



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

July 31, 2012

Ms. Dawn Burton
Assistant General Counsel
Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

OR2012-11972

Dear Ms. Burton:

You ask whether certain information is subject to required public disclosure under the Public Information Act (the "Act"), chapter 552 of the Government Code. Your request was assigned ID# 460649 (DSHS No. 20286).

The Texas Department of State Health Services (the "department") received a request for all records related to the department's investigation of a specified device and any correspondence with "industry or physicians" regarding the device. You state you will release some information to the requestor. You also state you will redact e-mail addresses under section 552.137 of the Government Code pursuant to Open Records Decision No. 684 (2009).¹ You claim some of the submitted information is excepted from disclosure pursuant to section 552.101 of the Government Code. You also state release of the requested information may implicate the proprietary interests of Advanced Aesthetic Concepts ("AAC") and RevecoMED ("Reveco"). Accordingly, you state, and provide documentation showing, you notified AAC and Reveco of the request for information and of the companies' rights to submit arguments to this office as to why the submitted information should not be released. *See* Gov't Code § 552.305(d); *see also* Open Records Decision No. 542 (1990) (statutory predecessor to section 552.305 permits governmental body to rely on interested third party to raise and explain applicability of exception in the Act in certain circumstances). We have received comments from AAC and Reveco. We have

¹Open Records Decision No. 684 is a previous determination to all governmental bodies authorizing them to withhold specific categories of information without the necessity of requesting an attorney general decision, including an e-mail address of a member of the public under section 552.137 of the Government Code.

considered the submitted arguments and reviewed the Declaration of Evan J. Rae, Special Agent with the United States Food and Drug Administration (the "FDA") Office of Criminal Investigations.

Section 552.101 of the Government Code exempts from disclosure "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101. The department asserts a portion of the requested information is deemed confidential by federal law and thus is excepted from required public disclosure under section 552.101. However, the FDA contends the information at issue is not the department's information, but instead belongs to the FDA.

You inform us the FDA provided a portion of the requested information to department employees who have accepted commissions as FDA officers pursuant to federal law. *See* 21 U.S.C. § 372(a). Mr. Rae states several department employees have signed Acceptance of Commission documents as officials of the Department of Health and Human Services ("DHHS") and the FDA.² In addition, Certificates of Commission for four department employees have been submitted. Mr. Rae explains these commissions include the ability to review and receive FDA records. You state any information acquired from the FDA is confidential pursuant to section 331(j) of title 21 of the United States Code, which prohibits

[t]he using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the [DHHS], or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of sections 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387i(b) of this title concerning any method or process which as a trade secret is entitled to protection[.]

21 U.S.C. § 331(j). Accordingly, we understand the FDA records the commissioned employees receive are subject to federal law, including the Freedom of Information Act, 5 U.S.C. § 552, which applies only to federal agencies and not state agencies, and the employee is subject to criminal penalties under federal law for the unauthorized release of confidential information.

You state the FDA considers the department's commissioned officers to be serving in concurrent jurisdiction of the FDA and any responsive documents remain the FDA's property. Indeed, Mr. Rae states in his Declaration that the information at issue consists of the FDA's records. He explains department employees have access to the records at issue only in their capacities as commissioned FDA officers and not in their capacities as state officers or employees. Mr. Rae also states the request for the information at issue should have been directed to the FDA rather than the department.

²The FDA is a component of DHHS.

The Food, Drug, and Cosmetic Act (“FDC Act”) grants DHHS the authority to conduct examinations and investigations by commissioning employees of any state as officers of DHHS. *See* 21 U.S.C. § 372(a)(1)(A). With regard to the disclosure of confidential information by these commissioned officers, section 20.84 of title 21 of the Code of Federal Regulations provides as follows:

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local governmental officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

21 C.F.R. § 20.84; *see also id.* § 20.88 (stating state or local governmental officer commissioned by FDA pursuant to 21 U.S.C. § 372(a) shall have same status with respect to disclosure of FDA records as any special government employee). Furthermore, section 20.2(a) of title 21 of the Code of Federal Regulations states any request for records of the FDA shall be handled pursuant to FDA procedures and requires compliance with the FDA rules governing public disclosure.³ *Id.* § 20.2(a); *see generally id.* pt. 20 (regulations concerning public disclosure of FDA records).

You state the information you have identified was sent to or received by the commissioned officers from the FDA pursuant to their commissions. Under section 372(a) of the FDC Act, “[t]he Secretary [of DHHS] is authorized to conduct examinations and investigations . . . through any . . . employee of any State . . . duly commissioned by the Secretary as an officer of the [DHHS].” 21 U.S.C. § 372(a). When an examination or investigation is conducted by an investigator as a commissioned officer of DHHS (or a component of DHHS, in this case, the FDA), it follows that the information gathered pursuant to such an examination is a record of DHHS, the commissioning agency. In other words, the records of such investigation are the records of the agency that authorized the investigation. As we have seen, FDA regulation requires commissioned officers to comply with the same federal laws and regulations with respect to disclosure of FDA records in the same way as any other FDA employee. *See* 20 C.F.R. § 20.84. In light of DHHS’s authority to commission as FDA officers the employees whom you state maintain the information at issue here, and after consideration of the relevant regulations on disclosure of FDA records by commissioned officers, we do not believe the FDA’s position that the records of the commissioned officers require treatment as FDA records is unreasonable.

³In particular, Mr. Rae states the information at issue contains non-public information that may be protected from disclosure by the deliberative process and open investigatory privileges, as well as protected personal information, trade secret, and confidential commercial information. *See* 20 C.F.R. §§ 20.61-.64.

Therefore, to the extent the FDA provided the information you have identified to department employees who have accepted commissions as FDA officers who are subject to the same restrictions on disclosure as other FDA employees and to the extent the FDA considers the information held by these commissioned employees to be the records of the FDA, we conclude that for purposes of responding to a request for information from a member of the public, the decision to release or withhold the information at issue is a decision for the FDA. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (agency interpretations in formats such as opinion letter are entitled to respect under decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), if persuasive). Thus, neither the department nor this office may determine the extent to which the information at issue is subject to required public disclosure. Upon receipt of a request for the information, the FDA must make that determination in accordance with federal laws and regulations.⁴

We next address the department's assertion some of the information is protected by the common-law informer's privilege. Section 552.101 of the Government Code encompasses the common-law informer's privilege, which Texas courts have long recognized. *See Aguilar v. State*, 444 S.W.2d 935, 937 (Tex. Crim. App. 1969). The informer's privilege protects the identities of persons who report activities over which the governmental body has criminal or quasi-criminal law-enforcement authority, provided that the subject of the information does not already know the informer's identity. *See Open Records Decision Nos. 515 at 3 (1998), 208 at 1-2 (1978)*. The privilege protects the identities of individuals who report violations of statutes to the police or similar law-enforcement agencies, as well as those who report violations of statutes with civil or criminal penalties to "administrative officials having a duty of inspection or of law enforcement within their particular spheres." *See Open Records Decision No. 279 at 2 (1981)* (citing 8 John H. Wigmore, *Evidence in Trials at Common Law*, § 2374, at 767 (J. McNaughton rev. ed. 1961)). The report must be of a violation of a criminal or civil statute. *See Open Records Decision Nos. 582 at 2 (1990), 515 at 4-5*. The privilege excepts the informer's statement only to the extent necessary to protect the informer's identity. *See Open Records Decision No. 549 at 5 (1990)*.

You have marked information the department seeks to withhold on the basis of the informer's privilege. You explain the marked information identifies individuals who reported alleged violations of chapter 431 of the Texas Health and Safety Code to the department. You explain the department is charged with enforcing chapter 431 of the Health and Safety Code. You inform us a violation of section 431.021 of the Health and Safety Code is punishable by civil and criminal penalties. There is no indication the subject of the complaint knows the identity of the complainants. However, we note one of the

⁴Mr. Rae states some responsive documents may be available on the FDA's internet site without the need for a written request. Mr. Rae also invites the requestor to submit his request to the following address:

Food and Drug Administration
Division of Freedom of Information (HFI-35)
12420 Parklawn Drive
Rockville, Maryland 20857

complainants listed is a government agency and not a person. The informer's privilege only protects the identity of an individual. *See Roviario v. United States*, 353 U.S. 53, 59 (1957); ORD 515 at 2. Thus, we conclude the department has not demonstrated the applicability of the common-law informer's privilege to this information, which we have marked for release, and it may not be withheld under section 552.101 of the Government Code on that basis. However, we conclude the department may withhold the remaining information you have marked under section 552.101 of the Government Code in conjunction with the common-law informer's privilege.

Next, we address AAC's and Reveco's arguments against disclosure of the companies' information. We note Reveco seeks to withhold information not submitted to this office by the department. Because this information was not submitted by the department, this ruling does not address that information and is limited to the information submitted as responsive by the department.⁵ *See* Gov't Code § 552.301(e)(1)(D) (governmental body requesting decision from Attorney General must submit copy of specific information requested).

We understand AAC asserts the company's information is not subject to the Act. The Act is applicable to "public information." *See id.* § 552.021. "Public information" is defined as information that is collected, assembled, or maintained under a law or ordinance or in connection with the transaction of official business:

(1) by a governmental body; or

(2) for a governmental body and the governmental body owns the information or has a right of access to it.

Id. § 552.002(a). Thus, virtually all information in the physical possession of a governmental body is public information that is encompassed by the Act. *Id.* § 552.022(a)(1); *see also* Open Records Decision Nos. 549 at 4, 514 at 1-2 (1988). AAC asserts its information is not "public information" because AAC is a privately held company. However, upon review, we find the department maintains the submitted information in connection with the transaction of official department business. Accordingly, we conclude the submitted information is subject to the Act.

Reveco asserts the submitted information is excepted from disclosure by the litigation exception, section 552.103 of Government Code. Because section 552.103 protects only the interests of a governmental body, as distinguished from exceptions intended to protect the interests of third parties, we do not address Reveco's argument. *See* Open Records Decision Nos. 542 (statutory predecessor to section 552.103 does not implicate rights of third party), 522 (1989) (discretionary exceptions in general). The litigation exception only applies when the governmental body is a party to the pending or reasonably anticipated

⁵As this determination is dispositive, we need not address Reveco's argument under the Medical Practice Act, subtitle B of title 3 of the Occupations Code.

litigation. *See* Gov't Code § 552.103(a); Open Records Decision No. 575 at 2 (1990). Accordingly, the department may not withhold any of the remaining information under section 552.103.

AAC and Reveco claim section 552.110 of the Government Code for portions of their respective information. Section 552.110 protects: (1) trade secrets; and (2) commercial or financial information, the disclosure of which would cause substantial competitive harm to the person from whom the information was obtained. Gov't Code § 552.110(a), (b). Section 552.110(a) protects the proprietary interests of private parties by excepting from disclosure trade secrets obtained from a person and privileged or confidential by statute or judicial decision. *See id.* § 552.110(a). The Texas Supreme Court has adopted the definition of trade secret from section 757 of the Restatement of Torts. *Hyde Corp. v. Huffines*, 314 S.W.2d 763 (Tex. 1958); *see also* Open Records Decision No. 552 at 2 (1990). Section 757 provides that a trade secret is

any formula, pattern, device or compilation of information which is used in one's business, and which gives [one] an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business . . . in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example the amount or other terms of a secret bid for a contract or the salary of certain employees A trade secret is a process or device for continuous use in the operation of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

RESTATEMENT OF TORTS § 757 cmt. b (1939) (citation omitted); *see also Hyde Corp. v. Huffines*, 314 S.W.2d 763, 776 (Tex. 1958); Open Records Decision Nos. 255 (1980), 232 (1979), 217 (1978).

There are six factors to be assessed in determining whether information qualifies as a trade secret:

- (1) the extent to which the information is known outside of [the company's] business;
- (2) the extent to which it is known by employees and others involved in [the company's] business;

- (3) the extent of measures taken by [the company] to guard the secrecy of the information;
- (4) the value of the information to [the company] and to [its] competitors;
- (5) the amount of effort or money expended by [the company] in developing the information; and
- (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

RESTATEMENT OF TORTS § 757 cmt. b (1939); *see also* ORD 232. This office must accept a claim that information subject to the Act is excepted as a trade secret if a *prima facie* case for exemption is made and no argument is submitted that rebuts the claim as a matter of law. ORD 552 at 2. However, we cannot conclude that section 552.110(a) is applicable unless it has been shown that the information meets the definition of a trade secret and the necessary factors have been demonstrated to establish a trade secret claim. Open Records Decision No. 402 (1983).

Section 552.110(b) protects “[c]ommercial or financial information for which it is demonstrated based on specific factual evidence that disclosure would cause substantial competitive harm to the person from whom the information was obtained[.]” Gov’t Code § 552.110(b). This exception to disclosure requires a specific factual or evidentiary showing, not conclusory or generalized allegations, that substantial competitive injury would likely result from release of the information at issue. *Id.*; Open Records Decision No. 661 (1999).

AAC and Reveco argue some of their respective information constitutes trade secrets. Upon review, we agree AAC’s and Reveco’s customer information, which we have marked, constitutes trade secret information under section 552.110(a); therefore, the department must withhold this marked information under section 552.110(a). However, we find AAC and Reveco have failed to demonstrate any of the remaining information for which the companies assert section 552.110(a) meets the definition of a trade secret, nor have AAC and Reveco demonstrated the necessary factors to establish a trade secret claim for this information. Accordingly, the department may not withhold any of the remaining information at issue on the basis of section 552.110(a) of the Government Code.

AAC and Reveco contend some of their respective information is commercial or financial information, release of which would cause substantial competitive harm to the companies. Upon review, we conclude AAC and Reveco have established the release of the companies’ respective pricing information would cause each company substantial competitive injury; therefore the department must withhold the information we have marked under section 552.110(b). However, we find AAC and Reveco have not made the specific factual or evidentiary showing required by section 552.110(b) that release of any of the remaining information would cause the companies substantial competitive harm. We, therefore,

conclude the department may not withhold any of the remaining information under section 552.110(b) of the Government Code.

In summary, to the extent the FDA provided the information you have identified to department employees who have accepted commissions as FDA officers who are subject to the same restrictions on disclosure as other FDA employees and to the extent the FDA considers the information held by these commissioned employees to be the records of the FDA, we conclude that for purposes of responding to a request for information from a member of the public, the decision to release or withhold the information at issue is a decision for the FDA. With the exception of the information we have marked for release, the department may withhold the information you have marked under section 552.101 of the Government Code in conjunction with the common-law informer's privilege. The department must withhold the information we have marked under section 552.110 of the Government Code. The department must release the remaining information.

This letter ruling is limited to the particular information at issue in this request and limited to the facts as presented to us; therefore, this ruling must not be relied upon as a previous determination regarding any other information or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For more information concerning those rights and responsibilities, please visit our website at http://www.oag.state.tx.us/open/index_orl.php, or call the Office of the Attorney General's Open Government Hotline, toll free, at (877) 673-6839. Questions concerning the allowable charges for providing public information under the Act must be directed to the Cost Rules Administrator of the Office of the Attorney General, toll free, at (888) 672-6787.

Sincerely,



Jennifer Burnett
Assistant Attorney General
Open Records Division

JB/tch

Ref: ID# 460649

Enc. Submitted documents

c: Requestor
(w/o enclosures)

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