



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

May 25, 2010

Mr. Marc Allen Connelly
Deputy General Counsel
Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

OR2010-07557

Dear Mr. Connelly:

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# 380487 (DSHS File 017098-2010).

The Texas Department of State Health Services (the "department") received a request for information pertaining to a specified complaint number and subsequent investigation, a copy of the initial complaint, and copies of all documentation associated with a specified detention number and sample number. You state you have released or will release some responsive information to the requestor. You claim the remaining requested information is excepted from disclosure under section 552.101 of the Government Code and federal law. We have considered your arguments and reviewed the submitted information.

Initially, you acknowledge, and we agree, the department failed to request a ruling or submit the responsive information within the statutory time periods prescribed by subsections 552.301(b) and 552.301(e) of the Government Code. *See* Gov't Code § 552.301(b), (e). Pursuant to section 552.302 of the Government Code, a governmental body's failure to comply with the requirements of section 552.301 results in the legal presumption the requested information is public and must be released, unless the governmental body demonstrates a compelling reason to withhold the information from disclosure. *See id.* § 552.302; *Simmons v. Kuzmich*, 166 S.W.3d 342, 350 (Tex. App.—Fort Worth 2005, no pet.); *Hancock v. State Bd. of Ins.*, 797 S.W.2d 379, 381-82 (Tex. App.—Austin 1990, no writ) (governmental body must make compelling demonstration to overcome presumption of openness pursuant to statutory predecessor to

section 552.302); *see also* Open Records Decision No. 630 (1994). A compelling reason exists when third-party interests are at stake or when information is confidential by law. Open Records Decision No. 150 (1977). Because section 552.101 can provide a compelling reason to withhold information, we will consider whether or not the requested information is excepted under the Act.

Next, we address your claim that some of the requested information is excepted from disclosure pursuant to federal law. You state that the Food and Drug Administration (the "FDA") contracts with the department to conduct inspections under the authority of federal law and that the inspections are conducted by department employees who are commissioned officers of the FDA. You inform this office that the inspection reports created by the department are then submitted to the FDA. You assert that the FDA has informed the department that the reports and any information obtained from the inspections are confidential pursuant to sections 301 and 331(j) of title 21 of the United States Code. Further, you indicate some of the requested documents consist of information, compiled by department investigators as FDA commissioned officers, which is confidential under section 20.64 of title 21 of the Code of Federal Regulations. *See* 21 C.F.R. § 20.64 (stating certain records compiled for law enforcement purposes may be withheld from public disclosure). Sections 301 and 331(j) of title 21 of the United States Code provide that the Federal Food, Drug, and Cosmetic Act prohibits the disclosure of certain confidential information, such as trade secrets acquired in an official capacity. You also refer to section 20.88, title 21, of the Code of Federal Regulations, which states in relevant part:

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the [FDA] at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the [FDA] as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to [FDA] employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the [FDA].

(2) Disclosure of investigatory records compiled for law enforcement purposes by the [FDA] to State and local government officials who perform counterpart functions to the [FDA] at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

21 C.F.R. § 20.88(c). You assert that because this office is not commissioned by the FDA, section 20.88(c) prohibits you from disclosing the requested investigatory records to this office. Thus, because you have not provided this office with the investigatory documents at issue, we are unable to make any determination regarding such documents.

Next, we address your claim that portions of the submitted information are excepted from disclosure under section 552.101 of the Government Code. Section 552.101 excepts from disclosure "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101. This section encompasses information protected by other statutes. You state the FDA has informed the department that the highlighted portions of the submitted consumer complaint reports are confidential under section 20.111, title 21, of the Code of Federal Regulations. Section 20.111 applies to release of information submitted voluntarily to the FDA, and provides in relevant part the following:

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the [FDA], whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the [FDA] but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

(c) The following data and information submitted voluntarily to the [FDA] are available for public disclosure unless extraordinary circumstances are shown:

...

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

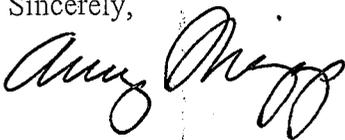
(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

21 C.F.R. § 20.111(a)–(b), (c)(3)(i). We understand you to assert the submitted consumer complaint reports were submitted voluntarily to the FDA. The information you have highlighted identifies the consumer who submitted the complaint at issue. You claim that pursuant to section 20.111 of title 21 of the Code of Federal Regulations, the department cannot release the identifying information you have marked in the submitted reports to the requestor. Upon review, we agree that the department must redact the consumer's identifying information, which you have marked, from the consumer complaint reports at issue pursuant to section 20.111(c)(3)(I), title 21 of the Code of Federal Regulations in conjunction with section 552.101 of the Government Code. The remaining submitted information must be released.

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,



Amy L.S. Shipp
Assistant Attorney General
Open Records Division

ALS/rl

Ref: ID# 380487

Enc. Submitted documents

cc: Requestor
(w/o enclosures)



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

May 25, 2010

Mr. B. Chase Griffith
Attorney for City of McKinney
Brown & Hofemister, L.L.P.
740 East Campbell Road, Suite 800
Richardson, Texas 75081

OR2010-07558

Dear Mr. Griffith:

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# 386023.

The McKinney Police Department (the "department"), which you represent, received a request for information pertaining to a specified incident. You claim the requested information is excepted from disclosure under sections 552.101 and 552.108 of the Government Code. We have considered the exceptions you claim and reviewed the submitted information.

Section 552.101 of the Government Code excepts from disclosure "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." Gov't Code § 552.101. Section 552.101 encompasses the doctrine of common-law privacy, which protects information if (1) the information contains highly intimate or embarrassing facts, the publication of which would be highly objectionable to a reasonable person, and (2) the information is not of legitimate concern to the public. *Indus. Found. v. Tex. Indus. Accident Bd.*, 540 S.W.2d 668, 685 (Tex. 1976). The types of information considered intimate or embarrassing by the Texas Supreme Court in *Industrial Foundation* included information relating to sexual assault, pregnancy, mental or physical abuse in the workplace, illegitimate children, psychiatric treatment of mental disorders, attempted suicide, and injuries to sexual organs. *Id.* at 683. Generally, only highly intimate information that implicates the privacy of an individual is withheld. However, in certain instances, where it is demonstrated that the requestor knows the identity of the individual involved, as well as the nature of certain