

GAO Access to Trade Secret Information

Section 301(j) of the Food, Drug, and Cosmetic Act of 1938 prohibits the Food and Drug Administration from providing the General Accounting Office with access to trade secret information submitted by drug manufacturers to the FDA.

September 13, 1988

MEMORANDUM OPINION FOR THE ACTING GENERAL COUNSEL DEPARTMENT OF HEALTH AND HUMAN SERVICES

This memorandum responds to your August 18, 1988, request for our opinion as to whether the Food and Drug Administration (“FDA”) may provide the General Accounting Office (“GAO”) with access to trade secret information submitted by drug manufacturers pursuant to the Food, Drug, and Cosmetic Act of 1938 (“FDCA”), 21 U.S.C. §§ 301–393. For the reasons discussed below, we concur with the conclusion of your office¹ that section 301(j) of the FDCA, 21 U.S.C. § 331(j), prohibits the FDA from providing the GAO with such access.

Section 301(j) prohibits the FDA from

revealing, other than to the Secretary [of Health and Human Services (HHS)] or officers or employees of [HHS], or to the courts when relevant in any judicial proceeding under [the FDCA], any information acquired under [specified sections of the FDCA] concerning any method or process which as a trade secret is entitled to protection.

Section 301(j) is clear on its face. It expressly provides that trade secret information may not be disclosed outside HHS with one exception: such information may be disclosed to a court in a judicial proceeding under the FDCA. Since the GAO is obviously not a court or part of HHS, under section 301(j) it is prohibited from gaining access to trade secret information.

Attorney General Griffin Bell previously interpreted section 301(j) to preclude the FDA from furnishing to a congressional committee trade secret information. 43 Op. Att’y Gen. No. 21, at 1–2 (Sept. 8, 1978) (relying “on the unqualified language of § 301(j), the consistent and longstanding interpretation to this effect by

¹ Letter for John O. McGinnis, Deputy Assistant Attorney General, Office of Legal Counsel, from Robert P. Charrow, Deputy General Counsel, Department of Health and Human Services (Aug. 30, 1988).

[HHS], and prior congressional approval of that interpretation through the rejection of an amendment to create an express exemption permitting disclosures to Congress”). The only question raised by your request, therefore, is whether the GAO is precluded from access to trade secret information to the same extent as congressional committees.

We have no hesitation in concluding, on the basis of the 1978 Attorney General Opinion, that section 301(j) should be interpreted to preclude the GAO from access to trade secret information covered by that section. Although whether to provide access to a congressional committee was the specific question presented, the Attorney General Opinion discussed the application of section 301(j) with respect to Congress as a whole. The opinion noted that “[o]n its face, this section imposes an absolute bar to disclosure of trade secret information outside [HHS],” with the one exception of a judicial proceeding; the opinion declined to find “any exception for disclosure to the Congress . . . to be implied.” *Id.* at 2. The Supreme Court has held that the GAO is part of the legislative branch and is “subservient to Congress.” *Bowsher v. Synar*, 478 U.S. 714, 727-32 (1986). It therefore follows that if there is no “exception for disclosure to the Congress,” as the Attorney General Opinion concluded, then there is also no exception in section 301(j) for disclosure to the GAO.

You also raised in your request the question of whether 31 U.S.C. § 716(a) authorizes the GAO to gain access to the trade secret information covered by section 301(j). Section 716(a) provides that:

Each agency shall give the Comptroller General information the Comptroller General requires about the duties, powers, activities, organization, and financial transactions of the agency. The Comptroller General may inspect an agency record to get the information. This subsection does not apply to expenditures made under section 3524 or 3526(e) of this title.

Your office suggested, but after consideration dismissed, the argument that section 716(a) supersedes section 301(j).

Under established rules of statutory construction concerning statutes that may arguably conflict, however, section 301(j) controls in this situation. It is a cardinal axiom of statutory construction that “[w]here there is no clear [congressional] intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.” *Morton v. Mancari*, 417 U.S. 535, 550–51 (1974); see also *Busic v. United States*, 446 U.S. 398, 406 (1980) (“[A] more specific statute will be given precedence over a more general one, regardless of their temporal sequence.”). Since section 301(j) is a specific statute directly addressing one executive branch agency’s handling of trade secret information, while section 716(a) is a general statute addressed to all kinds of information in possession of the executive branch, section 301(j) controls in the

absence of congressional intent to the contrary. We have reviewed the legislative history of section 716(a) and have found no evidence of any such intent.²

Conclusion

For the foregoing reasons, we concur with your conclusion that section 301(j) of the FDCA prohibits the FDA from providing the GAO with access to trade secret information submitted by drug manufacturers pursuant to the FDCA.

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² The judicial enforcement provisions contained in other subsections of 31 U.S.C. § 716 do not provide any basis for concluding that section 716(a) supersedes section 301(j). These other subsections set out a procedure by which the GAO may seek judicial enforcement of its right to executive branch information under section 716(a). See 31 U.S.C. § 716(b),(d). They also provide that certain types of information may be exempted from judicial enforcement. See 31 U.S.C. § 716(d). It might be argued on the basis of these other subsections that trade secret information must be provided to the GAO because it is not the kind of information that may be exempted from judicial enforcement. This argument has no merit. It ignores the fundamental distinction between a right and a judicial remedy to enforce the right: these other subsections simply address a method of enforcing GAO's right to information under section 716(a), they do not define in any way the right itself. The question of the applicability of GAO's right to information under section 716(a) is separate from, and does not depend on, any questions that may arise under other subsections of 31 U.S.C. § 716 concerning judicial enforcement of that right.