe"

2001-2002 OXFAM International, Brussels: Head of EU/Brussels office -EU

policy and advocacy directed towards achieving inter alia, improved

access to medicines for developing countries

1996-2001 SmithKline Beecham Pharmaceuticals (now GSK) - Director,

European Government Affairs and Public Policy, Head of EU/Brussels office – policy adviser and spokesperson for corporation on EU political and public policy issues affecting pharmaceuticals and consumer

healthcare businesses

(SmithKline Beecham Gold Impact Award 1998 and 1999, and CEO

Award, 1999)

1995-1996 GPC Market Access, Brussels - Deputy Managing Director

1993-1995 Market Access Europe, Brussels - Director

1987-1993	European Parliament, Brussels: policy aide to the Chair of the Committee on Environment, Public Health and Consumer Protection, Brussels (Sir Ken Collins MEP)
1987-1989	Hatfield Polytechnic, England: lecturer in European politics (part-time)
1986-1987	Charles Barker Watney and Powell, London: EU policy adviser
1984-1986	Defence Intelligence Staff, Ministry of Defence, London : intelligence analyst
1983-1984	Heriot-Watt University, Edinburgh: lecturer in European Union and comparative (national) European politics
1980-1983	University of Hull, Department of Politics: postgraduate research scholarship

Memberships:

University Association for Contemporary European Studies (London); European Union Studies Association (USA); Fellow, Royal Society for Arts (London)

Publications:

The European Parliament (Palgrave Macmillan, 2003), with David Judge

Numerous academic articles on EU decision making in peer-reviewed journals, for example, Journal of European Public Policy, Journal of Common Market Studies, Government and Opposition, Environmental Politics, Journal of Commercial Biotechnology, monographs and edited book chapters.

See attached list of publications.

Other

1989	Labour Party European Parliamentary candidate, London South East,
1982	European Parliament Schuman scholar, Luxembourg
2002-2003	United Business Institute Brussels: Associate Lecturer, "Globalisation,
	change and adapation – the major issues affecting today's corporation"
2003-	Vice Chair, Brussels Labour Party Group

SELECTED PUBLICATIONS

"The European Parliament's Quest for a Single Seat" in Journal of European Integration/Revue d'Intégration Européenne, Volume 8, No. 1, Autumn 1985

Socialism and the European Environment: Building a Clean Future (Brussels: Socialist Group of the European Parliament, 1988)

"1992: The Food and Drink Industry - The European Parliament's View" in 1992 and its Implications for the Food and Drink Industry (Campden Research Association, 1988)

"The Implementation and Enforcement of European Community Environment Legislation" in Environmental Politics, Volume 1, No. 4, Winter 1992, (with Ken Collins); published simultaneously in David Judge (ed.) A Green Dimension for the European Community: Political Issues and Processes (London: Frank Cass, 1992). Re-printed in Ludwig Kramer (ed), European Environmental Law, The International Library of Essays in Environmental Law (Ashgate, 2003)

"The European Parliament and the Sweeteners Directive: From Footnote to Inter-Institutional Conflict" (with David Judge) in *Journal of Common Market Studies*, Volume XXXI, No. 1, March 1993

"Weak European Parliament Influence? A Study of the Environment Committee of the European Parliament" (with David Judge) in Government and Opposition, Volume 29, No. 2, Spring 1994

"Ripples or Waves: The European Parliament in the European Community Policy Process", (with David Judge and Ngaire Cowan) in *Journal of European Public Policy*, Vol. 1, No. 1, May 1994

Prelude to Codecision: A Qualitative Assessment of the Cooperation Procedure in the 1989-94 European Parliament (with David Judge), European Parliament Directorate for Research, Project IV/93/54; submitted to European Parliament in February 1995

"From Cooperation to Codecision: the European Parliament's Path to Legislative Power" (with David Judge), in Jeremy Richardson (ed.) *Policy Making in the European Union* (Routledge, 1995)

"Early Days: The European Parliament, Codecision and the European Union Legislative Process post-Maastricht" (with David Judge), in *Journal of European Public Policy*, Vol. 2, No. 4, 1995

"The Life and Times of the European Union's Cooperation Procedure" (with David Judge), in *Journal of Common Market Studies*, vol. 35, No. 4, December 1997, pp. 543-564

"The European Parliament and biotechnology patenting: Harbinger of the future?" (with Josephine Wood), in *Journal of Commercial Biotechnology*, vol. 5, No. 4, Spring 1999, pp. 294-307 (see: http://container.pharmalicensing.com/features/disp/934294559_37b0341f92822?p=t2#AEN23)

"Access to medicines: an urgent need for solutions", in WHO Drug Information, Vol. 13, No. 4, pp. 220-222 (World Health Organisation, Geneva, 2000)

"The pharmaceutical industry and the European political environment", invited editorial, in World Pharmaceutical Developments, 2001 (see: http://www.worldpharmaceuticals.nct/eds/pmi04075.html)

"The European Parliament and the Commission Crisis: A New Assertiveness?" (with David Judge), in *Governance*, Vol. 15, No. 3, July 2002, pp. 345-374

"The European Parliament as Entrepreneur: New Trends, New Challenges" (with Alex Warleigh and Josephine Wood), in Alex Warleigh and Jenny Fairbrass (eds.), *Influence and Interests in the European Union: The New Politics of Persuasion and Advocacy*, London, Europa, 2002

The European Parliament (with David Judge), London, Palgrave Macmillan, 2003

"No Simple Dichotomies: Lobbyists and the European Parliament" (with David Judge), in *Journal of Legislative Studies*, Vol. 8, No. 4, Winter 2002; published simultaneously in Rinus van Schendelen and Roger Scully (eds.), *The Unseen Hand: Unelected EU Legislators*, London, Frank Cass, 2003

SELECTED CONFERENCE PRESENTATIONS:

- "Access to Medicines: the need for urgent solutions", Médecins sans Frontières/HAI/CPT conference, Amsterdam, November 1999; (see: http://www.haiweb.org/campaign/novseminar/earnshaw.html)
- "The pharmaceutical industry and EU trade policy making", Medicins sans Frontierès internal government affairs workshop, Brussels, May 2000
- "Models of patient / pharmaceutical industry cooperation, European Coalition of Positive People Prague 2000 conference, Prague, November 2000
- "The pharmaceutical industry in its political environment: five paradoxes in search of a strategy", Management Centre Europe Pharma 2000 conference, Brussels, November 2000
- "The TRIPs agreement, health and development", Quakers United Nations, Geneva (with developing country delegations to the WTO), May 2001
- "TRIPs and access to medicines: An example of why TRIPs is contested", Centre for European Policy Studies, Brussels, working group on International Protection of IPRs: Current Implementation and Future Challenges, June 2001
- "The Future of TRIPs, generic medicines and the quest for access", International Generic Pharmaceutical Association annual conference, Cannes, June 2001
- "The pharmaceutical industry: Demon or Saint?" Institute of Contemporary Arts, London, July 2001
- "TRIPS and access to Medicines: Why TRIPS is contested", Global Forum for Health Research, Geneva, October 2001
- "Globalisation, sustainable development and poverty eradication: key issues, current policy and potential policy objectives", High Level Seminar on Globalisation, sustainable development and the EU's external policies, Brussels, October 2001
- "Europe's Duty Towards the Third World", British-German Forum 2002: How has the world changed since 11 September? June 2002, Wilton Park special conference, UK Foreign and Commonwealth Office
- "Reinventing the business model: Commercial reality and shareholder expectations some political dimensions", the 9th Annual Economist Pharmaceuticals Conference, London, February 2003
- "The Future is Parliamentary? Parliamentarisation and Legitimation in the EU", European Union Studies Association Biannual Conference, Nashville (USA), April 2003
- "The European Parliament: Leadership and 'Followership'", Centre for European Union Studies Conference, University of Hull, England, September 2005

David Earnshaw

David is a respected Brussels based policy and government relations veteran and a specialist in European Union decision making. He joined Burson-Marsteller as a part time Managing Director in June 2002 after having worked immediately before that with Oxfam as its lead spokesperson on EU affairs. At Burson Marsteller he specialises in EU health and pharmaceutical policy issues, advising companies such as Novartis, Pfizer and Chiron as well as pharmaceutical and vaccine industry bodies. While with Oxfam he ran the organisation's media relations from Afghanistan during the US bombing of the country, as well as working more broadly to focus global attention and EU action on the plight of poor countries, directed especially to the problem of access to medicines at affordable prices.



Between 1995 and 2001 David was Director of European Government Affairs and Public Policy with SmithKline Beecham (now GSK), heading SmithKline Beecham's Brussels office. Among his legislative work David was critically involved in the controversial biotechnology patenting directive eventually adopted in 1998; and he conceived the 2003 Council Regulation on tiered pricing/trade diversion of key pharmaceuticals destined for developing countries. He has also undertaken consultancy work for DG Development of the European Commission regarding, inter alia, the Programme for Action on HIV/AIDS, TB and malaria, and the Commission's role in the Global Fund.

Prior to joining SmithKline Beecham in 1995 he was deputy managing director of GPC Market Access Europe. Before that he was researcher for the Chairman of the European Parliament's Committee on Environment, Public Health and Consumer Protection (Sir Ken Collins), a capacity in which he became recognised as an authority on the evolution and politics of European Union environment and health policy.

David has published widely in the peer-reviewed academic literature on EU decision making (for example in the *Journal of European Public Policy*, the *Journal of Common Market Studies*, the *Journal of Legislative Studies*, *Environmental Politics*, etc.) and during the 1980s he taught European politics at Heriot-Watt University, and Hatfield Polytechnic, in the UK. He also worked in British government during the 1980s. He has a MBA from Solvay Business School, Brussels.

David was a Labour candidate for a London constituency in the 1989 European Elections, and is currently Vice Chair of the Brussels Labour Party Group. His book (with David Judge) <u>The European Parliament</u> (Palgrave Macmillan) was published in May 2003. He is also a visiting professor at the College of Europe, Bruges.