

UPDATES – ISSUE NO. 2

The Internet Drug Business And how Google lost \$500m

It is all too well known that both prescription and OTC medications can be expensive, with or without medical insurance. Even when the patent protection for medications has expired and generic equivalents are available, the co-pay under many medical plans (not to mention the full price if no medication coverage is in place) can easily reach frightening proportions, especially when treatment over a longer period of time is required.

For some products, manufacturers of pharmaceuticals offer discounts or rebates to qualifying patients. In some cases, discounts are provided by pharmacies for individual prescriptions or on 90-day supplies. But there are many other instances where the only choice is either paying the full price for the original product or the generic equivalent.

Some while ago and taking full advantage of the internet, some regular medication users discovered that they could obtain their drugs at much lower prices from Canada or Mexico thanks to the emergence of *internet pharmacies*. The idea was really quite simple: a doctor's prescription was sent by fax or email to the internet pharmacy in Canada together with credit card details, the medication was dispensed, and then mailed to the patient. Depending on the drugs ordered, savings of 15% or more over US pharmacy prices were widely reported. And it was safe since the drugs dispensed were originally manufactured by the same Pharma companies that supplied US pharmacies. Really?

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Who or what is a *pharmacy* ?

Modern-day pharmacies emerged from the original drugstores in which the owner, without being subject to any regulation, license or education requirements, mixed and dispensed medications (and, from about 1820 onwards, also sold soda fountain drinks as a sideline).

With the emergence of companies specializing in the research of ailments and diseases and the manufacture of suitable medications, their concern was to protect their financial investments by prohibiting the duplication of the drug manufacturing process by a drugstore owner.

As a result, the role of the pharmacist began to change – the mixing of medications gave way and turned into the dispensing of already manufactured products.

In 1870, Rhode Island took the lead (based on earlier attempts in Louisiana) to formulate legislation, which set out the licensing and education requirements for pharmacists. By the end of the 19th century, 47 of the US states had adopted similar or comparable legislation.

Henceforth, the owners of drugstores had to become, or in the alternative, employ, a licensed pharmacist to be able to legally sell drugs and medications.

Thus, the brick-and-mortar

pharmacy as we know it was born.

But, some habits die hard, or not at all.

Even though the “new” pharmacists no longer manufactured the drugs they dispensed themselves (with some exceptions) and received most of their drugs directly from the drug manufacturer, the act of “dispensing” was not limited to pulling the required product from a shelf and handing it to the customer, but also involved (and continues to do so for most pills) removing the required number of pills from a bulk pack, placing it in a small plastic receptacle, labeling it, and providing the customer with a print-out of drug information (including contra-indications).

In your “brick-and-mortar” pharmacy, and provided you are prepared to wait, you can actually watch the pharmacist pulling the bulk pack from the shelf and watch him/her fill your prescription. Hence, you can be reasonably certain that the correct product is dispensed (errors and omissions excluded).

Interestingly, this process of “dispensing” is not found in most of the European countries where manufacturers supply pharmacies with pre-packed supplies of small quantities of their drugs (rather than bulk packs) so that the customer/patient is sold the manufacturer-sealed product.

But “brick-and-mortar” is, as we all know, slowly growing out of fashion as a result of the emergence of *virtual pharmacies*.

Enter: The *Virtual Pharmacy*

Virtual pharmacies come in two forms: (a) mail-order pharmacies and (b) internet pharmacies.

Mail-order pharmacies are brick-and-mortar distribution facilities that supply patients with their (nearly always prescription) medications by mail from a distribution center and warehouse. Often, medical insurers will require their plan members to order 60-or-more-day supplies from those facilities since cutting out a middleman (namely your local pharmacy) is a cost saving step. They need to be licensed, and employ licensed pharmacists, and the patient usually had no idea where they are located (inside the US), nor do they provide any personal consultations.

By contrast, internet pharmacies offer both prescription and OTC drugs to the world at large, and may be located (either in a “proper” brick-and-mortar distribution or warehouse facility or in the basement of an unlicensed entrepreneur) anywhere in the world. Apart from their presence on the internet, they can usually be quickly identified by their offers of substantial discounts on all of their medications sold. At times, their virtual “store fronts” can be impressive and highly professional, but how can the patient be certain that the drugs and pills supplied by such facility are genuine? In short, whilst there are certain protective steps that a patient can take to determine whether the virtual “pharmacy” is a deceptive enterprise, there are no foolproof methods to uncover a deceptive entrepreneur.

The Case of the Canadian Pharmacies

Some five years ago, press reports uncovered a practice to which a growing number of prescription drug dependent individuals resorted in order to reduce their monthly medical bills. They either ordered their drugs by mail, or collected them directly during a brief personal visit from pharmacies located in Canada.

Subsequent investigations showed that products from one and the same production process of a reputable drug manufacturer were supplied to pharmacies on both sides of the US/Canadian border (NB: at times, even products carrying the same lot numbers were found on different sides of the border). However, selling price agreements as well as market forces determined that these identical products were sold in Canada at often much lower prices than in the neighboring US.

There was no question of the Canadian medications being of an inferior, let alone: suspect, quality. The sellers were registered and licensed (under Canadian law) pharmacies. The US purchasers were treated, in every way, exactly in the same manner as regards drug counseling as Canadian customers. Unless the Canadian pharmacies were prepared to accept the prescription from a US licensed physician, a new prescription was (internally) re-issued by a licensed Canadian physician (albeit mostly without prior consultation). In the legal profession, this process would have been described as simple "forum shopping", namely finding a location where you gained an advantage, which in this case was at times a substantial saving.

This was, by no means, an innovative step. German, French as well as Belgian patients have for many years frequented Dutch pharmacies for their medical supplies since the drug price controls established by the Dutch government have often resulted in identical products being sold at significantly lower prices in Holland.

In fact, several US states (including Nevada, Minnesota, Illinois, and Wisconsin) encouraged its citizens to take advantage of drug purchases in Canada and even established state-run programs to explain the process.

None of this would, in all probability, have given rise to any major concerns, let alone any action by the Federal government, had it not been for the fact that these drug purchases began to be featured in press articles and TV programs, some of which even showed entire bus loads of retirees flocking across the border into Canada to purchase their medications. The matter was getting out of hand and was beginning to cost the drug manufacturers money.

Enter: "The Patient Concern Issue"

Washington lobbyists started their work. Suddenly, both Representatives and Senators began to voice concerns about the "safety" of such drug purchases, setting the wheels in motion to put a stop to the practice. The result was the addition of Sec. 21 U.S.C. 301 (aa), which now prohibits the importation of any prescription drug, even for personal use. Exempt herefrom are drug products for unapproved new drugs for which there is no approved US drug. The import prohibition even extends to foreign-made versions of US approved drugs.

As a very minor concession to the financial distress that Sec. 21 U.S.C. 301 (aa) might create, 21 U.S.C. 384 (j) provides that enforcement actions should be focused on cases where the importation of prescription drugs by an individual poses a threat to public health, leaving the possibility open for an individual to obtain an import license in circumstances when the imported drug does not appear to present an unreasonable risk to the individual (placing the burden of proof on the individual).

This rather controversial change of the law pacified the drug manufacturers, and nearly eliminated the additional business of the Canadian pharmacies.

Had the bone of contention only been pricing, the unhappiness of the medication users affected would have been understandable.

But there were other issues involved.

Whilst the Canadian government (not to mention the Canadians themselves) may have shown signs of indignation after being effectively accused of being part of a system that had the potential to cause physical harm to US citizens, the fact of the matter was that price advantages were not only offered by *Canadian* pharmacies.

Mexico and many other countries also offered huge savings on prescription drugs, and with many *virtual pharmacies* being in locations that could not be readily identified, who could actually say in good conscience that the medications supplied were *genuine*?

Scam Potential

The potential for scamming internet customers is unlimited as the closer examination of a very recent case demonstrates (NB: We shall be looking at one of many examples currently investigated by police and Public Prosecutors in Germany, which could easily have taken place anywhere else):

Various individuals created websites with rather catchy addresses such as "safeviagraordering", "pharmacyformen" or "pillservice", offering Viagra at comparatively low prices. Interested parties found links to these sites on well-known search engines, and the traffic generated by these search engine referrals led to well over 200,000 orders being placed. However, instead of receiving Viagra, the customers were supplied with either worthless or, in some cases, allegedly dangerous pills. Customer complaints, combined with investigations conducted by the Viagra-manufacturer Pfizer, ultimately led to the identification of the individuals operating the scam, many of which have already been arrested and will be tried in the near future.

In the US, the sale of Viagra is subject to a prescription, and many internet sellers of Viagra or

similar products require the completion of a (bogus) online questionnaire that is allegedly evaluated prior to a "prescription" being issued by a "licensed physician" before mailing the product.

As long as the product mailed is harmless and not required for any life-sustaining treatment, the scam may not cause more than financial loss and a dented ego. But there is, by all accounts, the potential of inflicting serious injury - and unless the patient submits the product to a full analysis (which is both an unrealistic expectation and also extremely costly), the purchaser/patient has no way of knowing whether the low-price product supplied is the genuine article or not.

If a deal sounds too good to be true, it usually is!

The rule of "caveat emptor" applies to all internet purchases, but in particular to those of medications (and not limited to those that require a prescription).

In a recent test, the Central Laboratory of the Organization of German Pharmacists ordered prescription medications from 11 internet pharmacies with the following results:-

- two internet pharmacies debited the credit card tendered for payment, but sent no product at all;
- none of the internet pharmacies asked for the required prescription;
- the medications were mailed from The Netherlands, the United Kingdom, India, Argentina, and Egypt, all without a product description in German;
- several deliveries consisted of individual pills packed in a simple ZIP-Lock bag;
- some of the pills supplies appeared to be porous or broken or showed signs of discoloration (all signs of lack of product integrity, lack of proper product handling, and/or the product shelf life having been exceeded);
- one delivered product contained a low percentage of the active product ingredient ("API").

That none of the 11 internet pharmacies requested a copy of the original physician's prescription was extremely disconcerting since the medication ordered contained two ingredients known to lead to a drug dependency!

Google's US\$500m loss

Between 2003 and 2009, Google (through AdWords) allegedly earned about \$500m from advertisements placed by Canadian pharmacies on the internet, who sought to attract US buyers. In about 2009 (i.e. after 21 U.S.C. 301 [aa] came into force), the US department of Justice started to investigate Google for its alleged assistance in the violation of 21 U.S.C. 301 (aa). To conclude the matter, Google did not only agree to ban the advertising of prescription drugs in the US by Canadian pharmacies, but also agreed to forfeit some US\$500m to the Justice Department, said to represent the revenue Google received from the contentious advertising.

As an aside: if the Canadian pharmacies spent (over 6 years) some US\$500m on advertising alone, it gives some idea of the profit margins (even at Canadian prices).....

Caveat Emptor?

Whilst it may at times seem somewhat antiquated to watch your local pharmacist count out 20 tablets from a bulk container instead of supplying you with a manufacturer-sealed package, and mistakes do happen at times, obtaining your medications at your local pharmacy is a (relatively) safe method. You will know that you will be served by a licensed pharmacist in a licensed pharmacy.

Equally, although requiring a higher degree of trust, obtaining your medications from your insurance approved mail-order supplier will usually be comparable to obtaining them from your local drug store.

Whilst it would be wrong to conclude that all internet pharmacies should be avoided, a customer invariably accepts a higher risk that the medications supplied are either not of the same quality, of dubious origin, not properly handled or dispensed, and/or ineffective if not dangerous. The saying "If a deal sounds too good, it usually is" often applies, especially when there are no means to establish the qualifications or bona fide of the actual product supplier. There is a reason why certain medications are available by prescription only, and you cannot have a clearer warning signal than the internet pharmacy not asking for it or requesting you to fill out a bogus questionnaire for "evaluation" by a "physician" you never meet.

JURGEN SCHULZE & CO LLC

114 E Lilac Road

Milford, PA 18337

Tel: 1 - 201 - 604-3284

Cell: 1 - 201 - 349 - 8304

Fax: 1 - 509 - 561 -2978

jurgenschulze@usa.net

www.jurgenschulze.net