

Briefing on 208(b)(3) Waiver Process

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18 U.S.C. 208(b)(3) Waivers

- 300 (b)(3) waivers per year
- Waiver Criteria Document available at <http://www.fda.gov/oc/advisory/default.htm>
- Alternate reporting form = FDA 3410
 - meeting specific
 - facilitates disclosure



Assessing Conflict of Interest Concerns - The Form 3410

- SGE completes Form 3410 - *Confidential Financial Disclosure Report for SGE's* - prior to each meeting
- Form 3410 is accompanied by a list of sponsors, affected firms, competitors, parent firms, etc. for each topic to be covered at the upcoming meeting

What are the types of interests screened?

- Stocks and Investments
- Primary Employment
- Consultant Work
- Contracts/Grants/CRADAS
- Patent/Royalties/Trademarks
- Expert Witness Activities
- Teaching/Speaking/Writing
- Department Heads/Administrative Duties
- Exceptions for Institutional Directors



FDA Waiver Process Screening Memo Example

Complete the FDA 3410, providing information only about your, and the entities whose interests impute to you under the law (i.e., spouse and minor children), current or past interests in the product and competing products listed, for the indication noted



Screening Memo Cont'd

- Provide any current or past (within 12 months) interests in the companies specified
- Interests relating to the firms specified must be reported even if unrelated to the product and competing products listed

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Competing Products

- Rituxan (rituximab)
- Blenoxane (bleomycin sulfate)
- Cytosan (cyclophosphamide)
- Adriamycin (doxorubicin hydrochloride)
- Leukeran (chlorambucil)
- Methotrexate sodium
- Oncovin (vincristine)
- Meticorten (prednisone)
- Deltasone (prednisone)
- Cortef (hydrocortisone)
- Medrol (methylprednisolone)
- Decadron (dexamethasone)
- Hexadrol (dexamethasone)
- Intron A (interferon alfa-2b, recombinant)
- BiCNU (carmustine, BCNU)
- Vepesid (etoposide, VP-16)
- Novantrone (mitoxantrone)

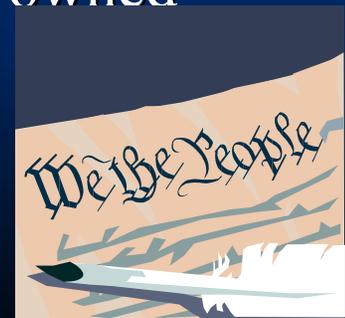
Sponsors

- Genentech
- IDEC Pharmaceuticals
- Roche Holdings Ltd.
- Bristol Myers Squibb
- Nippon Kayaku Company, Inc.
- Mead Johnson Oncology Products
- Pharmacia Corporation
- GlaxoSmithKline
- Catalytica Pharmaceuticals
- Catalytica, Inc.
- American Home Products
- Eli Lilly
- Schering Plough Corporation
- Merck

The Emoluments Clause

U.S. Constitution

- FDA requests information that will allow the Agency to screen for the Emoluments Clause
- The Constitution prohibits SGEs from accepting any employment with a foreign government or the political subdivision of a foreign government, including a public university or commercial enterprise owned by a foreign government
- This ban does not apply to a foreign privately owned corporation or an international



Next Steps

- FDA Form 3410 is reviewed
- The Center determines if a waiver is needed
- Based on the WCD and consultation with Ethics, the Center may proceed with a waiver or exclude the SGE



The Waiver Criteria Document 2000

- Table Format (categorized by type of interests)
- Grouped by Involvement Levels (monetary range)
- Grouped by General Matters v.s. Party Matters
- Circumstances Favoring Use
- Reflects Expected Agency Actions

OGE Waiver Requirements

- 5 CFR 2640.302 (208(b)(3))
 - Advisory Committee (FACA)
 - Must be written/issued by the appointing official after a review of the SGE's financial disclosure
 - Must cite need for service outweighs potential for COI



Waiver Requirements, Cont'd

- Waiver must include:
 - Nature of the interest
 - Particular matter the waiver covers
 - Any limitations (e.g., no vote)
 - Must be issued PRIOR to meeting
 - May cover present and future interests

Need for Service

■ Factors:

- Type/value of interest (stock, study)
- Imputed or actual interest of SGE
- Uniqueness of SGE's qualification
- Difficulty of locating alternate
- Extent to which disqualifying interest may be affected by committee actions

FDA Process

- Need for service is provided by the Division whose product is coming to the meeting
- The expertise is derived from the CV, the Nomination Package and the knowledge FDA Staffers have on the SGE's expertise

FDA FDAMA Requirements

- Require **2** or more members who are specialists or have other expertise in the particular disease or condition for the drug under review
- Often there are few specific experts available

Expertise Example:

Dr. Jones is Professor of Medicine, Ideal University and she is board certified in allergy and clinical immunology. Dr. Jones specializes in asthma, regulatory peptides and rhinitis, and allergies and nasal physiology. Her participation in the committee's deliberations is essential in determining whether the public can properly self-diagnose seasonal rhinitis and safely use Allegra, Zyrtec and Claritin as over-the counter products.



Conclusion

- Questions?
- Contact the FDA's Ethics and Integrity Branch
- 301-827-5511

