

## UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION WASHINGTON, D.C. 20580

Bureau of Competition Health Care Division

November 30, 2012

Dionne C. Lomax Vinson & Elkins LLP 2200 Pennsylvania Avenue NW Suite 500 West Washington, DC 20037

Re: The Methodist Hospital System Advisory Opinion

Dear Ms. Lomax:

This letter responds to your request on behalf of The Methodist Hospital System ("Methodist") for an advisory opinion concerning Methodist's proposal to sell certain critical shortage drugs to Baytown EMS, a division of the Baytown, Texas, city government, during the pendency of the shortage. Baytown EMS serves as the exclusive 9-1-1 emergency transport service for Baytown residents. You requested our view on the permissibility of these proposed sales under the Robinson-Patman Act. Specifically, you requested that we opine on the applicability of the Non-Profit Institutions Act ("NPIA") to the proposal. The NPIA provides an exemption from liability under the Robinson-Patman Act for purchases of supplies by certain non-profit organizations for their own use.

We need not reach the NPIA question, however, because Methodist's proposal, as presented, appears to be a permissible emergency humanitarian gesture. As explained below, Methodist proposes to sell pharmaceuticals to Baytown EMS for the sole purpose of assisting Baytown EMS in the care of patients during a time of nationwide shortages of certain critical drugs. Given these facts, it is our view that, pursuant to the Supreme Court's discussion of a hospital's role in an emergency in *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1 (1976) and the Commission's similar discussion in its *St. Peter's Hospital of the City of Albany*<sup>3</sup> advisory

<sup>&</sup>lt;sup>1</sup> 15 U.S.C. § 13.

<sup>&</sup>lt;sup>2</sup> 15 U.S.C. § 13c (exempting from the Robinson-Patman Act "purchases of supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit").

<sup>&</sup>lt;sup>3</sup> St. Peter's Hospital of the City of Albany, 92 F.T.C. 1037 (1978) (Commission advisory opinion).

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opinion, Methodist may resell the needed pharmaceuticals to Baytown EMS as a humanitarian gesture during the shortages.<sup>4</sup>

## **Factual Background**

As we understand the facts based on information you provided, Methodist is a non-profit hospital system that provides comprehensive care to its patients. It is based in Houston, Texas, and purchases its pharmaceuticals through a group purchasing organization at an NPIA-discounted price. Methodist is comprised of inpatient facilities, outpatient surgery centers, imaging centers, and emergency care centers. Currently, its facilities include five hospitals. One of Methodist's hospitals is San Jacinto Methodist Hospital, which is a 392-bed general acute care inpatient facility located about 30 miles east of downtown Houston, in Baytown, Texas. San Jacinto Methodist is the only hospital within Baytown's city limits. Further, it is the only hospital in the Baytown area that provides the full range of acute care inpatient health services.

Baytown EMS is the exclusive transport provider for the City of Baytown's 9-1-1 service. It is a division of the city of Baytown and was created under the Emergency Healthcare Act for the sole purpose of providing critical medical care and emergency medical transportation services to the citizens of Baytown. By city ordinance, Baytown EMS is the only emergency medical service transport allowed to respond within the city limits. It employs 21 paramedics and has four front-line ambulances. The vast majority of Baytown EMS's emergency transports go to San Jacinto

<sup>&</sup>lt;sup>4</sup> This advisory opinion should not be construed as taking the position that the Robinson-Patman Act necessarily applies to these facts, or that Methodist's proposed sale to Baytown EMS would violate the Robinson-Patman Act absent the shortage situation or other applicable exemption. We provide this opinion, under these unique circumstances of critical drug shortages, in an effort to provide reassurances that may be helpful to entities in their efforts to cope with the current drug shortages.

<sup>&</sup>lt;sup>5</sup> Letter from Dionne C. Lomax, Vinson & Elkins LLP, to Markus H. Meier, FTC (July 25, 2012) [hereinafter "July Letter"]; Letter from Dionne C. Lomax, Vinson & Elkins LLP, to Robert S. Canterman, FTC (Sept. 6, 2012) [hereinafter "September Letter"].

<sup>&</sup>lt;sup>6</sup> See http://www.methodisthealth.com (viewed September 17, 2012); July Letter.

<sup>&</sup>lt;sup>7</sup> September Letter.

<sup>&</sup>lt;sup>8</sup> July Letter.

<sup>&</sup>lt;sup>9</sup> July Letter; September Letter.

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Methodist.<sup>10</sup> Though it can collect fees for its services, Baytown EMS does not generate a profit.<sup>11</sup>

As you have explained, during transport of patients to hospitals for care, it may be necessary for Baytown EMS to administer certain pharmaceuticals prior to arrival at the hospital. Indeed, the administration of certain pharmaceuticals at the first point of care can be critical to a patient's clinical outcome. Recently, however, owing to well-publicized nationwide shortages of certain critical drugs, Baytown EMS has been unable to keep its ambulances stocked with safe inventory levels of certain of these critical pharmaceuticals. Efforts to secure supply from other vendors have not succeeded, and the problem appears to be prevalent throughout the region. <sup>12</sup>

To assist Baytown EMS in dealing with the drug shortages and to ensure that its patients, which comprise the vast majority of Baytown EMS's transports, receive the necessary clinical care en route to the hospital, Methodist proposes to sell, at cost, critical shortage drugs to Baytown EMS. As you explained to us, Methodist would continue this arrangement only for so long as the drugs are in shortage.<sup>13</sup>

## Analysis

The Supreme Court's opinion in *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1 (1976) guides our analysis of permissible uses of NPIA-discounted pharmaceuticals. There, in addition to clarifying the applicability of the NPIA exemption to the Robinson-Patman Act, the Supreme Court addressed the appropriate role of a hospital in an emergency situation. It stated:

We recognize, however, that there may be an occasion when the hospital pharmacy is the only one available in the community to meet a particular emergency situation. . . . So long as the hospital pharmacy holds the emergency situation within bounds, and entertains it only as a humanitarian gesture, we shall not condemn the hospital and its suppliers to a Robinson-Patman violation because of the presence of the occasional walk-in dispensation of that type. <sup>14</sup>

<sup>&</sup>lt;sup>10</sup> See id.

<sup>&</sup>lt;sup>11</sup> September Letter.

<sup>&</sup>lt;sup>12</sup> July Letter; September Letter.

<sup>&</sup>lt;sup>13</sup> See id.

<sup>&</sup>lt;sup>14</sup> See Abbott at 18. The Court further noted that the occasional emergency would likely be de minimis in any event.

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Applying the Supreme Court's reasoning in *Abbott*, the Commission previously has determined that a hospital could resell pharmaceuticals it purchased pursuant to the NPIA discount to the general public during an emergency caused by a Medicaid strike. In its *St. Peter's* opinion, the Commission concluded that "if needed pharmaceuticals are not available or difficult to obtain, [the hospital] may resell the needed pharmaceuticals to the general public as a humanitarian gesture during the emergency caused by the [Medicaid] strike." <sup>15</sup>

Methodist's proposal appears consistent with both the Supreme Court's reasoning in *Abbott* and the Commission's reasoning in *St. Peter's*. As we understand the facts you have presented, Methodist runs the only hospital within Baytown's city limits. To assist Baytown EMS during a time of well-publicized nationwide shortages of critical drugs, Methodist seeks to sell certain shortage drugs that it obtains at the NPIA-discounted price to Baytown EMS. These shortage drugs are necessary to the care of Baytown EMS's emergency transport patients, most of whom are transported to Methodist and ultimately become patients of Methodist. Despite its efforts to do so, Baytown EMS has been unable to secure adequate supply of these drugs from other sources. Methodist only proposes to assist Baytown EMS during the pendency of the shortages. Thus, applying *Abbott* and *St. Peter's*, it is our opinion that Methodist may resell the needed shortage drugs to Baytown EMS to assist Baytown EMS in its efforts to maintain safe inventory levels of those products for use in the treatment of its emergency transport patients.

## Conclusion

As discussed above, we conclude that Methodist's proposal to resell pharmaceuticals to Baytown EMS to assist Baytown EMS in its efforts to cope with shortages of certain critical drugs would be a permissible humanitarian gesture and that Methodist may resell the needed pharmaceuticals to Baytown EMS during the shortages.

This letter sets out the views of the staff of the Bureau of Competition, as authorized by the Commission's Rules of Practice. Under Commission Rule § 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by this staff opinion and reserves the right to rescind it at a later time. In addition, this office retains the right to reconsider the questions involved and, with notice to the requesting party, to rescind or revoke the opinion if implementation of the proposed program results in substantial anticompetitive effects, if the program is used for improper purposes, if facts change significantly, or if it otherwise would be in the public interest to do so.

Sincerely,

Markus H. Meier Assistant Director

<sup>&</sup>lt;sup>15</sup> St. Peter's Hospital of the City of Albany, 92 F.T.C. 1037 (1978) (Commission advisory opinion).