Virtual Mentor

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CASE AND COMMENTARY Drug Marketing and Patient Consent Commentary by Erica Ozanne Linden, JD, MPH

Case

Margaret Jacobs has diabetes. She takes medication to control the disease and for the past 5 years has had her prescriptions filled at ABC pharmacy. Last year, ABC implemented a new program to provide health care information to its pharmacy customers. As part of this program, ABC created a customer database that collected information on its customers, including names, addresses, social security numbers, birth dates, and medical and prescription information. In the course of filling her prescriptions, Margaret herself provided ABC with her home address, her social security number, her age, and disclosed that she was diabetic as well as other pertinent medical information. Margaret assumed this information would be kept confidential and at no time was she told why this information was collected.

A few months after the implementation of ABC's new program, Margaret received a letter from ABC discussing the dangers of high cholesterol. The letter informed Margaret that elevated cholesterol is a risk for those people with diabetes and recommended that she take Zilax, a drug used to control high cholesterol. No drugs other than Zilax were recommended for control of cholesterol.

Since the letter was written on the ABC Pharmacy letterhead, Margaret assumed that the letter was in fact from her pharmacy and took it to her primary care physician, Dr. Freeman, to discuss whether she should take Zilax. Dr. Freeman read the letter Margaret brought to him and recognized it as similar to numerous other letters patients had shown him recently. Over the past 2 months, Dr. Freeman had seen at least 15 letters sent to his patients by ABC either warning them of the dangers of certain diseases or urging them to take a specific drug made by a specific pharmaceutical manufacturer.

Dr. Freeman was concerned that the letters sent to his patients encouraged them to take medications that may not be appropriate for their particular circumstances and also wondered why the letters always recommended one brand name drug instead of several drugs that would be equally effective.

Upon further investigation, Dr. Freeman discovered that ABC had been in the news recently for allegedly giving patient prescription records to pharmaceutical companies who then used the information to market their products. Concerned that his patients' confidential medical information may have been given to drug

companies without their knowledge or consent, Dr. Freeman investigated. He discovered that ABC sent out a variety of letters to its customers. The letters took different forms; some gave information about the risks of certain health conditions, some encouraged customers to switch to other prescription medication, and others reminded users of a specific drug to refill their prescriptions.

The mailings were not paid for by ABC but were instead financed by drug manufacturers and a marketing firm was used to carry out the actual mailings. Each manufacturer gave ABC specific selection criteria for each mailing. The criteria were used to identify customers with certain medical conditions, and ABC used its databases to select customers according to the manufacturer's criteria. ABC provided the manufactures and marketing firms with patients' names, addresses, social security numbers, and medical conditions. The information was then used to create the letters that promoted use of drugs manufactured by the sponsoring manufacturer. At no time were ABC customers told of this practice or asked for their consent.

Questions for Discussion

- 1. Is the practice that ABC Pharmacy is participating in legal?
- 2. Is the practice ethical? Is it a breach of patient confidentiality? Does the pharmacy need patients' consent before sharing their medical information?
- 3. Does Dr. Freeman have a legal responsibility to his patients in this case? Does he have an ethical responsibility? What can or should he do to protect his patients from further sharing of their medical information and from unwanted drug marketing?

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