

1199SEIU

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Massachusetts Division

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November 1, 2007

Mr

Boston , MA 02199

RE: BIDMC Oversight of "SomRx" Business Venture

Dear Mr.

The 300,000 members of 1199 SEIU United Healthcare Workers East are committed to improving patient care as part of our mission to ensure comprehensive and affordable access to safe, high quality health care for all Massachusetts residents.

We are writing to you as a fiduciary of Beth Israel Deaconess Medical Center (BIDMC) to bring to your attention a matter of protection of the public interest and of the interest of BIDMC. As you know, nonprofit healthcare fiduciaries play a role in ensuring that their institutions balance the needs of patient care with the needs of running a business.

There exists a recent case in which BIDMC entered into a for-profit business relationship with an executive with a previous misdemeanor conviction of "shipment of adulterated devices" to healthcare institutions that, according to the US Attorney in the case, included Beth Israel itself, according to documents filed in related court proceedings¹⁰, which raises several questions for fiduciaries.

We bring this important matter to your attention as a board member so that the Board can determine the appropriate course of action. To ensure a strong fiduciary hand in protecting patient care and the public interest, we would encourage you to request further information and greater transpar

¹⁰ According to Steven A. Higgenson, Assistant US Attorney, *United States v. Prigmore, Crim. No. 93-10276-JLT*. Court Transcript, 20th Day of Jury Trial, August 15, 1995.

ency regarding the SomRx deal and other companies in which the institution has taken an equity position.

Further details regarding concerns of the potential breakdown of oversight and patient care implications are enclosed.

We look forward to your response and if you have any questions please contact me at (617) 284-1140.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Fadel". The signature is stylized and somewhat cursive.

Mike Fadel

Concerns for Fiduciaries Raised by the Beth Israel Deaconess Medical Center / SomRx Business Venture

Recent media coverage has highlighted relationships between nonprofit academic medical centers (AMC's) and for profit industry, in particular startup biotech, pharmaceutical and device companies. Common relationships between AMC's and spin-off companies – licensing fees, royalties, equity stakes – and attendant apparent financial incentives raise important questions about patient care. In addition, when an AMC takes an equity position in a company it should likely raise questions for nonprofit fiduciaries including potential oversight and compliance issues; consideration of potential benefit to insiders; proper use of nonprofit assets; and issues of transparency and disclosure to patients and the public.

A recent case in which BID entered into a for-profit business relationship with executive John F. Cvinar raises such questions for fiduciaries.¹ In 2004 Beth Israel Deaconess Medical Center (BID) helped to launch a company, SomRx, to develop and manufacture medical devices to treat sleep disorders. SomRx was incorporated in Delaware in April 2004 for the “research and development of medical devices” according to filings in Delaware and Massachusetts.² As of April 2007, SomRx was based at 94 Ridge Street, in Winchester, MA.

Given CEO John Cvinar's previous misdemeanor conviction of “shipment of adulterated devices” to healthcare institutions that, according to the US Attorney in the case, included Beth Israel itself,³ BID's business relationship may raise questions for fiduciaries as to whether proper oversight measures were followed. Incentives to BID insiders raise further questions, as does testing of the device at BID and the apparently unexplained dissolution of the company in April 2007.

A discussion of the details and a list of potential questions for fiduciaries raised by the BID/SomRx relationship follows.

▪ Business relationship between BID and John Cvinar

In 2001, according to documents filed in court proceedings, John Cvinar was found guilty of shipment of adulterated devices⁴ in a case related to what was at the time (1995) the largest fine ever imposed in an FDA fraud case, according to the Boston Globe.⁵ In fact, according to the US Attorney in the case, Beth Israel Hospital itself had been a victim of Cvinar's activities, as one of the hospitals that were sold unapproved heart catheters.⁶ Cvinar attested to

¹ John Cvinar is a “medical-device veteran” according to the Mass High Tech, “Beth Israel spinout aims to help sleep-deprived rest,” Friday, May 19, 2006.

<http://masshightech.bizjournals.com/masshightech/stories/2006/05/22/story9.html>

² Certificate of Incorporation of SomRx Corp, Secretary of State of Delaware, April 21, 2004. SomRx Foreign Corporation Certificate, Secretary of the Commonwealth of Massachusetts, May 6, 2004.

³ According to Steven A. Higgenson, Assistant US Attorney, *United States v. Prigmore, Crim. No. 93-10276-JLT.* Court Transcript, 20th Day of Jury Trial, August 15, 1995.

⁴ Judgments, *US v. John Cvinar Criminal No. 93-10276-02-JLT.*; See also: “Three former executives of heart catheter manufacturer sentenced”; The Associated Press State & Local Wire; June 7, 2001.

⁵ “3 ex-Bard executives guilty in health fraud, Unapproved heart catheters sold”; Boston Globe; August 25, 1995.

⁶ *United States v. Prigmore, Crim. No. 93-10276-JLT.* Court Transcript, 20th Day of Jury Trial, August 15, 1995, p.5, line 19-21. See also “3 ex-Bard executives guilty in health fraud, Unapproved heart catheters sold”; Boston Globe; August 25, 1995.

employability concerns in a 1999 affidavit, "I will likely never be able to become employed in a company like Bard or the other major corporate players in the health care field because of the stigma associated with this case."⁷

- **Incentives and equity positions to nonprofit insiders**

Device co-inventor Robert Thomas and BID itself⁸ were beneficial owners of SomRx, holding at least a 10% stake in the company, according to 2004 filings with the Securities and Exchange Commission (SEC).⁹ With the exceptions of Cvinar and co-inventor Robert Daly, all decision makers at SomRx were tied to BID (see table).¹⁰

Name	BID Role	SomRx Role
Mark Chalek	Chief, Business Ventures and Technology Ventures Office at BID	Former President, ¹¹ Director ¹²
Robert J. Thomas	Physician, BID	Inventor, Equity
Catherine Lenich	Senior Associate, Licensing Staff, Technology Ventures, BID	Treasurer Director
Peter B. Finn	Member, Research and Technology Development Committee/ Technology Transfer Committee ¹³	Clerk

That is, a majority of board members were affiliated with BID. It is likely that this board appointed John Cvinar CEO in 2004.¹⁴ Board members included two members of BID's technology licensing staff. Were these individuals representing the interests of BID, of SomRx or themselves personally? Since SomRx was licensing technology from BID, was there any conflict for these individuals between their duty to BID and their duty to SomRx? Were they compensated for their service to SomRx?

- **Transparency in informed consent**

Thomas carried out clinical testing of the device at BID, approved by BID's Institutional Review Board (IRB). This raises concerns of ethics and patient care, as it is unclear whether the financial incentives involved were disclosed to the IRB or subject participants, given that publication disclosures state that the study was not funded by industry but instead by the Periodic Breathing Foundation.¹⁵

⁷ Affidavit of John Cvinar, *United States vs. Prigmore*, Crim. No. 93-10276-JLT. September 29, 1999, p. 3, s. 5.

⁸ Patent Application 60/443,227, filed with U.S. Trademark and Patent Office January 28, 2003.

⁹ SomRx Form D, Notice of Sale of Securities filed with SEC, November 14, 2004.

¹⁰ SomRx Annual Report, Filed with the Massachusetts Secretary of Corporations, February 26, 2007; Filings with the Massachusetts Secretary of Corporations, Delaware Secretary of State, and SEC.

¹¹ SomRx FY2004-FY2006 Annual Reports filed with the Corporations Division of the Secretary of the Commonwealth of Massachusetts.

¹² SomRx Foreign Corporation Certificate, Secretary of the Commonwealth of Massachusetts, May 6, 2004.

¹³ <http://www.veritec.org/Pages/board.html>, http://www.evelexa.com/resources/legal_issues.cfm

<http://www.rubindrudman.com/Site/Biographies/PBF.htm>, accessed on April 27, 2007.

¹⁴ SomRx Restated Articles of Incorporation, filed with Delaware Secretary of Corporations

¹⁵ Thomas RJ, Daly RW, Weiss JW. "Low-concentration carbon dioxide is an effective adjunct to positive airway pressure in the treatment of refractory mixed central and obstructive sleep-disordered breathing." *Sleep*. 2005 Jan 1;28(1):69-77, submitted May 2004.

The Periodic Breathing foundation is in fact funded by co-inventor and investor Robert Daly.¹⁶ The Certificate of Organization of the Periodic Breathing Foundation states that the “primary business of the LLC is the manufacture, sale and marketing of a patented device...to improve sleep efficiency in...sleep apnea.” The Foundation does not appear in the Guidestar directory of non-profit organizations and is not registered with the MA Public Charities Division, according to staff there, raising additional questions as to the nature of the foundation.¹⁷ Fiduciaries could request informed consent documents and IRB documentation related to SomRx clinical testing.

▪ **Unexplained dissolution of SomRx**

Documents filed with the Massachusetts Secretary of the Commonwealth and the Delaware Secretary of State in May 2007 indicate that SomRx was dissolved in April 2007.¹⁸ Implications of the dissolution are unclear in terms of the intellectual property and other assets of SomRx. Notably, in a June 2007 presentation on related technology, Thomas continued to disclose an equity stake in SomRx.¹⁹ Fiduciaries could ask questions about why this company was dissolved, what happened to its investment of charitable assets and what role insiders played in these decisions.

¹⁶ Periodic Breathing Foundation, LLC Certificate of Organization, Secretary of the Commonwealth of Massachusetts, October 2003.

¹⁷ <http://www.guidestar.org/>; Conversation with Dianna Pelligrino, MA Attorney General Public Charities Division, May 3, 2007.

¹⁸ SomRx Foreign Certificate of Withdrawal, filed with the MA Secretary of the Commonwealth, May 7, 2007; Certificate of Dissolution filed with the State of Delaware, May 15, 2007.

¹⁹ Annual Meeting of the Associated Professional Sleep Societies (APSS), June 9 – 14, 2007. Accessed online August 7, 2007 at: <http://www.apss.org/program/Finalprogram.aspx>; <http://www.apss.org/pdf/COIDisclosures.pdf>