Disclosure of Conflicts of Interest of Members of FDA Advisory Panels

Special government employees who serve as members of a Food and Drug Administration advisory panel and who seek waivers of conflicts of interest must publicly disclose any conflicts of interest they may have that relates to the work to be undertaken by the panel. The FDA may not waive a panel member's conflict until the panel member makes the public disclosure.

The FDA has considerable discretion to determine how detailed the panel member's disclosure must be, so long as such disclosure is adequate to inform the public of the nature and magnitude of the conflict.

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MEMORANDUM OPINION FOR THE CHIEF COUNSEL
FOOD AND DRUG ADMINISTRATION

You have asked for our opinion whether the Food and Drug Administration ("FDA"), in granting conflict of interest waivers to special government employees serving as members of FDA advisory panels on new drugs and biological products ("drug advisory panels"), must require panel members to disclose publicly their conflicts of interest. You have further informed us that the FDA's current practice with respect to waivers of such conflicts of interest is to disclose the fact that a particular panel member has been granted a waiver of a conflict, but not to identify the nature of the conflict or provide any further details. *See* Memorandum for Daniel Troy, Chief Counsel, from Matthew Eckel, Associate Chief Counsel, Food and Drug Administration, *Re: Request for Advice from Office of Legal Counsel, Department of Justice Concerning Disclosure of Advisory Committee Member Conflicts of Interest* (Sept. 17, 2001) ("FDA Memorandum").

As discussed below, we conclude that special government employees who serve as members of an FDA drug advisory panel and who seek waivers of conflicts of interest must publicly disclose any conflicts of interest they may have that relate to the work to be undertaken by the panel.[1] The FDA may not waive a panel member's conflict until the panel member makes the public disclosure. The FDA has considerable discretion to determine how detailed the panel member's disclosure must be, so long as such disclosure is adequate to inform the public of the nature and magnitude of the conflict.

[1] We have not been asked to, and do not, opine on whether a drug advisory panel member must publicly disclose a conflict of interest that the member may have with a matter to be undertaken by the panel if the member, instead of seeking a waiver, chooses not to take part at all in the matter.

I. Panel Members Must Publicly Disclose Their Conflicts of Interest

Section 355(n) of title 21 provides that "[f]or the purpose of providing expert scientific advice and recommendations to the Secretary [of Health and Human Services] regarding a clinical investigation of a drug or the approval for marketing of a drug under section 355 of this title [(new drugs)] or section 262 of Title 42 [(biological products)], the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both." 21 U.S.C. § 355(n)(1) (Supp. III 1997). Within 90 days after a drug advisory panel makes its recommendations, the FDA must review the panel's conclusions and recommendations and notify the affected persons of any final decision. *Id.* § 355(n)(8).

Section 355(n)(4) sets out specific conflict of interest requirements for members of drug advisory panels:

> Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

Id. § 355(n)(4). Thus, the plain terms of section 355(n)(4) require that each member of a drug advisory panel "publicly disclose all conflicts of interest . . . with the work to be undertaken by the panel" and that the Secretary not waive any such conflicts before public disclosure has occurred.

You have asked, however, whether various other statutes relating to conflict of interest requirements for government employees should be read to negate or limit the obligation that section 355(n)(4) imposes.

Pursuant to section 107(a)(1) of the Ethics in Government Act of 1978, as amended, 5 U.S.C. app. §§ 101-111 (2000) ("EGA"), the FDA requires each member of a drug advisory panel to file a confidential financial disclosure report. *See* FDA Memorandum at 2. Section 107(a)(2) in turn provides that "[a]ny information required to be provided by an individual under this subsection shall be confidential and shall not be disclosed to the public." 5 U.S.C. app. § 107(a)(2). You further note that the Office of Government Ethics ("OGE") has advised that even with the consent of the individual filer, the agency is barred by section 107(a)(2) from publicly releasing information on the filer's financial disclosure report. *See Privacy of SF 450 Financial Disclosure Information and Waivers Issued to Advisory Committee Members under 18 U.S.C. § 208(b)(3)*, Informal

Advisory Op. 93x34, at 4 (Nov. 16, 1993), *available at* http://www.oge.gov/OGE-Advisories/Legal-Advisories/Legal-Advisories/ (last visited May 24, 2012) ("OGE Letter").[2] You therefore raise the question how section 107(a)(2) is to be read together with the plain language of section 355(n)(4).

We believe that section 107(a)(2) has no impact on how section 355(n)(4) should be read. Section 355(n)(4) imposes a disclosure obligation not on the FDA, but only on individuals who choose to be members of a drug advisory panel. The OGE Letter provides only that the filer's consent does not enable the *agency* to release the filer's financial disclosure report. The OGE Letter does not remotely suggest that section 107(a)(2) bars the *filer* from publicly releasing his own financial disclosure report. (Indeed, any such bar, apart from having no evident purpose, would likely violate the First Amendment.) We therefore see no conflict between section 107(a)(2) and section 355(n)(4).

Because section 107(a)(2) and section 355(n)(4) do not conflict, FDA regulations that would implement section 355(n)(4)'s command that drug advisory panel members publicly disclose their conflicts of interest would likewise not violate section 107(a)(2). We note further that section 355(n)(4) could reasonably be read to contemplate that panel members use FDA resources to make public disclosure of their conflicts; in the event that the FDA so reads section 355(n)(4), we believe that such an FDA role in facilitating panel members' disclosure would not violate section 107(a)(2).

You present an argument that the federal criminal conflict of interest statute, 18 U.S.C. § 208 (1994), permits an agency to grant a special government employee an exemption from its prohibitions in certain circumstances, *see id.* § 208(b)(3); that an agency, in providing the public a copy of any determination granting such an exemption, may withhold from disclosure any information that would be exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 (2000), *see* 18 U.S.C. § 208(d)(1); that FOIA exempts from its mandatory disclosure requirements any information specifically exempted from disclosure by another statute, *see* 5 U.S.C. § 552(b)(3); and that the FDA, in granting a drug

[2] The OGE Letter further advises that "[t]he agency must observe the [section 107(a)(2)] constraint against release of the information on the form, even if the individual filer has discussed the same or similar information in another forum or the nature of certain of the filer's holdings may be known in his or her industry or community." *Id.* at 5. Read broadly, this advice might mean that an agency may never disclose information if that information happens to be contained in a financial disclosure report, even if the agency relied on an independent source to obtain the information. Under such a broad reading, an agency would be barred, for example, from disclosing a filer's business address if that business address were contained in the filer's financial disclosure report, even if the agency relied on other records to determine the filer's business address (or even if that business address were in the phone book). Alternatively, the OGE advice may mean only that under section 107(a)(2) an agency may not release a financial disclosure report or information obtained from that report but may still release information from independent sources, even if that information is also contained in the financial disclosure report. We have not been asked to, and need not, decide which is the better reading of section 107(a)(2).

advisory panel member an exemption under 18 U.S.C. § 208(b)(3) from the application of the criminal conflict of interest prohibitions, is therefore authorized not to disclose information exempted from disclosure under section 107(a)(2) of the EGA. *See* FDA Memorandum at 3-7. We see no need to address the merits of this argument, for we do not believe that, even if correct, it is in any respect in tension with the plain language of section 355(n)(4). Just as we conclude above that a bar on the FDA's disclosure of a drug advisory panel member's financial disclosure report filed pursuant to the EGA is entirely consistent with section 355(n)(4)'s requirement that the member publicly disclose all conflicts of interest before obtaining a waiver, so we conclude here that the FDA's permissive authority not to disclose the member's report would be consistent with that same requirement.

We therefore conclude that none of the other statutory provisions you raise negates or limits the application of section 355(n)(4).

II. The FDA Has Discretion to Determine the Scope of the Required Disclosure

You have also requested our opinion concerning the scope of any disclosure required under section 355(n)(4)—in particular, the amount of background financial information a panel member must disclose with respect to a particular conflict of interest. *See* FDA Memorandum at 9, 12. The language of the statute provides little guidance in interpreting the phrase "publicly disclose all conflicts of interest," and thus appears to leave the agency some discretion in determining how best to implement the statutory mandate. Indeed, just as the statute explicitly gives the Secretary discretion to decide when the need for an individual's expertise justifies waiving a conflict of interest, we believe that it implicitly permits the Secretary, in developing administrative guidelines for disclosure, to consider the competing public interests at stake.

In enacting section 355(n)(4), Congress clearly sought to promote the strong public interest in knowing whether individuals involved in the approval of new drugs and biological products are potentially biased by conflicting financial interests. Accordingly, any regulations implementing section 355(n)(4) must require an advisory panel member, before receiving a waiver of any conflict of interest, to provide meaningful public disclosure that would adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the member would make. Mere identification of the conflicting interest may be insufficient to meet this standard; it will often be necessary also to provide information concerning the magnitude of a particular financial interest (e.g., whether it consists of a few shares of stock or a controlling interest in a company). On the other hand, Congress surely did not intend that the disclosure requirement should be so

intrusive or onerous as to make many individuals unwilling to serve on advisory panels, as such a result would deprive the FDA of the "essential expertise" Congress intended the advisory panels to provide. The FDA may therefore tailor the scope of the requirement so that it does not impose a greater burden than necessary to achieve the statute's goal.

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