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American Enterprise Institute for Public Policy Research

The market for inferior medicines:
Comparing the price of falsified and substandard
products with the legitimate medicines in emerging
markets

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The Market for Inferior Medicines: Comparing the Price of Falsified and Substandard Products with the Legitimate Medicines in Emerging Markets

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Background

The trade in inferior quality medicines kills innocent patients. In some countries' markets, half of the key antimalarial medicines contain no active ingredient.¹ Perhaps 15% of the global drug supply outside of advanced countries is counterfeit, rising in certain markets in parts of Africa and Asia to over 50%.² But counterfeits are not the only low-quality drugs on the market. Substandard drugs, which are legally but poorly produced, also kill and can contribute to the development of drug-resistant strains of some diseases.

One of the reasons fake drugs proliferate is that real medicines are expensive for people in emerging countries. In some places it may take three months' wages to purchase an innovator treatment of expensive antibiotics; even the generic treatment could cost roughly two weeks' wages.³

Poor-quality drugs are on average sold at cheaper prices than their high-quality counterparts, but the price signal is far from complete. While the literature on the topic is limited, partly due to the lack of data on poor quality medicines, available data suggests that even expensive drugs are not guaranteed to be high quality.⁴

The price within each market will be determined by a raft of factors, including:

1. Price control regulation, price ceilings, mandatory retail price, and price guidance⁵
2. Import tariff, sales taxes and other duties⁶
3. The penalties for counterfeiting and breaching quality regulations⁷
4. Whether most drugs are registered⁸
5. The literacy rate⁹

¹ "The Partnership for Maternal, Newborn & Child Health. G8 Communique 2010,"

http://www.who.int/pmnch/media/g8watch_2010/en/index1.html (accessed Sept 7, 2010).

² Sridhar D, Gostin L. "Caring about health." *Chatham House World Today*, 2010; 66: 26–28.

³ "Medicine Prices, Availability, Affordability & Price Components," Health Action International, <http://www.haiweb.org/medicineprices/>.

⁴ Roger Bate, Aparna Mathur, and Ginger Zhe Jin. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 Countries," *Journal of Health Economics*, August 18, 2011, page 5.

⁵ Atella, Vincenzo; Jay Bhattacharya and Lorenzo Carbonari. "Pharmaceutical Industry, Drug Quality and Regulation: Evidence from US and Italy" NBER working paper #14567, 2008.

⁶ Bate, Roger, Richard Tren, and Jasson Urbach. "Still Taxed to Death: An Analysis of Taxes and Tariffs on Medicines, Vaccines and Medical Devices." Washington, DC: AEI-Brookings Joint Center for Regulatory Studies, 2006.

⁷ Roger Bate, Aparna Mathur, and Ginger Zhe Jin. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 Countries," *Journal of Health Economics*, August 18, 2011, page 18.

⁸ Oxfam, "Eye on the Ball Medicine regulation – not IP enforcement – can best deliver quality medicines" 143 Oxfam Brief Paper, February 2, 2011.

6. Income¹⁰

Additionally, the local regulatory environment and business conditions will affect the prices of legitimate drugs. There are no tariffs, and often no taxes, on locally-produced drugs in order to give local producers an advantage as they compete with more efficient international manufacturers. Some countries, such as Ethiopia, also charge higher registration fees for imports (levied on both generic and innovator drugs) than for locally made drugs.¹¹

Distribution chains vary; some are short while others are convoluted and include many intermediaries. Generics often have higher-percentage markups (although usually smaller absolute amounts), because their manufacturing costs are lower.

All these factors will affect whether counterfeits or substandard products are prevalent in a particular market. This paper builds on earlier research, examining original data collected from 899 drug samples across 17 developing and mid-income countries to explore the price signal associated with inferior medicines.

Note that all the drugs were purchased without a prescription. In no case did the lack of a prescription prevent a drug sale. It is not clear whether there are local laws requiring pharmacists to only sell drugs if a prescription is available in the sampled countries and cities. If there are such laws, they were not followed by pharmacies or enforced by regulators.

Most of the above myriad factors are external to each market. By comparing legitimate and inferior products from within the same market, it is possible to control for these external factors and concentrate the analysis on price differences associated with a product's legality and quality.

Drug Supply and Distribution Cost Structures: Legitimate, Falsified and Substandard – theoretical explanations of pricing difference

In order to understand how a trader of falsified or substandard products may price his wares, it is instructive to first outline the main costs and markups for the players in the legitimate market.

The average proportions of costs of the final retail price of pharmaceuticals are varied across countries. Levison and Laing 2003¹² measure mark ups along the supply and distribution chain for a variety of poor and mid-income countries. Such charges include import tariffs, port charges, freight charges, inspection and other regulatory fees, importer fees, taxes, wholesaler and retailer markups. Across countries some of these costs are low or non-existent, while others are quite

⁹ Roger Bate, Aparna Mathur, and Ginger Zhe Jin. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 Countries," *Journal of Health Economics*, August 18, 2011, page 10.

¹⁰ "Medicines: spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines," World Health Organization, last modified January 2010, <http://www.who.int/mediacentre/factsheets/fs275/en/>.

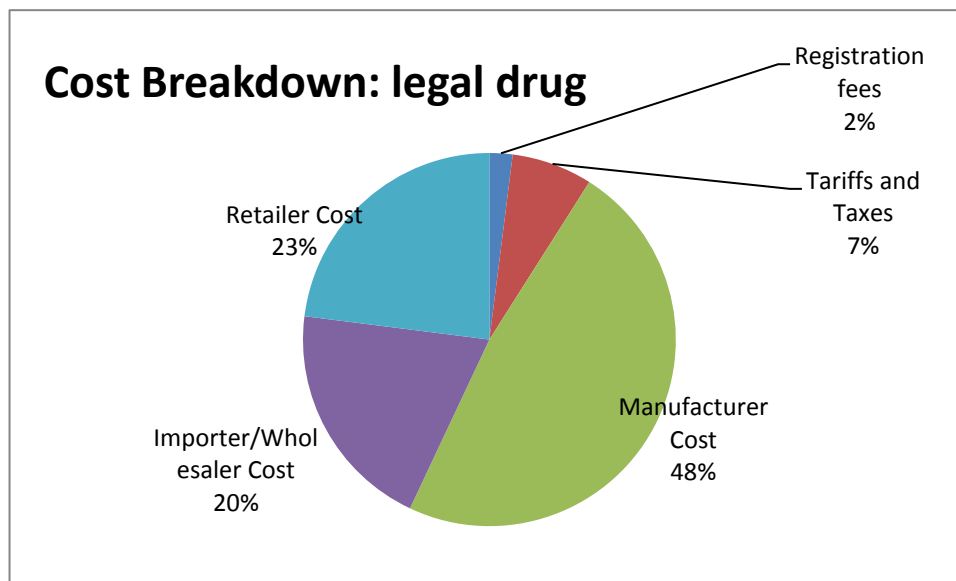
¹¹ "Survey on the Prices of Medicines in Ethiopia," World Health Organization and Federal Democratic Republic of Ethiopia Ministry of Health, <http://apps.who.int/medicinedocs/documents/s16554e/s16554e.pdf>.

¹² Levison L, Laing R. "The hidden costs of essential medicines," *Essential Drugs Monitor*, 2003, No.33:20-21, http://www.who.int/medicines/library/monitor/33/EDM33_20-21_Hidden_e.pdf.

high. In every country a retailer markups the price of medicines to consumers but they range from 16% to 50% of the price retailers pay.

Based on the countries from which the sample of 899 drugs is drawn for this study, and using Levison and Laing's assessment and other work by Laing and others¹³¹⁴, the following pie chart (Figure 1) is the rough allocation of how costs of a final drug price are broken down by the various parties in the legitimate private drug markets in emerging countries.

Figure 1



Counterfeiters Cost Structures

Counterfeiters are aware of the legitimate market cost structure and will know roughly what price each party expects to receive at each point in the supply chain. If, for example, a counterfeiter plans to infiltrate the wholesale market, he/she will determine the price wholesalers pay and ensure they are competitive with this price, often undercutting it. The size of the discount will be dependent on the wholesaler's knowledge: counterfeiters are more likely to, or may have to significantly, depress the price if the wholesaler is aware that the product is counterfeit (and is still happy to buy at a discount) than if the wholesaler believes the drug is genuine. If the counterfeiter can sell directly to a retailer, they are able to turn a greater profit per unit, but they would also sell fewer items per customer since retailers stock smaller drug quantities than wholesalers, exposing counterfeiters' activities to more players in the distribution chain.

¹³ Richard Laing and Müge Olcay. "Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?" The Commission on Intellectual Property Rights, Innovation and Public Health, 2-62, <http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf>.

¹⁴ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: AEI Press, 2012).

From original research on counterfeit traders in emerging markets (especially India and Nigeria),¹⁵ the median total cost of production for the counterfeiter is about 5% of the final sales price (varying between 1% to 30% depending on which product is faked and which country it is sold in; 1% for faking innovator ciprofloxacin in a city like Sao Paolo where it can sell for \$100 a treatment, to 30% for faking very cheap chloroquine selling for one dollar in Delhi). If the counterfeiter can convincingly pretend to be a legitimate manufacturer and sell to a retail pharmacy, it can charge the gap in the market by requesting normal wholesale price and generate a profit of about 72% of the retail price per unit sold: 77% (aggregate retailers' purchase price) minus 5% (aggregate counterfeit production cost) of the total price of the real treatment. That is nearly a fifteen-fold mark-up over the production cost. Figure 2 shows the pie chart of this hypothetical counterfeit manufacturer who is able to sell directly to a pharmacy.

Figure 2

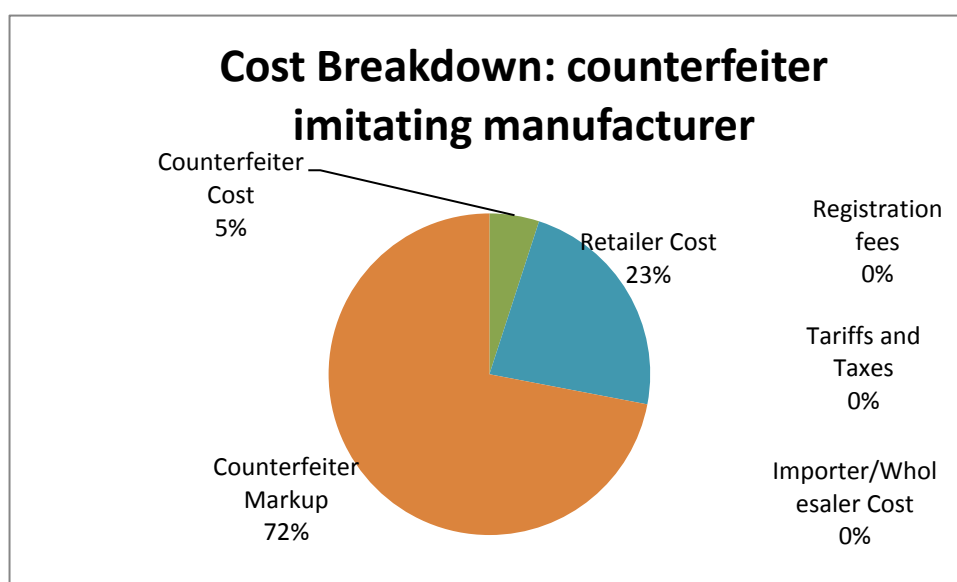


Figure 2 is just one possible allocation of the profits. The counterfeiter markup may be distributed among several players. In Egypt, for example, one counterfeiter sold fakes to a pharmacist for 20% of retail price; the pharmacist (aware the products were fake), sold them to an unwitting wholesaler at slightly below normal wholesale price. The wholesaler then sold the product at market rate to a retailer, who passed it on to unsuspecting patients.¹⁶

Assuming that the patient pays the same price for real and fake medicines, the counterfeiters' markup may be taken by a single entity or by many players, including most alarmingly by pharmacists (and even doctors who receive kickbacks from pharmacists).

Substandard Market

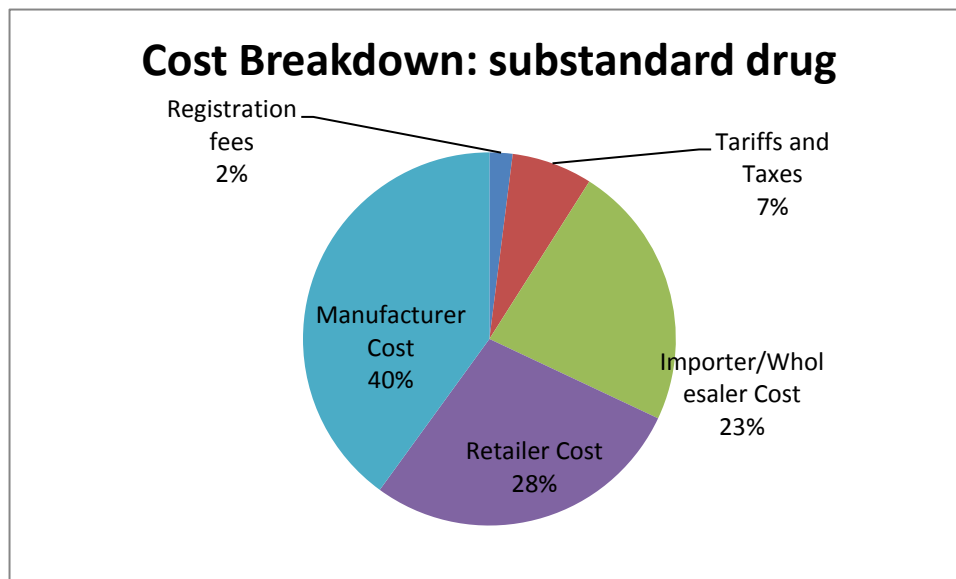
¹⁵ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: AEI Press, 2012).

¹⁶ Ibid.

The substandard market is, by and large, a legitimate market which functions similarly to the legal market described above. The main departure from the normal market is in the assumed lower production costs of substandard products. Lower costs are assumed because these drugs fail to meet quality control standards since manufacturers cut corners. The most common places to skimp are in the production process, where buying cheap ingredients, under-dosing ingredients, cutting the processing time, under-staffing the processes, or lowering hygiene controls may render a drug inefficacious and certainly make its production cheaper. These products breach regulatory standards in most countries but their manufacturers rarely breach criminal codes. The consumer will “benefit” from the cheaper price that lower production standards allow. Substandard products are assumed to be cheaper than the generics they copy since savings are accrued by using a cheaper manufacturing process; anecdotal evidence shows a substandard manufacturer’s costs are half to two thirds of those of a high quality manufacturer.¹⁷ Some of these savings should be passed on to consumers since there are similar percentage or absolute markups along the supply chain, making the final product cheaper. Substandard producers may also avoid registering their products, avoiding those fees too.¹⁸

Figure 3 displays one possible cost breakdown for a hypothetical substandard manufacturer. Note unlike Figures 1 and 2, where the retail price is assumed to be the same, in Figure 3 it is assumed to be cheaper.

Figure 3



Given the above analysis the following hypothesis is tested in this paper: Fake drugs will be approximately the same price as their legitimate equivalents and substandard drugs will be significantly cheaper than their legitimate equivalents.

¹⁷ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: AEI Press, 2012).

¹⁸ “Counterfeit Products,” United Nations Office on Drugs and Crime, http://www.unodc.org/documents/data-and-analysis/tocta/8.Counterfeit_products.pdf.

Results

Disaggregated samples

Within the 135 samples that failed quality control (out of the total sample of 899), it is impossible to perfectly identify all failures as either fakes or substandards, it is particularly hard to identify the latter type. Only 57 samples were positively identified when compared against legitimate innovator or generic medicines. The main reason for this is that not all manufacturers responded to information requests about fake versions of their drugs. Additionally, no manufacturer will admit that they produce substandard products.

It was possible to identify 42 failures as definite counterfeits by comparing them to legitimate versions of these products which were on sale in the same cities and sometimes in the same pharmacies. An additional 15 samples were almost certainly substandard since they either contained the right amount of ingredients but were poorly formulated, or contained an incorrect but non-trivial amount of ingredients. These inferior drugs were not well known products and have no known fake versions. This further supports the assertion that they are substandards since most counterfeit products fake well-known, market-dominant brands.

The prices of the 42 fakes were compared with the prices of the authentic drugs counterfeiters copied. The prices of the 15 samples were compared with the average price of generic (non-innovator) versions of the comparable product type.

The hypothesis is strongly confirmed.

The 42 fake products were on average only 0.6% cheaper than the authentic drug, with the individual price discrepancies ranging from zero to 8% (see Figure 4). The sample discrepancy is not statistically different from zero (see Table 1). In other words, fakes cost the same as authentic medicines that are sold in the same city. It is quite possible the fakes are sold at lower prices in other locations, perhaps where the real versions are not available, further research may comment on this possibility.

The 15 substandard products were on average 19.3% cheaper than the generics they copied, with the individual price discrepancies ranging from 2.5% to 41% (see Figure 5). The difference in price is statistically significant (see Table 2). In other words, from this limited sample, poorly produced drugs are cheaper than high-quality generic drugs.

Discussion

Previous research on these data revealed an average price discrepancy between poor quality and good quality drugs of about 14%. The smaller counterfeit price-set discussed immediately above (and graphed below) support the hypothesis that fakes are priced the same as authentic drugs. The more limited substandard data set indicates that these products are sold at a discount vis-à-vis authentic drugs of that type.

If the analysis based on these limited data is replicated in other studies, it has potentially important implications for policy decisions. The fight against fake drugs ought to be dealt with through a variety of forums discussed in some details elsewhere.^{19,20} But if substandard drug price signals are indeed widespread, combating such products may be easier than at first thought. The above research suggests that price information, which is relatively easily attained, could provide an interesting source of information on substandard drugs.

The product pricing structure of legitimate suppliers, and those hypothesized for counterfeiters and substandard producers, graphed above demonstrate that the incentives for producers and distributors of substandard drugs are quite different from those of counterfeit drugs. They also reinforce the notion that substandard drug producers and probably most distributors are aware that they are selling lower-quality products.

More data are required but the small samples collected so far suggest that some companies and wholesalers vary their pricing based on quality. These price signals could throw up a red flag to a buyer or regulator, which could ultimately help both purchasers and regulators fight against dangerous products in their markets.

Conclusion

Price is the most obvious market signal of quality, and cheaper drugs have been shown to on average be inferior in quality. But the price signal from the original dataset analyzed previously was weak. This paper disaggregates the sample into two groups, counterfeit products and substandard products. The disaggregated data show two statistically significant and opposing results, which account for the weak price signal overall. Counterfeit products are sold at a negligible discount (0.6%) to legitimate products they copy and substandard products are sold at a noticeable discount (19.3%) to the generic drugs they copy.

These results are entirely explicable and a brief theoretical justification was given for them. Only larger studies will be able to determine whether the finding of this paper is strongly replicated and hence have relevance for policy makers.

¹⁹Roger Bate and Amir Attaran. "A Counterfeit Drug Treaty: Great Idea, Wrong Implementation," *The Lancet*, last modified October 30, 2010, www.thelancet.com.

²⁰ Roger Bate, Aparna Mathur, and Ginger Zhe Jin. "Does Price Reveal Poor-Quality Drugs? Evidence from 17 Countries," *Journal of Health Economics*, August 18, 2011, page 3.

Table 1**Fakes t-Test: Paired Two Sample for Means**

	<i>Genuine</i>	<i>Fake</i>
Mean	3.138292683	3.103902439
Variance	3.165464512	3.01209439
Observations	41	41
Pearson Correlation	0.998657455	
Hypothesized Mean Difference	0	
Df	40	
t Stat	2.180862949	
P(T<=t) one-tail	0.017566551	
t Critical one-tail	1.683851014	
P(T<=t) two-tail	0.035133102	
t Critical two-tail	2.02107537	

Figure 4: Fake Price Deviation from Quality Drug

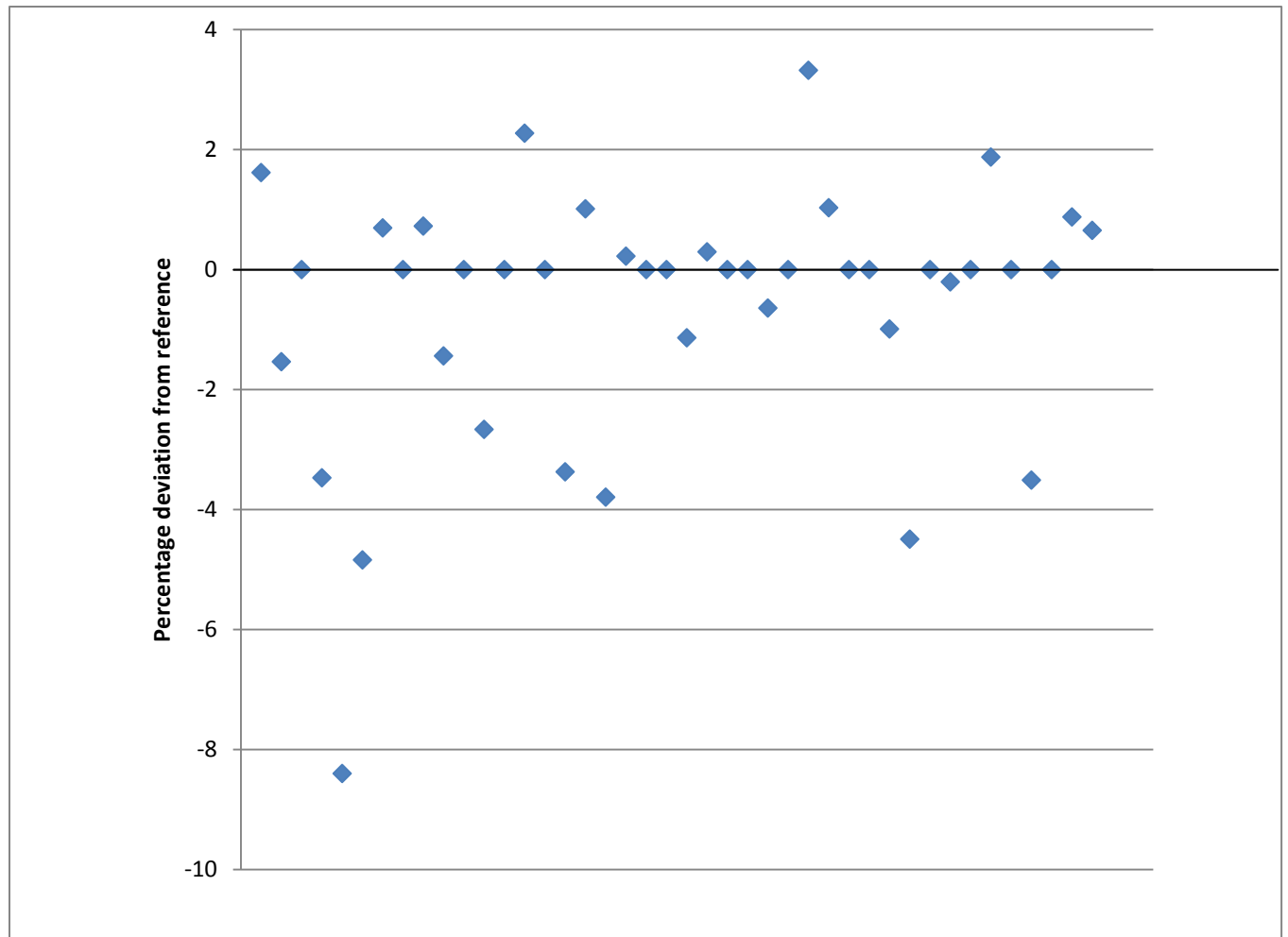


Table 2**Substandard t-Test: Paired Two Sample for Means**

	<i>Generic</i>	<i>Substandard</i>
Mean	2.327333333	1.876666667
Variance	0.928449524	0.71482381
Observations	15	15
Pearson Correlation	0.94644308	
Hypothesized Mean Difference	0	
Df	14	
t Stat	5.486514178	
P(T<=t) one-tail	4.00702E-05	
t Critical one-tail	1.761310115	
P(T<=t) two-tail	8.01405E-05	
t Critical two-tail	2.144786681	

Figure 5: Substandard Price Deviation from Generic

