

MEDICATION USE, SAFETY, AND NURSING CULTURE: A VIEW OF POTENTIAL COUNTERFEITS FROM THE FRONT LINES

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ABSTRACT

Nurses are primarily concerned with the health and safety of their patients. Counterfeit medicines pose a serious threat to patient safety. As frontline, direct health care providers, nurses can help with the problem of counterfeit medicines by educating patients and other health care providers about the dangers of counterfeit medicines, by monitoring and assessing patients for evidence of counterfeit medicines, by supporting regulatory efforts to prevent the introduction of counterfeit medicines into the drug distribution chain, and by reporting suspected cases to the appropriate authorities.

INTRODUCTION

Counterfeit drugs pose a serious risk to the safety of patients who take them. Counterfeit drugs are not only unsafe, ineffective, and fail to treat the patient's disease, but can also result in poisoning, disability, and death.¹ Counterfeit medicines also affect the health of the public at large by increasing the risk for antimicrobial resistant organisms.²

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1. INT'L COUNCIL OF NURSES, NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES 5 (2005), available at http://www.rcna.org.au/content/ind_2005_e_final.doc.

2. *Id.* at 17.

The current counterfeit drug problem is a global one, evidenced by counterfeit drug operations having been uncovered in nearly all countries.³ Although the exact prevalence rates in the United States are unknown, “outside the [United States] drug counterfeiting is... widespread and affect[s] both developing and developed countries.”⁴ “In some countries, more than half of the drug supply may consist of counterfeit drugs.”⁵ Patients in these countries have a better chance of receiving a fake medicine than a real one.⁶ For example, one recent article reported that the majority of anti-malarial drugs in Africa are likely counterfeit.⁷

Counterfeit medicines are more commonly found “in countries with weak drug regulation control and enforcement, scarcity [in the] . . . supply of basic medicines, unregulated markets, and unaffordable prices.”⁸ Within the United States, the extensive federal and state regulatory oversight system has resulted in various measures being taken by drug manufacturers, distributors, and pharmacies to prevent counterfeiting; thus the problem is not as rampant.⁹ However, the FDA “has recently seen an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce” counterfeits into the U.S. pharmaceutical system.¹⁰

ISSUES IN THE UNITED STATES

Responding to the increasing threat of counterfeit drugs, the FDA formed a Counterfeit Drug Task Force in July 2003.¹¹ The goals of the task force are to prevent the introduction of counterfeit drugs and biologics into the U.S. drug distribution chain, to provide strategies to facilitate the identification of counterfeit drugs, to minimize consumers’ risk and exposure to counterfeit drugs, and to avoid the addition

3. FDA, COMBATING COUNTERFEIT DRUGS 2 (2004), available at <http://www.fda.gov/counterfeit/>.

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. World Health Org. [WHO], *Fact Sheet No. 275: Substandard and Counterfeit Medicines* (2003), <http://www.who.int/mediacentre/factsheets/fs275/en> [hereinafter *Fact Sheet No. 275*].

9. FDA, *supra* note 3, at 1.

10. *Id.*; see also FDA, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION ANNUAL UPDATE (2005), available at <http://www.fda.gov/oc/initiatives/counterfeit/update2005.html>.

11. FDA, *supra* note 3, at i.

of unnecessary costs to the prescription drug distribution system or unnecessary restrictions on lower-cost sources of drugs.¹² Some task force strategies include using advanced technology to protect legitimate drugs against tampering, securing business practices amongst participants in the drug supply chain, increasing regulatory oversight and enforcement, creating rapid alert and response systems, developing education and public awareness programs, and increasing international collaboration.¹³

Since the implementation of the task force, the FDA has announced significant progress in the battle against counterfeit drugs.¹⁴ In 2004, the FDA conducted fifty-eight counterfeit drug investigations.¹⁵ This represents a dramatic increase from the thirty cases investigated in 2003.¹⁶ The FDA attributes the increase to “heightened vigilance and awareness by all parties in the drug distribution system,... more effective coordination [between] state, federal, and foreign law enforcement agencies and improved communication with drug manufacturers.”¹⁷

However, despite the increased awareness and efforts by the FDA to prevent the introduction of counterfeits into the United States, many patients and consumers remain unaware of the problem and continue to purchase medicines from unapproved sources. Additionally, there is a “potential for an increase in the number of counterfeit[s] [in the United States] because of the increasing global nature of the pharmaceutical business and the ease with which counterfeit products can be distributed by ‘pharmacies’... on the Internet, by drug diverters, and by other sources outside the prescription system.”¹⁸ Patients and the public at large need to be provided with information and education about the increasing threat to their safety that counterfeit drugs pose. As direct health care providers, nurses can play a crucial role in not

12. *Id.* at 1.

13. Press Release, U.S. Dep’t of Health & Human Servs., HHS Takes New Steps to Protect Consumers from Counterfeit Drug Threats (Feb. 18, 2004), <http://www.hhs.gov/news/press/2004pres/20040218.html>.

14. Press Release, FDA, FDA Continues Combating Counterfeit Drugs Annual Update Reports on Progress (May 18, 2005), <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01179.html>.

15. *Id.*

16. *Id.*

17. *Id.*

18. Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD & DRUG L.J. 537, 541 (2004).

only screening for counterfeit medicines, but also in reporting counterfeit products and providing the necessary information and education.¹⁹

COUNTERFEIT DRUGS INCREASE THE RISK TO PATIENTS' HEALTH AND SAFETY

The Scope

The World Health Organization defines counterfeit medicines as those that are “deliberately... mislabeled with respect to identity and/or source.”²⁰ The term pertains to both brand name and generic products.²¹ Counterfeit medicines can “include products with the correct ingredients but fake packaging, [products] with the wrong ingredients, [products] without the active ingredients, or [products] with insufficient active ingredients.”²²

Counterfeit drugs are “look-alike” products that contain little or no active ingredients or possibly harmful ingredients.²³ Counterfeits also include rejected medicines that have been kept off the market by the manufacturer or regulatory authorities for quality reasons, and re-labeled medications that have expired but have been repackaged and remarketed with a later expiration date.²⁴ Identical copies or counterfeit products manufactured with the same ingredients, formulation, and packaging are not as common.²⁵

The most frequently counterfeited medicines in the wealthier, more affluent countries are expensive lifestyle medicines such as hormones, steroids, and antihistamines.²⁶ In fact, one of the most frequently counterfeited drugs has been Viagra, which is sold extensively on the Internet.²⁷ Medicines to treat life-threatening conditions such as malaria, tuberculosis, and HIV/AIDS are the most counterfeited medicines in developing countries.²⁸

19. INT'L COUNCIL OF NURSES, *supra* note 1, at 9.

20. *Fact Sheet No. 275*, *supra* note 8.

21. *Id.*

22. *Id.*

23. Albert I. Wertheimer et al., *Counterfeit Pharmaceuticals: Current Status and Future Projections*, 43(6) J. AM. PHARMACEUTICAL ASS'N 666 (2003).

24. *Id.*

25. *See id.* at 2.

26. *Fact Sheet No. 275*, *supra* note 8.

27. *Id.*

28. *Id.*

The Effects

Counterfeit medicines can have serious, life-threatening effects for patients taking them. “Each type of counterfeit drug can affect a victim in a different way” and injury “can be caused by the lack of active ingredients or the presence of harmful agents.”²⁹ Some of the major consequences of taking counterfeit drugs include treatment failures, prolonged illness, unexpected side effects, antimicrobial resistance, and even death.³⁰ The regular use of counterfeits by an unsuspecting patient would minimally lead to therapeutic failure or drug resistance.³¹ The most severe consequence is death.³²

The damage caused by counterfeit drugs is not confined to the individual patient consuming the product but extends to all of society.³³ Medications that lack active ingredients or deliver sub-therapeutic doses endanger the public health. In particular, anti-infectives contribute to the global problem of increasing drug resistant organisms.³⁴

THE NURSING ROLE

Nurses play an integral role in the care of patients and their medicines. Nurses receive orders, administer medicines, monitor effects and side effects, and educate patients about their medicines in a variety of settings. Because of their role, nurses are well-positioned to assist in the fight against counterfeit drugs and to educate patients and other providers about the dangers of consuming counterfeit medicines.

Nurses, as frontline health care providers, can be key players to vigilantly attempt to identify counterfeit drugs and report possible counterfeit products.³⁵ For example, while examining and administering medications, “nurses can assist in the identification of counterfeit products by direct observation of people and products.”³⁶ Further, nurses can monitor the product by looking for visible variations in appearance, packaging, and labeling of the drug.³⁷ Nurses can also monitor patients when they report the medicine has no effect or has an

29. *Id.*

30. INT’L COUNCIL OF NURSES, *supra* note 1, at 5.

31. *Fact Sheet No. 275*, *supra* note 8.

32. *Id.*

33. Wertheimer et al., *supra* note 23.

34. *Id.*

35. INT’L COUNCIL OF NURSES, *supra* note 1, at 5, 19.

36. *Id.* at 19.

37. *Id.*

effect that is different from the expected outcome.³⁸ While dispensing medications, nurses should also look for “products that are not intact, that have been altered, damaged or that have unsealed packaging.”³⁹ Nurses should inquire about the price of the products purchased because very low prices are another primary indicator of counterfeit medicines.⁴⁰ Additionally, nurses should educate their patients about all of these indicators so the patients themselves can avoid counterfeit drugs.

Indeed, in various health care settings, nurses can also routinely “monitor drug effects and side effects and must be vigilant for signs of counterfeiting.”⁴¹ Nurses can therefore play a key role in educating the public about the dangers of buying medicines through the Internet, from street corners, in foreign countries, and from other unauthorized sources. Nurses who uncover counterfeit drugs can report suspected cases to the appropriate authority. Finally, nurses can guide patients to resources to protect themselves.⁴²

NURSING AWARENESS

As direct care providers and because patients place them in a position of trust, nurses are in the ideal position to intervene on behalf of patients and to provide education, monitoring, and reporting of counterfeit drugs. However, the reality at the current time is that within the nursing culture, there is no index of suspicion about counterfeit drugs. Nurses, particularly in the United States, usually do not ask to see patients’ medications, nor do nurses ask where patients purchase their medications. Moreover, nurses are usually unable to recognize counterfeit drugs. In order for nurses to participate in the battle against counterfeit medicines, they themselves must be provided with sufficient information and education.

During International Nurses Day 2005, the International Council of Nurses (ICN) recognized the importance of this topic, the general lack of awareness about it, and possible tools to fight counterfeit drugs. The ICN chose counterfeit drugs as their topic at International Nurses Day 2005 to provide nurses with the relevant means and methods to deal with this increasing patient safety problem.⁴³ The goals of

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.* at 5.

42. *Id.* at 20.

43. *Id.* at 5.

the campaign are numerous: to educate nurses, health professionals, and patients about the dangers of counterfeit drugs; to increase awareness of the existence and consequences of counterfeit medicines; to provide tools to identify counterfeit drugs; to report any suspicious medicines; and to support regulatory authorities in their fight against counterfeit drugs.⁴⁴ By providing the necessary information and education to nurses, nurses everywhere can begin to educate patients, increase monitoring for counterfeits, report suspected cases to authorities, and support regulatory efforts to prevent counterfeit drugs from entering the drug distribution system.⁴⁵

Such an approach is a strong and important beginning. At the present time, nurses have the ability, but do not have the knowledge, to protect patients against potential fake medicines in clinics and in hospital wards. However, the culture of nursing still has a considerable distance to go before additional risks of medicine safety are placed upon the health delivery system. Important weaknesses in drug safety as experienced by patients due to problems in FDA oversight, drug importation, and nursing staff shortages create additional pressures and burdens that prevent nurses from being able to advocate for the safety of their patients in this crucial area of care. Attention must be focused on the practical nature of the culture of health care delivery to understand what policy proposals can improve health care for a particular society. Part of that assessment should be how patients can be protected based on the resources, knowledge, and tools nurses have to carry out their ethical duty to the patient. With the problem of counterfeit drugs increasing in developed and less-developed countries, it is incumbent upon policymakers to ensure that the risks to patients are not increased through policies that would require overburdened providers and agencies to assume additional responsibilities they are currently unable to engage in, however much they wish to.

CONCLUSION

Drug counterfeiting is no longer confined to developing countries; it has become a global problem.⁴⁶ With increased free trade and usage of online pharmacies, counterfeit drugs are even reaching developed countries, such as the United States, that have well-established drug

44. *Id.*

45. *Id.*

46. *Id.*

policies and regulations.⁴⁷ Thus, drug counterfeiting poses serious public health and safety concerns. Counterfeits may pose an even greater threat in the future if preventative measures are not taken now.⁴⁸ As counterfeiters find new procedures “to make deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively” and much more proactively.⁴⁹ As frontline care providers, nurses can play a key role in the battle against counterfeit drugs. However, policies that create additional responsibilities for those accountable for ensuring safety, frontline providers and overseeing agencies, should be sensitive to the risks inherent in asking each to do more when the culture and resources are inadequate to reasonably perform their duties now.

47. Wertheimer et al., *supra* note 23.

48. FDA, *supra* note 3, at 1.

49. *Id.* at 1-2.