SMG 2120.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

EXTERNAL RELATIONS

EXTERNAL EXPERT GRATUITOUS SERVICES IN AN EMERGENCY

Effective Date: 10/15/2010

1. PURPOSE

To outline the policy and procedures FDA uses to work with external scientific and other experts in emergency situations when the services are provided on a gratuitous basis.

2. POLICY

In an emergency, FDA will consider and obtain any and all appropriate resources, including external scientific experts and other persons who are considered authorities in their fields, to respond to, and resolve, the crisis. It will obtain these resources expeditiously, while giving due consideration to risks that may be presented in collaborative arrangements with external entities, including conflicts of interest. The responsible FDA staff will consult internally with the appropriate FDA offices as it addresses such risks and will document its decisions about such issues. The agency will also disclose to the public its consideration of, and decisions about, such issues to preserve the integrity of the process.

A. Scope

This guide applies to permit the agency to act as quickly as possible to obtain outside scientific and other expert services on a gratuitous basis when the agency is responding and managing an incident as an emergency as described in the FDA Emergency Operations Plan (EOP). The FDA EOP defines an ***emergency*** as: *An unforeseen occurrence or a combination of circumstances that poses a significant risk to public health and that involves the safety, efficacy, or security of a human or veterinary medicine, a biological product, a medical device, a food, a cosmetic, a product that emits radiation, or a tobacco product that calls for immediate actions by FDA staff.* Examples of emergencies include chemical and

biological terrorism, drug contamination, food-borne illness outbreaks, radiological incidents, and chemical spills affecting food or animal feed supplies.

This guide applies to significant collaborations and exchanges of scientific or other information between FDA scientific staff and outside experts during an emergency.

B. Federal Advisory Committee Act

If FDA convenes a group (consisting of two or more) of outside experts to obtain the group's consensus opinion on specific policy issues or proposals, it will generally trigger certain procedural requirements under the Federal Advisory Committee Act (FACA), 5 U.S.C. App. II. Individuals brought together to express their individual opinions generally do not trigger FACA. FDA staff are encouraged to consult with the agency's Advisory Committee Oversight and Management Staff if they have questions about the applicability of FACA to a particular matter. For FDA's current thinking on factors that FDA considers in deciding whether to refer a matter to an advisory committee for consideration, please refer to FDA's Draft Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings (Aug. 2008):
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf

3. RESPONSIBILITIES AND PROCEDURES

The Commissioner, the responsible Center Director, or other senior agency official(s) delegated by the Commissioner determines when agency emergency actions are warranted to prevent, prepare for, protect against, respond to, or recover from a threat or hazard. The Secretary may also direct FDA to provide emergency support to maintain the safety, efficacy and security of FDA regulated products.

In an emergency, the involved Center Director or ACRA should, as necessary, work with FDA experts within the Center/ORA to identify and contact prospective outside persons with any necessary scientific expertise. The Center or ORA expert will prepare a memo (the expertise memo) to describe the external persons' expertise and why their expertise is essential for the agency to address the emergency.

A. Documentation of Agreement to Provide Gratuitous Services

Prior to providing any gratuitous services to the agency, the experts must agree in writing that they will receive no compensation and waive any future claims against the government for their services. The experts must agree in writing that, if access to non-public information from agency files is required in the performance of their services with the agency, they will not further use, release, publish or disclose such information and will protect such information in accordance with applicable laws and regulations governing the confidentiality of non-public information.

As discussed in Sections B and C below, the experts must also agree in writing to provide an accurate listing of their current financial interests and other financial involvements to

the extent requested by FDA, and consent to the public release of certain general information about their financial interests.

FDA staff should use Gratuitous Services Agreement Template, Attachment A, to document agreements with experts to provide gratuitous services to the agency in an emergency.

B. Conflicts of Interest

FDA intends to screen any person who provides expert services during an emergency for conflicts of interest. Conflicts of interest may arise if financial interests of the expert, certain family members, or outside parties with which the expert is affiliated may be affected by the particular matter on which the expert is working at FDA, and if the particular matter involves deliberation, decision, or action that may affect the financial interest of specific persons or organizations or a discrete and identifiable class of persons. The purpose of the screening process is to determine if the external expert has financial interests that relate to the matter in which the expert has been engaged. The agency will weigh the disclosed interests against the need for the services and determine whether, in light of any conflicts, it is appropriate to continue to receive the expert's services. When conflicts are found to exist, the agency will make informed decisions regarding how to assess and utilize the services provided.

The Center/ORA staff member will request that an expert who provides gratuitous services to the agency during an emergency complete a Conflicts of Interest Screening Template, Attachment B, as soon as reasonably possible. The staff member should provide the expert a list of the names of any affected products, sponsors and competing firms, or the names of any entity whose legal rights would be uniquely affected by the services rendered when all affected entities are taken into consideration. Experts are requested to provide information about financial interests relating to those products, firms, and issues identified on the list, including information about their financial interests and the interests of their spouses, minor children, employers, and business partners, as well as, if they act as an officer or director of an organization, the financial interests of the organization so that the agency can determine whether they have any conflicts of interest specific to the particular matter or matters for which the agency is seeking their services. Although an individual is not required to provide this information to FDA, FDA will not accept an individual's services unless the individual has (i) agrees to provide the requested financial and other information to FDA and (ii) consents to the public release of certain general information about their financial interests as discussed below in Section C. Where the expert or consultant is determined to be a Special Government Employee, the individual will be required to complete Form OGE 450 in lieu of the template at Section C, and all requirements of 18 USC 208 will be observed.

The Center/ORA staff member will ask the expert to provide the completed screening template to FDA's Ethics and Integrity Staff for review, and will provide the expertise memo and the signed gratuitous services agreement to the Ethics and Integrity Staff. The Ethics and Integrity Staff will review (and consult as necessary with relevant FDA staff) the screening template, expertise memo, and signed gratuitous services agreement, considering, among

other things, the type of interest, the identity of the person whose interest is involved (and if the interest is not the prospective expert's, the person's relationship to the prospective expert), the estimated value of the interest, the nature, importance, and, the need of the prospective expert's expertise to the matter, and the extent to which the agency is able to exercise independent judgment or otherwise insulate its decisions from discretionary input of the prospective expert. The Ethics and Integrity Staff will provide a written assessment of the financial disclosure to the Commissioner (or designee) or the Center Director for review and decision on whether to continue to accept the expert's gratuitous services. The Ethics and Integrity Office will maintain the assessment, the expertise memo, and the gratuitous services agreement in a project-specific file.

C. Public Disclosure

After the emergency is resolved, the FDA will publicly disclose a list of the outside experts whose gratuitous services the agency relied upon during the emergency and any relevant conflicts of interest. FDA does not intend to publicly disclose financial interest information if the information is exempt under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, other than due to the fact that it is personal financial information provided to the agency. For example, FDA would not disclose the name of a company or institution if doing so would reveal that company's confidential commercial information.

4. EFFECTIVE DATE

This guide is effective October 15, 2010.

5. Document History -- SMG 2120.1, External Expert Gratuitous Services in an Emergency

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/15/2010	N/a	OC/OPPB	David Dorsey, Director, Office of Policy, Planning and Budget

STAFF MANUAL GUIDE 2120.1 - ATTACHMENT A

Gratuitous Services Agreement Template

Name:

Description of Services: [detailed description of the services that will be provided to the agency]

I will provide the services listed above to the Food and Drug Administration (FDA) without compensation. I waive any future claims against the government for these gratuitous services.

I hereby acknowledge and understand that I will provide an accurate listing of my current financial interests and other financial involvements to the extent requested by FDA. I understand that should any financial interest be determined by FDA to be a potential conflict of interest, and FDA determines my services are necessary despite a real or perceived conflict of interest, FDA intends, to the extent permitted by law, to publicly disclose the existence of these financial interests.

If access to non-public information from the files of the FDA is required in the performance of my services under this agreement, I hereby agree that I shall not further use, release, publish or disclose such information and that I shall protect such information in accordance with 21 USC 331(j), 21 USC 360(j), 21 USC 379, 18 USC 1905, and other pertinent laws and regulations governing the confidentiality of non-public information.

_____ _____

Signature Date

STAFF MANUAL GUIDE 2120.1 - ATTACHMENT B

Conflicts of Interests Screening Template

Name:

Description of issues/matters that FDA has identified as relevant [to be completed by FDA staff]:
(The list below is a sample of the kind of information that should be provided by FDA staff to potential expert)

Product: Doxil (liposomal doxorubicin)
Indication: For the treatment of Kaposi's Sarcoma in AIDS patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy

Competing Products: Roferon A (interferon alpha-a)
Taxol (paclitaxel)
Vinblastine
Adriamycin (doxorubicin hydrochloride)
Intron A (interferon alfa-2b, recombinant)
CONFIDENTIAL

Companies: Johnson & Johnson
Gilead
Roche
Hoffmann LaRoche
Lilly
Schering-Plough

[To be completed by external experts]
List holdings where the aggregate value of the holdings of you, your spouse, and your minor children in the securities of all entities estimated to be $15,000 or more.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family [Describe type of interest; e.g.: Stocks/investments; Employment; Work as consultant/advisor; Contracts/grants; Patents/royalties/trademarks; Work as an expert witness; Teaching/speaking/writing]	[Describe nature of interest; i.e.: name of company or institution]	[Describe magnitude of interest; e.g.: $15,000 – $50,000; $50,001 or more]

Type of Interest	Nature	Magnitude
II. Other Imputed Interests [Describe type of interest; e.g.: Stocks/investments; Employment; Work as consultant/advisor; Contracts/grants; Patents/royalties/trademarks; Work as an expert witness; Teaching/speaking/writing]	[Describe nature of interest; i.e.: name of company or institution]	[Describe magnitude of interest; e.g.: $15,000 – 50,000; $50,001 or more]

The above information is true and complete to the best of my knowledge. If there are any changes to the information disclosed above, I will promptly notify FDA of such changes.

I understand that should any financial interest be determined by FDA to be a potential conflict of interest, and FDA determines my services are necessary despite a real or perceived conflict of interest, FDA intends, to the extent permitted by law, to publicly disclose the existence of these financial interests.

_____ _____

Signature Date