



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

November 20, 2012

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

OR2012-18699

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# 471977 (DSHS File No. 20772).

The Texas Department of State Health Services (the "department") received a request for information pertaining to several licenses issued by the department to Medtronic, Inc. ("Medtronic"). You state the department has provided or will provide some of the responsive 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 requested information is excepted from disclosure under section 552.101 of the Government Code and federal law. Additionally, although you take no position as to whether the remaining information is excepted under the Act, you state release of the remaining information may implicate the proprietary interests of Medtronic. Accordingly, you state, and provide documentation showing, you notified Medtronic of the request for information and of the company's right to submit arguments to this office as to why the information at issue 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

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.

governmental body to rely on interested third party to raise and explain applicability of exception in the Act in certain circumstances) We have considered your arguments and reviewed the submitted representative sample of information.²

Initially, we address your claim that some of the requested information is excepted from disclosure pursuant to federal law. You state the Food and Drug Administration (the "FDA") has commissioned particular department staff to conduct investigations under the authority of federal law. *See* 21 U.S.C. § 372(a). You inform this office that some of the requested information consists of information the FDA provided to commissioned department staff. You assert any information obtained from the investigative files is confidential pursuant to section 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). Section 331(j) of title 21 of the United States Code provides 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

²We assume the representative sample of records submitted to this office is truly representative of the requested records as a whole. *See* Open Records Decision Nos. 499 (1988), 497 (1988). This open records letter does not reach, and therefore does not authorize the withholding of, any other requested records to the extent that those records contain substantially different types of information than that submitted to this office.

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.³

Next, we note an interested third party is allowed ten business days after the date of its receipt of the governmental body's notice to submit its reasons, if any, as to why information relating to that party should not be released. *See Gov't Code § 552.305(d)(2)(B)*. As of the date of this ruling, we have not received comments from Medtronic. Thus, we have no basis to conclude Medtronic has a protected proprietary interest in any of the submitted information. *See id.* § 552.110(a)-(b); Open Records Decision Nos. 661 at 5-6 (1999) (to prevent disclosure of commercial or financial information, party must show by specific factual evidence, not conclusory or generalized allegations, that release of requested information would cause that party substantial competitive harm), 552 at 5 (1990) (party must establish *prima facie* case that information is trade secret), 542 at 3. Accordingly, the department may not withhold any of the submitted information on the basis of any proprietary interest Medtronic may have in the information. As no exceptions to disclosure have been raised for the submitted information, it must be released to the requestor.

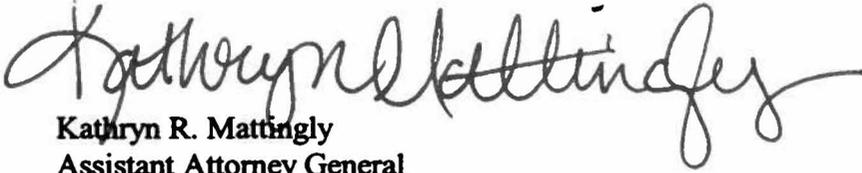
This letter ruling is limited to the particular information at issue in this request and limited to the facts as presented to us; therefore, this ruling must not be relied upon as a previous determination regarding any other information or any other circumstances.

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

³Accordingly, we do not address your argument under section 552.101 of the Government Code.

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,

A handwritten signature in cursive script, appearing to read "Kathryn R. Mattingly".

Kathryn R. Mattingly
Assistant Attorney General
Open Records Division

KRM/dls

Ref: ID# 471977

Enc. Submitted documents

c: Requestor
(w/o enclosures)

Ms. Karen Rhodes
Logistics Manager
Medtronic Sofamor Danek USA, Inc.
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Fort Worth, Texas 76137
(w/o enclosures)