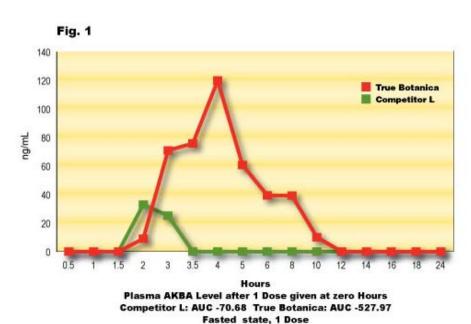


# Pilot Study: Bioavailability of several commercial Boswellia formulations

#### Introduction

The inflammatory cascade relies to a large extent on the 5-lipoxygenase (5-LO) and the COX enzyme pathways. Among the many extraction fractions of the frankincense (Boswellia serrata), AKBA (3-O-acetyl-11-keto- $\beta$ -boswellic-acid) is the most potent 5-LO and leukotriene (LT) synthesis inhibitor and the one with the highest anti

inflammatory activity. It has a premier 5-LO and LT inhibiting place even among all the natural substances. Clinical studies have confirmed its beneficial role in asthma, allergies, arthritis and colitis. Since the role of the 5-LO and LT's is being increasingly appreciated in over 35 major chronic diseases the role of the boswellia is also gaining in importance. One major problem in clinical practice is the lack of standardization of the AKBA content of the various boswellia extracts offered for sale. This makes it extremely difficult to determine what the most effective dose of any one preparation would be. It might also explain why reports on clinical success range from spectacular to ineffective.



### **Materials & Methods**

One healthy male volunteer was enrolled. The experimental protocol was approved by an IRB. The participant was administered the following four protocols, each protocol on a particular day (with a seven day wash out period in between):

- 1. After fasting the subject ingested one dose of the boswellia product of Competitor L. The recommended dose of that manufacturer is 1 capsule containing 70 mg boswellia standardized to 30% AKBA.
- 2. After fasting the subject ingested one dose of the boswellia product of True Botanica. The recommended dose of that manufacturer is 2 capsules containing a total of 112 mg boswellia standardized to 90% AKBA.
- 3. At 4 hour intervals the recommended dose of Competitor



S was ingested, each time with a fatty meal. (Dose= 450 mg boswellia stand. to 65% boswellic acids. No data on AKBA as such given.)

4. At 4 hour intervals the recommended dose of True Botanica boswellia formula was ingested, each time with a fatty meal. (Dose=112 mg boswellia stand, to 90% AKBA.

The plasma concentration was analyzed by an independent lab with the reversed phase HPLC method.

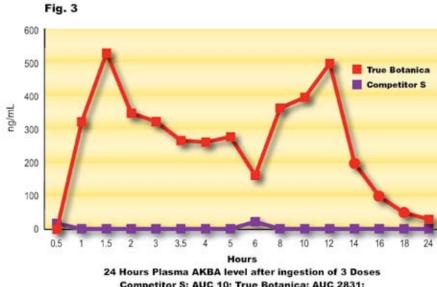
#### Results

The most meaningful expression of the total plasma level over time of the test substance is the Area Under the Curve (AUC). The single dose comparison between the True Botanica and the competitor L product showed a more than 7x larger AUC for the True Botanica formula. (see Fig.1) Even when unequal mg amounts between the products were accounted for the difference was still nearly 5x more for the TB formula. (see Fig.3)

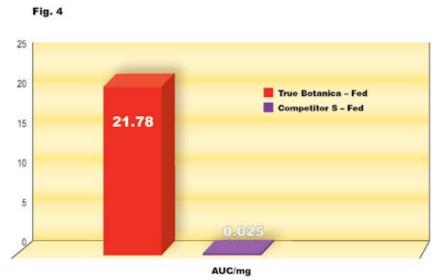
When multiple doses are given in one day the comparison between the different formulas becomes even more significant. The AKBA AUC for the Competitor S is essentially zero! The True Botanica AUC is consistently high. When adjusted for differing amounts of boswellia mgs the True Botanica AUC is more than 800x higher than the non-standardized product.

## Conclusion

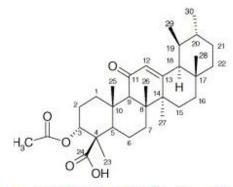
Before a boswellia formulation is chosen for the patient, the AKBA content must be known in order to determine the appropriate dosage regimen. Manufacturers who do not list the AKBA content of their boswellia formulation should be avoided since the actual plasma level delivered may actually be non-existent as shown here. Considering the nearly complete plasma clearance of the boswellia fraction in about 8 hours the best regimen for boswellia administration would be about three times daily at 8 hourly intervals. Last, but not least, Boswellia preparations should be given preferentially with fatty meals since as seen in the comparison between the identical amounts of the True Botanica formula the fed state improves the absorption rate by nearly fivefold!



24 Hours Plasma AKBA level after ingestion of 3 Doses Competitor S: AUC 10; True Botanica: AUC 2831; Dose given at 0, 4, 8 hours Fed state: • These values only estimated



Plasma level of True Botanica is 871.2 times larger than Competitor S Standardized Plasma levels; Fed state; 3 doses



Structure of AKBA (3-O-acetyl-11-keto-β-boswellic-acid)

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