Say It Ain’t So!

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In an academic medical center in a galaxy far, far away, the chairman of the P&T committee’s subcommittee on medication quality received a disturbing phone call from the institution’s Chief Medical Officer, who hurriedly related a most extraordinary story. The account went something like the following:

A critically ill post–bone marrow transplant patient develops a rare skin condition, known as steroid-refractory graft-versus-host disease (GVHD). An attending oncologist, well respected in the local community, desperately searches for a way to help the patient.

(For our story, let’s call the galaxy far, far away the local community.)

The attending oncologist, eager to maintain his devotion to lifelong learning, goes to a local national conference sponsored by the American Society of Hematology. Serendipitously, while at the conference, he sees a poster presentation on the same malady afflicting his patient. Armed with new information based on an observational study of 14 patients [sic], the oncologist, emboldened with a new approach for the clinical challenge at hand, returns to the academic medical center. He then writes an order for this new therapy and continues on his rounds to visit other ill patients.

Hours later, the pharmacy department informs him that the new therapy is not on the formulary and is not stocked by the hospital—not even a single dose or a single vial. Reportedly upset by the news but still wanting to do the best he can for his patient, our oncologist calls another academic medical center in a nearby galaxy.

“Yes,” the second center replies, “we do stock this new product, but, of course, we can’t give you any samples, as our two institutions are in competing galaxies.”

Undaunted, the oncologist calls the pharmaceutical manufacturer’s representative, who happily hand-delivers two doses of the drug to the oncologist, for the benefit of our patient in need.

Meeting the representative at the door, the oncologist hand-delivers the medication to the pharmacist in the satellite pharmacy closest to the patient’s room. Here, he dispatches the pharmacist (himself a relative newcomer simply finishing his busy shift) to mix the medication and deliver it to the patient. The patient receives the medication without incident.

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I cannot reveal the galaxy in question, but many readers might recognize such a scenario. To me, living in this “post-Institute of Medicine report” world, which is heavily focused on medication safety and stricter adherence to practice by protocol, this story appears even more unbelievable.

A situation such as the one depicted here represents a system failure at an exponential level—failure to follow agreed-upon standards of practice; failure to adhere to hospital policy with regard to nonformulary products; failure to enforce pharmaceutical representative behavioral limits; and, worst of all, pulling professional rank to violate policy in the name of “improved patient care.” This behavior has effectively short-circuited the procedures in place that are intended to ensure safety and quality, including P&T committee review, determining safe handling and administration by pharmacists and nurses, checking for drug interactions, and the like.

While exposing our galaxy to a staggering level of liability in terms of not only clinical practice but also research compliance, our story’s attending physician has requested and received samples for the ill patient and, subsequently, for other patients in the same institution—in effect running a clinical trial without approval of the institution’s review board or oversight of any kind.

I hope that your P&T committee rigorously defends its formulary decision-making procedures and that it holds accountable anyone in its galaxy who is found to have violated this collective trust. Here’s hoping that your P&T chairman never utters the phrase, “Say it ain’t so!”

As usual, I am interested in your views. You can write to me at david.nash@mail.tju.edu.

(Editor’s Note: Dr. Nash wishes to affirm that although the basic outline of this story is true, it bears no relation to any actual physician, pharmacist, nurse, hospital, or pharmaceutical manufacturer.)