

June 29, 1978

**78-37 MEMORANDUM OPINION FOR THE CHIEF  
COUNSEL, FOOD AND DRUG ADMINISTRATION**

**Advisory Committees—Food and Drug  
Administration—Conflicts of Interest  
(18 U.S.C. § 208)**

This responds to your inquiry regarding the scope of the term "particular matter" as used in 18 U.S.C. § 208(a), in connection with the service of persons from the private sector on advisory committees in the Food and Drug Administration (FDA).

Section 208 requires an officer or employee of the executive branch to disqualify himself in any "particular matter(s)" in which, to his knowledge, he, his spouse or minor child, or an organization in which he is serving as an officer, director, trustee, partner, or employee has a financial interest. Thus, the meaning of the term determines the sort of occasions on which an advisory committee member must disqualify himself under the statute.

We understand that the advisory committees involved in the inquiry are utilized by FDA in the areas of premarketing approval of prescription drugs, classification of medical devices, and drafting of monographs for ingredients used in over-the-counter drugs. Your Office indicated in conversations with this Office last spring that without the use of these advisory committees, the members of which are expert in the areas involved, FDA could not discharge its statutory responsibilities at the level which the safety and the health of the public warrant.

Four examples of participation by members of various FDA advisory committees were given to us. Three of the members were on the faculties of universities that received research grants from pharmaceutical firms or manufacturers of medical devices. At least two actually worked on the university projects funded by the firms. You state that none of the individuals participated as an advisory committee member in any deliberations relating specifically to the firm or the product of the firm that funded the particular research grant to his university, but that each did participate in the committee's deliberations relating to general categories of medical devices or ingredients of

a certain classification of products, some of which were manufactured by the firm that funded the research.

The fourth example involved a member of the National Advisory Food and Drug Committee who had substantial holdings in a cattle feedlot operation and who participated in deliberations concerning the desirability of continuing the use of low levels of antibiotics in animal feeds for prophylactic purposes and growth promotion. He was not a manufacturer of any of the products involved and no competitive advantage or disadvantage would be conferred upon him vis-a-vis other members of his industry<sup>1</sup> regardless of the Agency's ultimate decision. It was also pointed out that this example and those of the university faculty members involved advisory committees established to advise the FDA about matters that involve segments of the regulated industry as a whole rather than particular products or companies.

The relevant statute, 18 U.S.C. §208(a), provides:

(a) Except as permitted by subsection (b) hereof, whoever, being an officer or employee of the executive branch of the United States Government, of any independent agency of the United States, or of the District of Columbia, including a special Government employee, participates personally and substantially as a Government officer or employee, through decision approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest—

Shall be fined not more than \$10,000, or imprisoned not more than two years, or both.

You have informed us that the members of FDA advisory committees are designated as special Government employees. The question presented is whether participation in deliberations of the committees concerning a class of related products or an ingredient common to many products involves participa-

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<sup>1</sup>It was not indicated whether the phrase "his industry" refers to the feedlot industry or to the cattle industry as a whole. It is possible, for example, that the banning of antibiotics in animal feeds would work to the competitive advantage of those portions of the cattle industry that do not rely on animal feeds to the degree that feedlot operators do.

tion in a "particular matter" within the meaning of § 208(a). We believe that it does.<sup>2</sup>

As an initial matter, some confusion regarding the scope of § 208(a) may arise because of the use of the word "particular." It is our understanding that the word "particular" was included to make clear that an individual would not be disqualified from an entire area or range of activities merely because he might have a financial interest in a certain decision, proceeding, transaction, or recommendation arising within that area or range; disqualification is only required in the "particular" matter, not as to the entire area or range. *Cf.*, *Hearings on Federal Conflict of Interest Legislation before Subcommittee No. 5 of the House Judiciary Committee*, 87th Cong., 1st sess. 38 (1961). But it was evidently the purpose to make the enumeration of particular matters in § 208(a) and the other sections of the conflict of interest laws, in which the same enumeration appears, "comprehensive of all matters that come before a Federal department or agency." *Id.*; *see also id.*, at 41. Thus, it has been and continues to be our view that § 208(a) applies to any discrete or identifiable decision, recommendation, or other matter even though its outcome may have a rather broad impact. Accordingly, the word "particular" serves to limit the application of § 208(a) in terms of discrete areas of the employee's activities, not the number of outside parties who may be affected.

Our reading of § 208(a) in this manner finds support as well in the structure of the statute and its contemporaneous interpretation. To determine the proper scope of the language of §208(a), it must be examined as part of a comprehensive statutory scheme rather than in isolation. Utilizing that approach, we find, for example, that 18 U.S.C. § 203(a) and the first paragraph of §205 both bar regular Government employees from representing other parties in all "particular matters" involving the United States. However § 203(c) and the second paragraph of § 205 impose narrower restrictions on special Government employees, barring them from acting as agent or attorney only in "particular matter[s] involving a specific party or parties" that are pending before the Departments or agencies in which they are serving. Similarly, the postemployment statute, 18 U.S.C. § 207, bars a former Government employee, whether regular

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<sup>2</sup>There may be some question whether a "financial interest" within the meaning of the statute is present on the facts involving the three faculty members. It may be that if the research grant to a university concerns the types of products involved in the advisory committee's deliberations, the committee's deliberations could influence FDA's decision with respect to the products. This could in turn have an impact on the continuity of a research grant pertaining to the same products. But it is arguable that neither the faculty member nor his employing university has a "financial interest" in the advisory committee's recommendations where the university's research has no relation to the products the advisory committee is considering.

On the other hand, there is at least some basis for concluding that a substantial contractual relationship with an affected company could itself give the university a financial interest in matters touching on the company's products. *See* Association of the Bar of the City of New York, *Conflict of Interest and Federal Service*, 200-201 (1960). Moreover, where a faculty member is actually a principal participant in a university research grant funded by a company, the situation presents much the same type of potential for divided loyalty in governmental matters affecting the company as if the member were actually employed directly by the company and therefore expressly required by § 208(a) to disqualify himself in matters relating to the company.

or special, from representing another person in a “particular matter involving a specific party or parties” in which he participated or had official responsibility while in Government.

The Memorandum of the Attorney General Regarding Conflict of Interest Provisions of Public Law 87-849, 18 U.S.C. §201, n., points out that “the phrase ‘particular matter involving a specific party or parties’ does not include general rulemaking, the formulation of general policy or standards, or other similar matters. Thus, past participation in or official responsibility for a matter of this kind on behalf of the government does not disqualify a former employee from representing another person in a proceeding which is governed by the rule or other result of the matter.” The clear implication is that general rulemaking and the formulation of general policy would be covered in the absence of the reference to specific parties.

Bayless Manning, an authoritative commentator on the conflict of interest laws, describes the importance of the limiting phrase “involving a specific party or parties” as follows:

Where the language is used [in the conflict of interest laws], it is clear that the statute is concerned with discrete and isolatable transactions between identifiable parties. Thus, the former employee of the Defense Department who worked on the establishment of contract procedures is not on that account forbidden by subsection (a) of Section 207 to act as agent or attorney with respect to any particular Defense contract . . . .

The significance of the phrase “involving a specific party or parties” must not be dismissed lightly or underestimated. Law 87-849 discriminates with great care in its use of this phrase. Wherever the phrase does appear in the new statute it will be found to reflect a deliberate effort to impose a more limited ban and to narrow the circumstances in which the ban is to operate. [B. Manning, *Federal Conflict of Interest Law*, 204 (1964)]

The implication of this passage would appear to be that the establishment of general contracting or similar procedures is a “particular matter,” but that participation in formulating such procedures does not trigger the postemployment bar of 18 U.S.C. § 207 because no specific parties are involved. *See also, id.*, at 70-71.

By way of contrast, a Presidential Memorandum of May 2, 1963, entitled “Preventing Conflicts of Interest on the Part of Special Government Employees,” explains the broader scope of the term “particular matter” in § 208(a) as follows:

The matters in which special Government employees are disqualified by section 208 are not limited to those involving a specific party or parties in which the United States is a party or has an interest, as in the case of sections 203, 205 and 207. Section 208 therefore undoubtedly extends to matters in addition to contracts, grants, judicial and quasi-judicial proceedings, and other matters of an

adversary nature. 'Accordingly, a special Government employee should in general be disqualified from participating as such *in a matter of any type* the outcome of which will have a direct and predictable effect upon the financial interests covered by the section. However, the power of exemption may be exercised in this situation if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization. The power of exemption may of course be exercised also where the financial interests involved are minimal in value. 28 Fed. Reg. 4539, 4543. [Emphasis added.]<sup>3</sup>

The broad statement in the memorandum that the disqualification requirement in § 208(a) applies to a "matter of any type" in which the employee has a financial interest does not on its face suggest that certain types of governmental decisionmaking should be excluded merely because they involve rules, policies, or recommendations that affect several or a number of different companies or products. Indeed, the further statement in the memorandum to the effect that the power of exemption in § 208(b)(1) may be exercised to permit a special Government employee to participate notwithstanding the ordinary disqualification requirement if the special Government employee renders "advice of a general nature from which no preference or advantage over others might be gained" necessarily proceeds on the assumption that "advice of a general nature" is covered by § 208(a).

Based on the contemporaneous construction of the statute reflected in the Presidential memorandum, we have consistently interpreted § 208(a) to apply to rule-making proceedings or advisory committee deliberations of general applicability where the outcome may have a "direct and predictable effect" on a firm with which the Government employee is affiliated, even though all other firms similarly situated will be affected in a like manner. An example might be the drafting or review of environmental regulations which would require considerable expenditures by all firms in the particular industry of which the company is a part.<sup>4</sup>

In one example cited in your letter, banning the use of antibiotics in animal feed could well have a direct and predictable effect on the operations of the feedlot owned by the advisory committee member, even though other feedlot owners would also be affected. Similarly, we would suppose that FDA's decision with respect to the classification of medical devices or use of

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<sup>3</sup>The Presidential memorandum was drafted by the Office of Legal Counsel and therefore reflects a contemporaneous interpretation of the conflict of interest laws by the Department charged with construing them. The substance of the paragraph of the Presidential memorandum quoted in the text is now incorporated at page 4 of Appendix C, Chapter 735 of the *Federal Personnel Manual*, which prescribes the policies and procedures for appointing special Government employees.

<sup>4</sup>Of course the outcome of the particular matter must affect the firm distinctively, and not merely as a member of the general public or as part of the entire business community. For example, a member of an FDA advisory committee would not be disqualified from participating in the formulation of a recommendation about ingredients in aspirin merely because he purchased aspirin as a consumer.

ingredients in drugs could have a direct and predictable effect on a manufacturer of a given device or drug although the manufacturer's competitors who produce the same drug or device were affected in a like fashion.

Interpreting the term "particular matter" in the manner described above is consistent with the purposes of § 208(a). A benefit conferred on an industry generally can be as much of a boon to a firm within that industry as a competitor's going out of business. Typically, stockholders are primarily interested in the earnings of their corporation, and only secondarily in the corporation's relative standing in the industry. Thus, the fact that others will also be affected should not render wholly inapplicable the prohibition against a Government employee's participation in a matter in which he would have the opportunity to further his firm's financial interests. Moreover, to interpret § 208(a) in the way you have suggested—*i.e.*, requiring disqualification only where the firm with which the advisory committee member is affiliated is specifically involved—would be to introduce by way of construction the phrase "involving a specific party or parties" that was deliberately omitted from that section at the time of enactment.

A determination that the term "particular matter" includes recommendations affecting a category of products or a number of firms similarly situated does not, however, automatically foreclose participation on advisory committees by persons with related outside affiliations. Section 208(b)(1) provides that the disqualification requirement in § 208(a) shall not apply if the Government employee first advises the Government official responsible for appointment to his position of the nature and circumstances of the particular matter, makes full disclosure of the relevant financial interest, and receives an advance written determination from the appointing official that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee.<sup>5</sup> There may be a question, of course, whether the financial interests involved in each of the four examples you cite are "insubstantial" in an absolute sense. However, the paragraph in the 1963 Presidential memorandum quoted above states that in addition to situations in which the financial interest is minimal, "the power of exemption may be exercised . . . if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization." This is an interpretation of § 208(b)(1) given soon after its enactment, and, as indicated above, this policy has been carried forward in Appendix C to Chapter 735 of the *Federal Personnel Manual*.

The effect of this interpretation is to put a gloss on the statutory language that the interest "is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect" from the special Government

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<sup>5</sup>Although by its literal terms § 208(b)(1) would appear to require the appointing official to issue a separate exemption for each particular matter in which a given financial interest may arise, we have consistently taken the position that a blanket exemption covering a given financial interest may be issued in appropriate circumstances if the appointing official concludes that the financial interest will not be so substantial as to affect the integrity of the employee's services in whatever context it arises.

employee. It seems to be particularly geared to special Government employees, members of advisory committees, who are often specifically chosen because of an expertise that results from their affiliation with particular organizations, firms, or groups having a general interest in the very matters before the advisory committee.

The responsibility for issuing exemptions under § 208(b)(1) lies with the Agency concerned. We should stress, however, that § 208(b)(1) contemplates a close scrutiny of each special Government employee's outside affiliation to determine whether an affiliation may properly be deemed unlikely to affect the integrity of service as an advisory committee member. It may also be appropriate in certain cases to tailor the exemption in a way that permits the employee to participate in general policy matters but not in those proceedings which more narrowly affect the organization or firm with which he is affiliated. While the ultimate result of utilizing the exemption procedure in this manner to facilitate participation in general policy matters may be the same as if § 208(a) were construed to be wholly inapplicable in such a setting, this does not mean that granting an exemption should be viewed as a mere formality or an empty exercise. The process of granting an exemption compels the responsible Agency official to focus on the question of the special Government employee's outside affiliations and to make a specific, written finding with respect to the expected integrity of the individual's services. We may assume as well that this procedure will also have a beneficial effect on the advisory committee member's own perception of his responsibilities.

Finally, it should be noted that § 208(b)(1) requires that an exemption be granted prior to the employee's participation in the particular matter. We assume that separate exemptions were not granted to the four individuals described in your letter. It cannot be said with certainty whether the decisions with which the advisory committees were concerned would have a direct and predictable effect on the members' outside interests. Because your letter refers to past conduct, the determination of the application of § 208(a) in a case such as this would ordinarily be for the Criminal Division of this Department to make. However, after consultation with the Criminal Division regarding the facts described in your letter, we can advise you that in the absence of some element of bad faith or other aggravating factor, a referral to the Criminal Division is not in order here. In the future, the principles outlined in this letter should be followed and advisory committee members should be notified of their obligations under whatever arrangements are made in each case.

The Office of the General Counsel of the Department of Health, Education, and Welfare is familiar with the application of § 208(a) to special Government employee members of advisory committees and the exemption procedures under § 208(b)(1). That Office no doubt can assist you in these matters, and we are of course prepared to offer additional guidance if necessary.

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