The “Gray Market” Raises Concerns about Cost, Safety, and Ethics

By Eric T. Rosenthal

A “gray market” for certain oncology drugs is one of the particularly unpleasant side effects of the current drug shortage, causing the gaming of prices many-fold and the potential to adversely affect patient safety.

On Oct. 31 President Barack Obama signed an executive order directing federal agencies to deal with the drug shortage and to look into high prices in the so-called gray market.

Although there is general agreement that something has to be done, there seems to be no established definition for the term gray market when it comes to pharmaceuticals, and efforts so far have not been very well-coordinated, with minimal sharing of information among organizations, and with the possibility that Congressional oversight of the situation may be hampered by partisan politics, according to people familiar with the matter.

During November JNCI interviewed a number of representatives from various organizations and agencies dealing with the gray market and found limited coordination, resulting in the lack of a plan to create some sort of national clearinghouse for information about questionable sources of drugs in short supply but high demand.

The reality of the gray market was documented by two studies conducted earlier this year.

The first, “Buyer Beware: Drug Shortages and the Gray Market,” was published in August by the Charlotte, NC-based Premiere Healthcare Alliance (http://www.premierinc.com/about/news/11-aug/Gray-Market/Gray%20Market%20Analysis%20David%20Ed.pdf) of more than 2,500 U.S. hospitals and more than 75,000 additional health care sites.

Premiere noted that the gray market is also known as “a parallel market,” and described it as a drug supply channel that is unofficial, unauthorized, or unintended by the original manufacturer.

Stating that the average markup was 650%, it listed three oncology drugs as among the top four marked-up drugs—cytarabine (3,980%); dexamethasone 4 mg injection (3857%); leucovorin (3,170%), with only the cardiology drug, labetalol, being sold at a higher percentage (4,533%).

Marketing offers were usually made through emails and fliers containing language such as: “We only have 20 of this drug left and quantities are going fast,” and Premiere found that the drugs offered were all in short supply or completely backordered by their manufacturers and were specifically indicated for critically ill patients.

The study noted that cost was not the only concern with gray market drugs since “there are also myriad safety issues that need to be factored in.” It said that “when vendors emerge with products that reputable drug distributors can’t supply, it begs several questions: Where and how are these organizations getting the drugs when other sources cannot supply the drug? How can the integrity of these drugs be ascertained? Is this practice legal? Is it best practice—or even acceptable—for providers to purchase from these markets?”

The study concluded that “more often than not, the answer is no.”


ISMP is a federally certified patient safety organization headquartered in Horsham, Pa.

In a telephone interview ISMP President Michael R. Cohen, R.Ph., M.S., Sc.D., said that the survey was prompted by requests from those being solicited by gray marketers.

“We were getting call after call from pharmacists and purchasing agents who were seeing marketing materials every day and were frustrated since they couldn’t get these drugs and then others were offering them the next day.”

He said that ISMP was concerned not just by the price gouging and safety issues, but also because of the ethical issue of placing doctors and pharmacists in the middle of a situation where they would have to tell patients that life-saving drugs were not available and then finding that they could purchase these drugs from questionable vendors at exorbitant costs.

Cohen said that there are no standardized drug pedigree standards since they are enacted by individual states, with some having no regulations at all.
Pedigrees document the authenticity of pharmaceutical products.

Connie Jung, acting Associate Director for Policy and Communication with the Food and Drug Administration’s Office of Drug Security, Integrity and Recalls in the Center for Drug Evaluation and Research, said that the Prescription Drug Marketing Act created a federal pedigree requirement to increase the safeguards of potentially dangerous or substandard drugs entering the supply chain, but that the FDA’s mandate was involved in safety, security, and integrity rather than cost issues.

The FDA is also more focused on recommendations than in enforcement, and President Obama’s directive asked that the agency provide the U.S. Justice Department with warnings about possible price gouging.

According to Jung, there is no federal definition of what constitutes gray market drugs, but she said it would probably involve acquiring drugs through illegitimate supply chains.

The FDA recommends that pharmacists and other health care professionals only purchase prescription drugs from wholesale drug distributors licensed in the state or states where they are conducting business, and provides a website listing state agencies responsible for verifying wholesale drug distributor licensure (http://www.fda.gov/...

The ISMP survey suggested four strategies to end the gray marketing of drugs in short supply:

• enhancing FDA’s authority to address the drug shortage (legislation is currently being explored in Congress);
• strengthening regulations for distributing pharmaceutical products and standardizing pricing to prevent gouging during shortages;
• encouraging health care provider organizations to take steps to minimize the need to buy drugs from gray market vendors;
• instituting regulatory and law enforcement action against such illegal activities as counterfeiting and theft.

Michael P. Link, M.D., president of the American Society of Clinical Oncology, noted a number of unfortunate aspects of the gray market.

“It’s not just the price gouging and taking advantage of patients, but it’s also the idea that when you buy gray market drugs it doesn’t have the legacy of the drug. It’s not the same quality assurance and you don’t know its authenticity.”

He said that through education and awareness ASCO was making sure the issue of ensuring safe, effective drugs obtained through the gray market was prominent on the radar screen of its members.

“This situation has the potential for added harm in addition to the usual problems using toxic drugs,” he said.

Cynthia Reilly, Director of the American Society of Health-Systems’ Pharmacists’ Practice Development Division, said her organization prefers using the terms “non-contracted or secondary distributors” instead of gray market.

These terms would refer to unfamiliar distributors that are not normally used by hospitals or oncology practices and could be reputable or disreputable companies, she said.

“Although there is a lot of questionable business going on, there are also some very legitimate distributors helping to make products available.”

She said that pharmacists should work with wholesalers or distributors they are familiar with to insure the integrity of the drugs, and should go through all the necessary steps to prove pedigree, rejecting those lacking appropriate documentation regardless of pressure from those insisting they be obtained.

Reilly said that she had not heard of any patients being hurt by drugs bought through the gray market but said that no one should wait until that happens.

“The impulse to buy at any cost is not in the best interest of patient safety.”

She added that 40% of shortages are due to quality issues, and without shortages there would be no gray market.

On Oct. 5, several weeks before the president’s executive order, Rep. Elijah E. Cummings, a Democrat from Baltimore who is the ranking member of the House Committee on Oversight and Government Reform, opened an investigation into five drug distributors suspected of “drug speculation and gray market sales of drugs in critically short supply.”

The congressman also announced the creation of a tip line (https://forms.house.gov/oversight_majority/webforms/grey_market.html) to report price gouging and speculation in drugs in critically short supply.

However, sources who preferred not to be identified speculated that Cummings’ efforts might not get support from the full Oversight and Government Reform Committee.

None of the sources interviewed had anything to disclose.

This is the first in a series of JNCI articles on the gray market.

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