

Letter to the Editor

Herbal therapies: Are they alternative medicines or fast-forward science?

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Confronted with spiraling cost of orthodox medicines and a high level of either treatment failure or poor patients' satisfaction, herbal therapies have been presented as alternatives to orthodox therapies. They have are frequently registered by appropriate authorities and packaged in the forms of orthodox medications. On face value, these pathways may be quite healthy for the overall health service; however the so called "business of medicine" is notorious for sometimes putting profit over science. This paper takes a critical review of herbal patents in this regard.

Key words: Herbal therapies, herbal patents, dietary additives.

INTRODUCTION

Herbal patents are plant based medications that have been screened and approved by appropriate authorities and presented to the health consumers for use (Archer and Boyle, 2008). This definition immediately presents us with a conflict. Why are they called herbal patents? They are called herbal patents because the main requirement for registration is a demonstration of safety; efficacy data is considered important but not compulsory (Gibson et al., 2008; McGuffin, 2008; Tsuji and Tsutani, 2008; Calapai and Caputi, 2007). For registration of herbal agents, efficacy studies are considered redundant because 'efficacy' is pharmacologically ascribed to a defined substance (structure, weight, formulation etc.) while most herbal agents presented for registration are multi component entities that tend to vary quantitatively and qualitatively even in the same cultivar (McGuffin, 2008; Firenzuoli and Gori, 2007). Herbal patents are therefore Registered and allowed into the market as dietary additives and not drugs. The undeniable truth is that they are not consumed as dietary additive but as herbal therapies. Such inconsistency where herbs that are known to be marketed as drugs are not registered as such may be argued to be an attempt to present a quick solution to a registration dilemma or an attempt to fast forward the tedious process of drug discovery.

Drug discovery and the business of medicine

The pathway to putting a drug in the market is succinctly

described as 'drug discovery and development' (Nikitenko, 2006; Bayés et al., 2006) while the intricacies that dictate the decision making process may be described as "the business" of medicine (Zalesky, 2006; Lee Chang, 2006).

Drug discovery involves painstaking science that starts from identifying a library of substance that promises a good yield of likely drug candidates when screened. A screening method that has the highest likelihood of identifying such candidates drugs then have to be designed, the pharmacological profiles have to be worked out before finally presenting the discovered drug for development (Mahecha, 2006; Wang et al., 2005). The science of discovering drugs is controlled by scientists, but they rarely control the money; this is the realm of business managers.

Business managers are financial gurus that control the overall pathway that leads to a drug product being in the pharmacy shops. The science of drug discovery is concerned with getting the most efficacious and safest drug to the health services while the business managers of medicine have monetary profit as the main goal. It is therefore easy to predict that conflicts would arise. The available evidence is that such conflicts of science versus profits are the rule rather than the exceptions (Caughey and Urato, 2007; Serajuddin and Serajuddin, 2006). One way such conflict may play out is that drugs that get to be marketed may not necessarily be the most efficacious. For example, a cure for hypertension or diabetes may excite the scientific community in the research and disco-

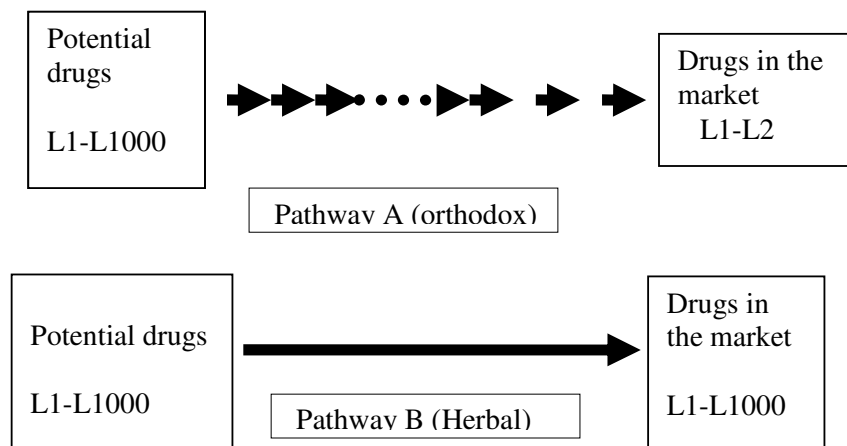


Figure 1. Alternative pathways to getting potential therapies to the market.

very (RD) division of a company but may be considered bad products by the managers because such product may destroy billions of dollars of the market values of competing drugs already in the market and owned by the same company. Another way conflicts between science and business may play out in drug discovery is in making a decision whether to market herbal agent “as it is” or pursue the uncertain and much costly pathway of further refinement to be marketed as an orthodox formulation (Figure 1). The estimated cost that took the oral hypoglycemic called Tolbutamide (and most orthodox drugs) to the marketing stage was placed as \$500 million (Steinmeyer, 2007). Not many drug developers have or may be prepared to spend such an amount on the uncertain market of orthodox medication. Another quagmire of labeled drugs is the huge amount that could be spent to settle litigations. Billions of dollars have been spent to cover in or out of court settlements and legal fees (Kesselheim and Avorn, 2007; Brushwood, 1993). An orthodox drug in the market is essentially undergoing a phase four clinical trail. This phase is a ‘never ending’ phase that connotes a ‘never ending’ risk to drug developers. Have herbal therapies been exploited as a welcomed pathway to fast profit and much reduced risks to drug developers?

Herbal therapies and fast forward science

Herbal formulation is now a multibillion dollar market and is rapidly growing (Calapai and Caputi, 2007). Globally, it is reported to control 30% of the drug market and draws almost 1 billion dollars in profit every year (Tsuji and Tsutani, 2008; Ritchie, 2007). This scenario may not be too alarming in the developing world where plant based medications have always been native. It might be important to note that the above data are from industrialized countries! What could be the explanation? Are herbal therapies more effective or cheaper than orthodox ones? Over 90% of herbal therapies now in the world market have not undergone rigorous test of efficacy, are not standardized

and are not labeled as drugs (Schmidt et al., 2007). Labels attached to herbal packages frequently make stupendous claims as all cure medicine (including anti aging) without breaking the law provided the label dietary additives is also included, even if such label are cleverly hidden from the routine buyer.

Implication for health services

Labeling herbal remedies as dietary additives has wide implications for the health services. Herbal medicines are the undeniable root of modern pharmacology. Nearly 75% of all orthodox medicines are of herbal origin (Luzhetskyy et al., 2007; Lam, 2007). If most drug developers take the fast forward pathway presented by direct marketing of herbal therapies, this may lead to attrition in orthodox drug options (Luzhetskyy et al., 2007). In a world with increasing disease burden, this could be devastating. Basic toxicology are not done in human which suggest that even safety evaluations may not be taken as particularly re-assuring. Also, herbs are usually sold without post marketing surveys for adverse events. This may be a prerequisite for disaster. Furthermore, herbal therapies may increase disease burden by delaying the institution of orthodox treatment in chronic diseases. This is because their listings promise a cure for almost all diseases. To the sick person, such claims exploit what has come to be called ‘the savior complex’ (Ernst, 2007a, b; Burton, 2006; Saad et al., 2006; Brodie and Levitt, 2002).

Conclusion

Herbal remedies predate orthodox remedies but poor regulatory control is a major problem. Herbal remedies should be labeled as drugs and not dietary additives. They will then have to be subjected to the same control strategies as orthodox medications.

Starting with the same number of leading herbal agents

(L1-L1000), only two (L1-L2) may survive pathway A and with a market value in billions of dollars but a litigation value that has no limit. On the other hand many more agents tend to survive pathway B because basic toxicological screening is all that is needed. The market value of this pathway is usually in billions of dollars with essentially zero litigation cost.

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