

Access to Safe and Effectiveness Medications

CJ is a female in her mid-60s who is being treated for high cholesterol, hypertension, and hypothyroidism. During her recent visit to the medical center for her annual check-up, she received a new prescription for Mevacor® (cholesterol medication) because her diet and exercise interventions were not working. She had seen several ads for it and one of her best friends at church had used it successfully, so she requested the product by name. The physician knew she was on a fixed income, so he checked the box for “generic substitution allowed” on the prescription. This would allow CJ to opt for either the brand name, Mevacor®, or the generic, lovastatin, when she fills the prescription. He forgot to mention this to CJ.

CJ has been retired for almost eight years and is enrolled in a private health insurance program for her health care. The plan includes tiered pharmacy benefits with three levels: generics, brand names, high cost medications. The company uses a restrictive formulary which means not all products are covered; uncovered products will be paid for entirely by the patient. Generic medications are available for \$10 per 30 day supply, Brand name products have a \$30 or 10% of price co-pay (whichever is lower) for 30 days, and the high cost medications require the patient to pay 60% of the charge as the co-pay.

When CJ dropped off her new prescription, she indicated that she wanted the brand name product. When asked if she would like a generic version of the medication, she replied that she did not want a “second-rate” product. Even though the pharmacist explained there would be no difference between a brand name product and a generic one except price, she remained firm in her decision. While filling the prescription, the technician discovered that the brand name product was not on the formulary, so it would cost CJ almost \$150; the generic would cost only \$10 for a month supply.

The patient does not fill her thyroid or hypertension medications at the pharmacy. Apparently she has her grandson order those products online from a Canadian pharmacy (Drugs-eh.com). She says she gets them for a low price and they look just like the expensive pills she used to get at the pharmacy last year. Since she switched to the internet pharmacy, she noticed that she has been gaining weight and her memory isn't as sharp as it used to be. She blames these symptoms on her high cholesterol levels. No one responded to her email questions about the products, so she isn't completely sure.

CJ is not easily convinced that what she sees on television, reads in magazines, or see on the internet may not true. She figures it must be true or it wouldn't be allowed. Like many, she assumes the FDA or some other watchdog agency is monitoring the content to ensure the information is accurate and the products are safe. She is also a big fan of the television medical shows and can recall the disease topics for each episode.

Patient-level interventions:

1. Which statin product should be used to fill the prescription – the brand name product or the generic?
2. How would you explain the concept of therapeutic equivalence when describing branded and generic products as well as two different products from the same class of drugs?
3. It sounds like CJ has private health insurance. Are there public health insurance options she might be eligible for?

4. Suppose you were able to convince CJ to bring her internet medications into your pharmacy so you could identify them. In the process, you discover that one product looks highly suspicious as a fake. What do you do?
5. What risks to CJ's health exist if her medication products are either substandard or completely fake?
6. If CJ's conditions are not contagious, how could failure to treat them be considered a public health issue?
7. What are your responsibilities as a pharmacist to this patient and how will that affect your actions?

Population-level interventions:

1. Who is responsible for ensuring medication products are safe and effective?
2. Who monitors and regulates internet pharmacy sites to ensure their products and advice are safe and effective? Where can you report a site that is questionable or has sold faulty products?
3. Which populations in the U.S. are at increased risk for poor access to healthcare and medications? Does CJ fit into one of those groups?
4. What can a society do to ensure access to care and medication? Do any of those programs or interventions exist in the U.S.?
5. What are the pros and cons of allowing a pharmaceutical manufacturer to advertise a product directly to the general public?
6. How are television medical shows monitored to ensure content is true?

This case was inspired by a case written by Erika Caine, Pharm D Candidate, during her public health APPE rotation for the University of Arizona, Autumn 2009.