US FDA FOIA Officer
United States Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
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Rockville, MD 20857
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8 June, 2010

SUBJECT: FOIA Request

Dear FOIA Officer:

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, on behalf of Knowledge Ecology International (KEI), for documents and communications prepared or received by the FDA regarding the Partnership for Safe Medicines (PSM) India Collaboration Summit held at the Imperial Hotel in Delhi, India, on May 11th, 2010 and called "Empowering Indian Patients, Healthcare Professionals and Policymakers Against Unsafe Drugs".

INTRODUCTION

KEI is a 501(c)(3) tax exempt, nonprofit nongovernmental organization with offices in Washington, DC and Geneva that researches, advocates and influences global negotiations on knowledge goods related matters. We are very involved in research and advocacy on issues of the access of populations living in developing countries to quality and affordable medicines.

KEI has been informed that FDA representatives recently attended a summit in India on the issue of counterfeited and spurious medicines organized by the Partnership for Safe Medicines (PSM), a US-based organization with clear links to pharmaceutical corporate interests. KEI has been following and reporting on the multinational pharmaceutical companies efforts to try to influence the debates against substandard medicines to interfere with legitimate generic competition. One of the strategies used by pharmaceutical companies is to bring confusion between counterfeit medicines – a trademark issue – and lawful generic medicines. The records requested in this FOIA request will contribute to the public interest by allowing the public to better understand what role is the US government taking, how are the discussions with Indian government and stakeholders are being framed and who is influencing the US government positions.

In submitting this FOIA request, KEI is encouraged by the Transparency Memorandum issued by President Obama in January 2009 which declared that "My Administration is committed to creating an unprecedented level of openness in Government" and that "Openness will strengthen our democracy and promote efficiency and effectiveness in Government."

FOIA REQUEST

In order to conduct our investigation and with a view to serving the public interest, KEI requests all documents, including email, letters, faxes and other communications, memorandums, power point presentations, and any other information which address:

- The names and titles of any officials, employees or representatives of the FDA who attended the Partnership for Safe Medicines (PSM) India Collaboration Summit held at the Imperial Hotel in Delhi, India, on May 11th, 2010.
- The agenda, list of participants, and topics of discussion of the aforementioned summit.
- Presentations, position papers, analysis, reports, conclusions or minutes distributed or prepared before, during or after the summit.
- Budget or expenses report for the summit and information of who paid for FDA expenses to participate.
- Contracts or Memorandum of Understanding signed or discussed with the Partnership for Safe Medicines (PSM), the government of India or any relevant third party concerning the summit and any possible follow up, including the possible establishment of a public private partnership, which the exception of contracts for food, lodging or meeting facilitates.
- A list of any past of future events that the U.S. FDA has or expects to organize with the Partnership for Safe Medicines (PSM).
- All communications related to the summit and documents prepared or received by FDA officials, employees or representatives concerning the summit. This request would include, but should not be limited to, position papers, analysis, and communications with Members of the United States Congress or their staff, the White House, foreign governments, the United States Embassy in India, staff or consultants working for the USFDA, communications with other US federal agencies, the Partnership for Safe Medicines (PSM), private sector or nongovernmental organizations or their representatives, or other members of the public.

The responsive records are likely to include communications or documentation involving:

- Dominc Keating, First Secretary for Intellectual Property at U.S. Embassy, New Delhi/USPTO
- Bruce Ross, Country Director, India, U.S. FDA
- Representatives of the U.S. FDA and Department of State

- Partnership for Safe Medicines (PSM) or one of its representatives including: Marvin D. Shepherd, Bryan A. Liang, Thomas T. Kubic, James N. Class, and Scott A. LaGanga.

The time period of our request is from January 2009 to the present, as we would like all records containing information about the planning, execution and possible follow up of the meeting.

When possible, we prefer that the documents be released in electronic form in order to avoid the cost of duplication of documents and to assist in the dissemination of the documents.

REQUEST FOR WAIVER OF SEARCH AND DUPLICATION FEES

KEI requests a waiver of all fees associated with this request under 5 U.S.C. § 552(a)(4)(iii) because this request is not for any commercial purpose, and the information sought will be widely circulated and will be used in a way that meaningfully contributes to the public understanding of the US government practices and policies, and in advancing the public interest.

KEI is able to significantly contribute to the understanding of a diverse audience of persons following negotiations and discussions involving access to affordable and high quality medicines, including the policies and practices of the US FDA. KEI is making this FOIA request for a scholarly or scientific purpose and has no commercial interest in the requested information. KEI seeks to disseminate the information, analyze it and to educate the public on critical issues relating to the activities of the United States government.

KEI is actively engaged in public policy research and advocacy, and searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups, and policies to manage knowledge resources in ways that are more efficient, more fair, and responsive to human needs.

KEI advocates on behalf of consumer interests and provides salient research and analysis in relation to initiatives aimed at access to quality of medicines. The requested information will help KEI and the public to better understand the positions of the US FDA and other federal agencies and non-federal actors in consideration of access to medicines, and issues of counterfeiting, sub-standard and spurious medicines, and the relation between the US government and the different stakeholders in related discussions. KEI will serve the public interest by presenting the requested information within the relevant historic and political context so it is accessible to a large audience and allows for more transparent and democratic policy making.

The information that KEI expects to receive through this FOIA request is not already in the public domain. KEI will disseminate the information received through this request to

the public and to policy makers in several ways. KEI publishes research in scholarly journals, general interest and specialty newspapers and periodicals, in-house and third party blogs and web pages, and provides technical advice to governments, NGOs and firms. KEI provides a variety of forums for interested persons to discuss and debate Knowledge Ecology topics, including the organization of seminars and meetings, through the management of several discussions mailing lists, and through the interactive use of social information media such as Twitter and Facebook. The articles written by KEI are often based upon or informed by information obtained from federal agencies, including information obtained under FOIA requests. KEI anticipates using information received in this FOIA request in future publications. The KEI webpage provides links to the many publications of the KEI staff: http://www.keionline.org. KEI work, including the information obtained with FOIA requests, is often used by journalists, who have an interest and expertise in the topics[1].

KEI is well known for its ability to monitor government operations, process information about complex public policies, and explain issues and policy options to a broad audience. KEI and its predecessor organization, the Consumer Project on Technology (CPTech) have been credited with playing an important role in stimulating public debate and civil society engagement in a variety of policy areas that have led to changes in U.S. Trade policy[2]. In 2006, KEI was awarded the MacArthur Award for Creative and Effective Institutions for "advancing the public interest in intellectual property policy". KEI's work program includes but is not limited to influencing the outcome of global norm setting at the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the Hague Conference on Private International Law, in a plethora of plurilateral, bilateral and unilateral trade disputes, and in national legislative debates and actions by executive branch agencies.

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[1] Examples of publications, news services and blogs that quote KEI Staff: New York Times, Wall Street Journal, Washington Post, LA Times, CNN, Financial Times, the Associated Press, Reuters, Bloomberg New Service, Inside US Trade, Wired Magazine, IP-Watch, CNET News, Tech Dirt, ZDNet, Ars Technica, The Standard, Bridges Weekly Trade News, Boletin Farmacos, Slashdot, BoingBoing, Pharmalot, Spicy IP, Micheal Geist Blog, the Huffington Post. See also the Addendum concerning KEI activities to disseminate information.

[2] Examples of sources recognizing KEI/CPTech ability to monitor government operations, process information about complex public policies, and explain issues and policy options to a broad audience: Doha Hurrah, *Wall Street Journal*, November 2001; Peter Drahos & John Braithwaite, *Information feudalism: who owns the knowledge economy?*, Earth Scan, 2002; Susan K. Sell, *Private power, public law: the globalization of intellectual property rights*, Cambridge University Press, 2003; Greg Behrman, *The Invisible People: How the US Has Slept Through the Global AIDS Pandemic, the Greatest Humanitarian Catastrophe of Our Time*, Simon & Schuster, 2004; "Unitaid Executive Board Approves Breakthrough Plan To Make Aids Treatment More Widely Available At Lower Cost, Patent Pool Could Save Over One Billion Dollars A Year," UNITAID Website, 2009, or the discussion about the proposed WIPO Treaty for persons who are blind or have other disabilities at the recent Access to Knowledge conference at Yale Law School: ttp://yaleisp.org/2010/02/a2k4strategies/. See also the Addendum concerning KEI activities to disseminate information.

Upon request, KEI will provide your office with additional details of the extent to which KEI has demonstrated its ability to disseminate information to the public, and to contribute significantly to public policy debates, including through deepening public understanding of complex issues involving federal government policies and practices regarding the management of knowledge resources.

For any document(s) or portion of document(s) to which you deny KEI access, please provide an index itemizing and describing justification of your grounds for claiming each exemption, explaining why each exemption is relevant to the document or portion of the document withheld. KEI looks forward to receiving your written response within twenty working days as required by law.

Thank you for your consideration of our request. You may contact KEI directly by phone or by electronic mail to discuss this request further.

Sincerely,

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