### <u>Chocolate becomes Medicine,</u> <u>a Functional Food</u>

www.kukaxoco.org/ChocForum2015-En.pdf





### **Chocolate becomes Medicine**

Coca leaf extracts completely de-bitter cacao,

eliminating need of sugar/sweeteners and much fat from chocolate, unleashing the medical benefits of cacao

FORO INTERNACIONAL DEL CHOCOLATE OCTUBRE 1ºDE 2015, LONDRES

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fppt/com



### What are you talking about?



#### Brew up to two bags of coca tea



Stir in two tablespoons of unsweetened cocoa



Drink! Bitterness is all eliminated, retaining much color, smell and taste of chocolate – without sweeteners or fat, and no aftertaste. Both ingredients consumer safety tested for 300+ years.

No need for pre-processing of cacao to de-bitter, which destroys nutrients.



### Cocoa/Coca Simplicity





One ton of cacao is de-bittered by 2 ounces of coca leaf extract, replacing 900 pounds of sugar, saving \$500 per ton



### Our (Dark) Chocolate (Fudge): 15% Fat / Glucose

&



Currently chocolates average 75% fat and sugar



Our 15% formulation for chocolate (a room-temperature mixing process):

85% Cocoa unsweetened (12 grams)14% Fat (cocoa), lecithin (2 grams)

1% vanilla, salt, glucose, non-bitter stevia, etc.

1-2 tablespoons of coca tea

The Yungas Process

no aftertaste with no alkalinization needed

Concentrates phytonutrients by four times



### Global Chocolate Market



#### **Chocolate Market Statistics:**

- \$100+ billion annual sales
- 7.2 millions tons of chocolate
- Africa sources 72%
- Latin America sources 16%
- Asia/Oceania sources 12%

Liability: 5 million tons of sugar and fat





Manufacturing Chocolate for \$1 billion less a year (using coca)



### - \$250 ADDED SUGAR/TON

One ton of chocolate is typically 75% fat and sugar, the average ratio of fat/sugar being 40%/60%. Thus, one ton of chocolate has ~900 pounds of sugar, which at \$0.55/pound, costs about \$500 per ton of chocolate.

Using coca extract to eliminate 50% of the sugar - save \$250.

### + \$100 COCA EXTRACT/TON

One ton of chocolate is 1,000,000 grams, or 100,000 units of 10 grams. Each unit is de-bittered without sweeteners, using the extract of 1.5 coca leaves. 150,000 leaves weigh 19-25 pounds. One *taqui* (a large sack of coca leaves legally sold in Bolivia) weighs 50 pounds and costs \$200

Buying coca extracts to eliminate 50% of the sugar – spend \$100.

\$150 saved, multiplied by 7 million tons, is ~\$1 billion saved each year with coca extracts



### Cocoa/Coca Aesthetics



**<u>AESTHETICS</u>**: De-bittering effect produces a hot cacao beverage with an aesthetic appeal similar to black coffee – a \$6 billion/year retail market.

**SPECIFIC:** De-bittering effect is food specific – little to no de-bittering of coffee (suggesting de-bittering is not related to anesthetic properties of coca alkaloid).

**<u>COMPATIBLE</u>**: De-bittering effect does not interfere with other taste sensations. Drink some coca tea, and then drink some orange juice – juice retains "orangeness". **No aftertaste.** 

<u>NO COST</u>: De-bittering effect is easy to capture in manufacturing processes (adding milligrams of extract to kilogram quantities), and effectively at no cost (cost of extract less than manufacturing cost of sugar currently being used).

<u>SAFE:</u> High LD50 (> 3000, > salt). De-bittering effect does not lead to dependence – amounts of <u>water insoluble coca</u> alkaloid / per serving are in the microgram levels.



### Coca Tea non-Toxicity



#### Coca leaf extracts are safer than most food ingredients.

Additive	LD50 (mg/kg)	Additive	LD50 (mg/kg)	
				Chocolat
Inulin	> 5000	Sodium Benzoate	1600	Mountair
Cinnamon	< 4500	Sodium Citrate	1580	
COCA extracts	3450	Theobromine	1000	
Table Salt	3000	Phenethylamine	< 1000	
Citric Acid	3000	Codeine	800	
Vanilla	< 3000	Alum. Sulphate	400-800	<b>C</b> ""
Menthol	2900	Oxalic Acid	275	See: " Lethal
BHT	< 2900	Caffeine	192	And C
PGPR	> 2600	Sodium Nitrate	180	$B_{10}$ Bloche
DisodiumEDTA	~2500	Potas. Bromate	157	VI/ (I
Aspirin	1750	Brom. Veget. Oil	???	
Benzoic Acid	1700	Nicotine	1	

Chocolate	
Mountain Dew	

See: "Comparative Lethality of Coca And Cocaine", Pharm. Biochem. Behav., v17 (1982), 1087-1088



### Coca tea extracts? Safe!



"Cocaine in herbal tea" – <u>Journal of the AMA, 1986</u> "Coca tea drinkers did not satisfy the diagnostic criteria for either cocaine intoxication or abuse."

#### "History of Cocaine Abuse" - WHO/UNICRI Study, 1995

Recommendations re <u>coca chewing</u>: for future education and prevention efforts – NONE; for future treatment efforts – NONE; for future research and data gathering – NONE. Only recommendation of the report for simple coca?

"*The Program on Substance Abuse and the World Health Organization should undertake a study of the nutritional and therapeutic advantages of the coca leaves.*" The WHO study could not find enough concerns about coca chewing to warrant any further action – coca chewing is not a health or social problem.

And consumption of coca tea and its extracts is a factor of ten safer.



# Alternative: non-addictive coca alkaloid analog



#### U.S. Patent 8,557,842

#### Cocaine analogs and methods of preparation

Temple University, October 2013

A compound that acts as an antagonist or agonist of cocaine in its binding to various receptors could in principle be used in the treatment of cocaine addiction, as long as it is **not addictive** or cause the same degree of euphoria in individuals. In another aspect, such compound could be used as an anesthetic agent, mimicking the anesthesia provided by cocaine **without its well-known addictive properties.** 

Such a non-addictive coca alkaloid analog, if it offered similar de-bittering capabilities, and if when consumed, caused similar physiological reactions to the consumption of coca tea, will allow immediate supermarket/retail sales of our chocolate around the world (maybe preceded by a year of testing to verify safety).

We are contacting these researchers to test their analogs for de-bittering potential.



### Cacao/Coca Opportunities



- Turning chocolate into a medicine using coca extracts
- Doubling chocolate sales to \$200 billion/year
- Helping to fight world's addiction to toxic/deadly sugar
- Reducing trillion dollar costs of diabetes / heart disease
- Using the images of cacao and coca as a logo for a new fashion line celebrating the Andean peoples
- Helping to end South America's drug war miseries



### Chocolate's Medical Potential



#### **EXCEPT FOR ITS SUGAR AND FAT, CHOCOLATE:**

Can lower central systolic blood pressure Can lower arterial stiffness Can decrease effects of atherosclerosis Can prevent/cure prostate hyperplasia (Barry Callebaut, U.S. 8,435,576) Can increase levels of the "good" serum HDL cholesterol Can treat some tumors/cancers (Mars, U.S. 7,820,713; Hershey U.S. 9,040,906) Can help decrease absorption of excess iron in diet Can increase blood flow in elderly people to improve cognition Can re-mineralize teeth May delay progression of type 2 diabetes ... and more (see PubMed)

#### **EXCEPT FOR ITS FAT AND ADDICTIVE SUGAR!!!**





### Chocolate >60% Sugar/Fat



CHOCOLATE PRODUCTS	Serving	Fat	Sugar	Percent
	Size (grams)	(grams)	(grams)	Fat/Sugar
Dagoba 74% Dark	56	24	14	68%
Dove Silky Smooth Dark	42	14	19	78%
Endangered Species 88% Dark	43	20	5	58%
Equal Exchange 71% Dark	37	16	10	70%
Equal Exchange Organic Hot Cocoa	17	0	11	64%
Ferrero's Nutella	37	12	21	89% TOXIC
Ghiradelli Double Hot Chocolate	35	1.5	27	81%
Godiva 70% Dark	40	17	11	70%
Godiva 31% Milk	40	13	20	82%
Green & Blacks Organic Dark	35	15	9	68%
Hershey's Special Dark	41	12	21	80%
Hershey's 2%-Fat Chocolate Milk	38	5	25	78%
Lindt 70% Dark	40	19	12	78%
Mars' 3 Musketeers Bar	54	7	36	80%
Original Chocolate – Tesco	100	35	59	94% TOXIC
Newman's Own 70% Super Dark	64	28	16	68%
Scharffen Berger 82% Extra Dark	43	19	8	63%
Swiss Miss Dark Hot Chocolate	35	3.5	19	64%
Theo Chocolate 70% Organic Dark	42	16	12	66% AVG= 75%
AHA DAI	LY ADDED-SUG	GAR MAX	37 - men	

25 - women

Much Consumed SubstanceAddictivenessDeaths (U.S., per year)LethalityTreatment Costs (U.S., per year)Social HarmNicotine $\swarrow$ Most Addictive DSM-5480,000 (2007, CDC)Most Deadly\$300+ billion (2014, CDC)Most HarmfulAlcohol $\downarrow$ DSM-5 $\delta$ (2008, CDC) $\downarrow$ \$223 billion (2006, CDC) $\downarrow$ Sugar * $\checkmark$ DSM-677 $\delta$ (200, ADA) $\downarrow$ $\delta$ (2013, ADA) $\delta$ (2007, ADA)Sugary Drinks $\downarrow$ $25,000$ (2013, CDC) $\downarrow$ $\delta$ (2007, CDC) $\downarrow$ Oxycontin & other legal opioids $\downarrow$ DSM-57 $5,000$ (2010, NIH) $\downarrow$ DEA II $\delta$ St billion (2007, CDC) $\downarrow$ Caffeine $\downarrow$ DSM-58 $<100$ (2013, CDC) $\downarrow$ CO (2013, CDC) $\downarrow$ CO CO DEA II $\downarrow$ CO CO CO $\downarrow$ CO CO CO CO $\downarrow$ CO CO CO CO CO CO CO CO CO CO CO CO CO CO CO CO CO CO $\downarrow$ CO <br< th=""><th></th><th>Sugar:</th><th></th></br<>		Sugar:				
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Alcohol $\downarrow$ DSM-5 $\begin{array}{c} \$88,000\\(2008, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} \$223 \text{ billion}\\(2006, CDC)\end{array}$ $\downarrow$ Sugar * $$ $$ $\begin{array}{c} 69,000\\(\text{diabetes})\\(2000, ADA)\end{array}$ $\downarrow$ $\begin{array}{c} \$245 \text{ billion}\\(2013, ADA)\end{array}$ $\begin{array}{c} \$0,000+\\(\text{LE Amputations})\\(2007, ADA)\end{array}$ Sugary Drinks $\downarrow$ $\begin{array}{c} 25,000\\(2015, Tufts)\end{array}$ $\downarrow$ $\begin{array}{c} \$25 \text{ billion}\\(2007, CDC)\end{array}$ $\downarrow$ Oxycontin & other legal opioids $\downarrow$ $\begin{array}{c} 16,000\\(2013, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} \$25 \text{ billion}\\(2007, CDC)\end{array}$ $\downarrow$ Cocaine * $\downarrow$ $\begin{array}{c} \$000\\(2010, NIH)\end{array}$ $\downarrow$ $\begin{array}{c} \$25 \text{ billion}\\(2007, CDC)\end{array}$ $\downarrow$ Caffeine $\downarrow$ $\begin{array}{c} \$100\\(2013, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} \$1 \text{ million}\\(est.)\end{array}$ $\downarrow$	Nicotine	Most Addictive DSM-5	<b>480,000</b> (2007, CDC)	Most Deadly	<b>\$300+ billion</b> (2014, CDC)	Most Harmful
Sugar * $\downarrow$ $\begin{array}{c} 69,000\\ (diabetes)\\ (2000, ADA)\end{array}$ $\downarrow$ $\begin{array}{c} $245 \text{ billion}\\ (2013, ADA)\end{array}$ $\begin{array}{c} 50,000+\\ (LE Amputations)\\ (2007, ADA)\end{array}$ Sugary Drinks $\downarrow$ $\begin{array}{c} 25,000\\ (2015, Tufts)\end{array}$ $\downarrow$ $\downarrow$ $\begin{array}{c} \downarrow\\ (2007, ADA)\end{array}$ $\downarrow$ Oxycontin & other legal opioids $\downarrow$ $\begin{array}{c} 16,000\\ (2013, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} 525 \text{ billion}\\ (2007, CDC)\end{array}$ $\downarrow$ Oxycontin & other legal opioids $\downarrow$ $\begin{array}{c} 5,000\\ (2013, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} 825 \text{ billion}\\ (2007, CDC)\end{array}$ $\downarrow$ Occaine * $\downarrow$ $\begin{array}{c} 5,000\\ (2010, NIH)\end{array}$ $\begin{array}{c} \downarrow\\ DEA II\end{array}$ $\begin{array}{c} < $55 \text{ billion}\\ (est, DoJ.)\end{array}$ $\downarrow$ Caffeine $\downarrow$ $\begin{array}{c} <100\\ DSM-5\end{array}$ $\begin{array}{c} <100\\ (2013, CDC)\end{array}$ $\downarrow$ $\begin{array}{c} < $1 \text{ million}\\ (est.)\end{array}$ $\downarrow$ DEA IIDEA IIDEA II $\begin{array}{c} < 100\\ (est.)\end{array}$ $\begin{array}{c} < 100\\ (est.)\end{array}$ $\downarrow$ $\begin{array}{c} < 100\\ (est.)\end{array}$ $\downarrow$	Alcohol	↓ DSM-5	<b>88,000</b> (2008, CDC)	$\downarrow$	<b>\$223 billion</b> (2006, CDC)	$\downarrow$
Sugary Drinks $\downarrow$ $25,000$ (2015, Tufts) $\downarrow$ $\downarrow$ $\downarrow$ Oxycontin & other legal opioids $\downarrow$ $16,000$ (2013, CDC) $\downarrow$ $\$25$ billion (2007, CDC) $\downarrow$ Cocaine * $\downarrow$ $5,000$ (2010, NIH) $\downarrow$ $\$25$ billion (2007, CDC) $\downarrow$ Cocaine * $\downarrow$ $5,000$ (2010, NIH) $\downarrow$ $\$55$ billion (est, DoJ.) $\downarrow$ Caffeine $\downarrow$ $\$354,500$ (2010, NIH) $\downarrow$ $\$55,000$ 	Sugar *	↓ DSM-6?'	<b>69,000</b> (diabetes) (2000, ADA)	$\downarrow$	<b>\$245 billion</b> (2013, ADA)	<b>50,000+</b> (LE Amputations) (2007, ADA)
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Cocaine * $\downarrow$ DSM-5 $5,000$ (2010, NIH) $\downarrow$ DEA II $< $5 billion$ 	Oxycontin & other legal opioids	↓ DSM-5	<b>16,000</b> (2013, CDC)	↓ DEA II	<b>\$25 billion</b> (2007, CDC)	$\downarrow$
Caffeine $\downarrow_{DSM-5}$ $\stackrel{<100}{(2013, CDC)}$ $\downarrow_{Cattrian (est.)}$ $\downarrow_{Cattrian (est.)}$	Cocaine *	↓ DSM-5	5,000 (2010, NIH)	↓ DEA II	< \$5 billion (est, DoJ.)	$\downarrow$
Caffeine $\downarrow$ $\downarrow$ $\stackrel{<100}{}_{DSM-5}$ $\stackrel{<100}{}_{(2013, CDC)}$ $\downarrow$ $\stackrel{<\$1 \text{ million}}{}_{(est.)}$ $\downarrow$						
	Caffeine	↓ DSM-5	<100 (2013, CDC)	$\downarrow$	< \$1 million (est.)	$\downarrow$
Coca Leaf Tea     NOT Addictive     NONE – globally     NOT Deadly     NONE – globally     NOT Harmful	Coca Leaf Tea	NOT Addictive	NONE – globally	DEA II NOT Deadly	NONE – globally	NOT Harmful



### Sugar: Toxin Worse than Cocaine



"Intense sweetness surpasses cocaine reward", M. Lenoir, et al., *PLoS ONE, August 2007* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0000698

"Food addictions to fat and sugar similar to cocaine and heroin in brain response", National Monitor, Beth Balen, *12 December 2014 (referencing article in the Am. Journal of Clinical Nutrition* http://natmonitor.com/2014/12/12/food-addictions-to-fat-and-sugar-similar-to-cocaine-and-heroin-in-brain-

response/

fppt.com

"Differences in bingeing behavior and cocaine reward following intermittent access to sucrose, glucose or fructose solutions", JM Rorabaugh et al., *Neuroscience, June 2015, 213-220* 

http://www.ncbi.nlm.nih.gov/pubmed/26079112

Evidence for sugar addiction: behavioral and neurochemical effects of intermittent, excessive sugar intake", N. Avena et al., *Neurosci Biobehav Review*, 2008 v1, 20-39 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2235907/

"Animal models of sugar and fat bingeing: relationship to food addiction and increased body weight", N. Avena et al., *Methods Mol Biol, v 829, 2012, 351-65* http://www.ncbi.nlm.nih.gov/pubmed/?term=22231826

Sugary drinks linked to 180,000 deaths a year", Gitanjali Singh et al., *Circulation, June 2015* <u>http://circ.ahajournals.org/content/early/2015/06/25/CIRCULATIONAHA.114.010636</u>



Chocolate: 4+ million tons of sugar and fat a year



#### Risk Factor from Coca-Cola's 2014 10-K Annual Report:

Consumers and public health and government officials are highly concerned about the public health consequences of **obesity**, particularly among young people. In addition, some researchers, health advocates, and dietary guidelines are suggesting that consumption of **sugar-sweetened** beverages is a primary cause of **increased obesity rates** and are encouraging consumers to reduce or eliminate consumption of such [**sugar-sweetened**] products. Increasing public concern about obesity and additional governmental regulations concerning the marketing, labeling, packaging, or sale **of sugar-sweetened** beverages may reduce demand for or increase the cost of our **sugar-sweetened** beverages. ..... **Limitations on our ability to provide any of these types of products or otherwise satisfy changing consumer preferences relating to nonalcoholic beverages could adversely affect our financial results.** 

12 ounce Coca-Cola (39 grams sugar) Hershey Chocolate Bar (27 grams sugar)

**Does Hershey's 10-K Annual Reports Now Need Same Language?** 



### Solutions to sugar problem?



#### **NEW ARTIFICIAL SWEETENERS / FATS?**

Old ones either taste bad, are expensive, cause weight gain, don't degrade in environment, kills dogs (xylitol), and/or cause gastrointestinal distress – sugar is a subtly delicious addictive drug to replace

#### **EXTRACT FLAVONOLS / THEOBROMINE?**

People still mostly don't like pill food – they like tastes, textures and odors (as opposed to Soylent). People already are burdened with too many pills, and are turned off by anything equal to seedless watermelons/grapes.

#### **MORE FARMING HYBRID CACAOS?**

Maybe some new, easier to grow, variety of Criollo – but that smacks of the consumer-suspicious GMOs (genetically modified organism)



### The Coca Leaf Solution



#### Brew up to two bags of coca tea



Stir in two tablespoons of unsweetened cocoa



Drink! Bitterness is all eliminated, retaining much color, smell and taste of chocolate – without sweeteners or fat. Both ingredients consumer safety tested for 300+ years.

No need for pre-processing of cacao to de-bitter that destroys nutrients.



### The Coca Leaf Solution



#### Prepare two teaspoons of coca tea



Mix with one tablespoon of unsweetened cocoa & dry



#### It tastes like non-bitter, sugar-rich, fat-rich, but stale, chocolate



### Our (Dark) Chocolate (Fudge): 15% Fat / Glucose



Currently chocolates average 75% fat and sugar



Our 15% formulation for chocolate (a low-temperature mixing process):

84% unsweetened cocoa (12 grams)15% fat (cocoa), lecithin (2 grams)

1% vanilla, salt, glucose, stevia, etc.1-2 tablespoons of coca tea

Design team: a computational physicist / technology transfer tax planner; and a mechanical engineer / power systems designer. With industry support, we can find 5% to 10% formulations.



Our (Dark) Chocolate (Fudge): 15% Fat / Sugar



#### The fine tuning aspects of using coca leaf extract

There is a synergy – micrograms of coca extract to completely de-bitter cacao, and grams of sugar or sweetener to bring out the chocolate taste.

In one formulation, we de-bitter 220 grams of unsweetened cacao using one bag of coca tea (providing about <u>10 milligrams</u> of coca alkaloid), 1 teaspoon (<u>3 grams</u>) of stevia, and 20 grams of fat/lecithin. Varying the fat/lecithin mostly just affects texture.

We first used Stevia Dul-C produced in Bolivia. An (unusually) non-bitter stevia that did not leave the usual stevia bitter aftertaste. Too unusual, as Stevia Dul-C is 85% cyclamate and 15% saccharin. But it did result in a zero aftertaste sugar-free chocolate. We switched to E.N.D. Stevia, also produced in Bolivia. A real stevia, but with a low enough natural bitterness to not leave an aftertaste with our chocolate.

Stevia, and/or, cyclamate/saccharin, on its own can't de-bitter cacao. Coca extracts creates a chocolate taste "flatter" than expected. Together, we achieve the 15%. Additional grams of sugar to make a 25% version allows flavor tuning.

# Image: Second second

<u>Parameters</u>	<u>KukaX0co</u> <u>"85% Cocoa"</u>	<u>"85% Cocoa"</u>
Sample Size	42 grams	42 grams
Total Fat Total Sugar	6 grams <1 gram	22 grams 6 grams
% of Fat/Sugar	15%	67%
Maximum Quantity of Cacao Powder	36 grams	6 grams
opt.com		



### KukaXoco as medicine



As an illustrative example of a formulation of coca extract and unsweetened cocoa, we have:

- unsweetened cocoa (theobromine)
- red yeast rice (lovastatin)
- rice bran oil (tocotrienol)
- Protium heptaphyllum resin (triterpenes)
- purple tea extract
- coca leaf extract

- blood pressure
- cholesterol
- obesity
- obesity
- fat absorption
- diabetes

When mixed with cacao, red yeast rice and rice bran oil do not alter flavor. *Protium* traditionally has been used by coca chewers, and recently has been reported to reduce obesity in mice with high-fat diets.

A delicious formulation of natural products that can be sold globally within six months, solely with a DEA license (in the U.S.).



### 10% of Chocolate Sales as a Medicine (using Coca)





### anti-Obesity Cacao Clinics



#### Adult Obesity Rate by State, 2014





### anti-Obesity Cacao Clinics



The Affordable Care Act in the U.S. requires insurers to pay for nutrition and obesity screening, and some states require coverage for obesity therapy. The previous formulation, using no sugar and fat, but some quinua for all amino acids:

unsweetened cocoa (theobromine)

red yeast rice (lovastatin)

rice bran oil (tocotrienol)

Protium heptaphyllum resin (triterpenes)

purple tea extract

coca leaf extract

- blood pressure
- cholesterol
- obesity
- obesity
- fat absorption
- diabetes

will allow anti-obesity programs to be based on cacao, which could prove to be most effective – a diet based on eating lots of chocolate. Chocolate companies can profit from setting up such ACA clinics.



### anti-Obesity Cacao Clinics



Problem:

At least 70 million Americans (30%) have high blood pressure Solution:

Cacao's theobromine

Problem:

At least 70 million Americans (30%) have diabetes At least 70 million Americans (30%) are obese Solution:

KukaXoco's sugar-free, mostly fat-free chocolate Opportunity:

1 KukaXoco bar (\$3) a day to 100 million of these people?
\$100 billion/year in new chocolate sales





Why Our Use of Coca Leaf is Completely Legal



#### 1961 Single Convention on Narcotic Drugs, medicine exception:

"4. Preparations of Cocaine [HCl] containing not more than <u>0.1 per cent of cocaine calculated as cocaine base ......</u>

compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health."

Not only do our formulations meet this condition (using < 0.01%), we also are NOT using cocaine HCl (salt form of coca alkaloid).



### U.S. DEA – Schedule II



Coca leaves and extracts of coca leaves are Schedule II in the United States. Thus, they are legal to sell with a DEA license, and legal to buy with a prescription.

<u>21 CFR 1304.32</u> governs import regulations for coca leaf extracts. <u>21 CFR 1308.12(b)(4)</u> governs the Schedule II status of coca leaf extracts.

#### A problem? No, an opportunity!!!

DEA license & prescriptions? Cause to charge prescription product prices at CVS.

Schedule II status? Marijuana is Schedule I (completely useless), yet sales are now over \$1 billion/year, and investors are putting hundreds of millions of dollars into marijuana start-ups.



### Coca Alkaloid Blood Levels



Hershey's Milk Chocolate bar weighs 43 grams, of which 37 grams is fat and sugar, leaving at most 6 grams of cacao – about one tablespoon.

Under some conditions, we can de-bitter one tablespoon of cacao with 1/12th of a cup of coca tea (about 20 milliliters). One cup of tea has 6 milligrams of coca alkaloid, so we need 1/2 of a milligram to de-bitter, of which 80% is destroyed in the stomach before absorption, leading to 1/10th of a milligram of coca alkaloid being absorbed, or 100 micrograms (µg).

Average human body has 5.5 liters (L) of blood. Eating three coca/cocoa bars a day leads to a blood exposure level of  $3 * 100 \mu g / 5.5 L == 55 \mu g/L$ .

Initial threshold for cocaine testing is  $300 \ \mu g/L$ . Eating 3 coca/cocoa bars (55  $\mu g/L$ ) a day will not lead to drug testing detection.



### U.S. FDA – Additive Safety



**GRAS:** Generally Recognized As Safe – FDA's partial regulatory approach to new food additives. See their Web pages: <u>http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/</u>

Currently cacao and de-cocainized coca leaves are GRAS by law: see <u>21 CFR 182.20</u> (essential oils and natural extractives)

Thus, in conjunction with South American governments, we are currently preparing a GRAS Eligibility Claim for the full coca leaf. See:

www.cienciadelacoca.org/GRAS.html



### **GRAS** Notified Substances



A 1996 NIH analysis of coca tea (a superset of the extracts we use), determined four coca alkaloids for which GRAS eligibility is sought: methylbenzoylecgonine (PubChem CID 446220) benzoylecgonine (PubChem CID 338223) ecgonine methyl ester (PubChem CID 104904) trans-cinnamoylcocaine (PubChem CID 6440936).

A cup of tea can have, respectively, 4-5 milligrams, 0.5-1.0 milligrams, 1-2 milligrams and up to 0.1 milligrams of these four alkaloids. The latter three alkaloids have no euphoric or stimulating effect, and LD50 values safer than most common food additives. GRAS eligibility rests on a determination for methylbenzoylecgonine (non-salt version). NIH analysis at:

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2705900/

### Non-Toxicity of Coca Tea



#### One factor in GRAS eligibility is non-toxicity of coca extracts.

Additive	LD50 (mg/kg)		Additive	LD50 (mg/kg)	Chocolate		
Inulin	> 5000		Sodium Benzoate	1600	Mountain Dew		
Cinnamon	< 4500		Sodium Citrate	1580			
COCA extracts	3450		Theobromine	1000			
Table Salt	3000		Phenethylamine	< 1000			
Citric Acid	3000		Codeine	800			
Vanilla	< 3000		Alum. Sulphate	400-800			
Menthol	2900 Oxalic A		Oxalic Acid	275	Lethality of Coca		
BHT	< 2900		Caffeine	192	And Cocaine", Pharm.		
PGPR	> 2600		Sodium Nitrate	180	Biochem. Behav., $v_{17}$ (1982) 1087-1088		
DisodiumEDTA	diumEDTA ~2500		Potas. Bromate	157	vir (1962), 1007-1000		
Aspirin	1750		Brom. Veget. Oil	???			
Benzoic Acid	1700		Nicotine	1			



### Coca Leaf? A Healthy Food



#### Harvard Study - Nutritional Value of Coca Leaf (Duke, Aulick, Plowman 1975)

A study done by a team at Harvard University found that the coca leaf contains a rich store of nutrients, more than many other well-known food plants. These were analysed individually in the full study, and then lumped together for a general comparison, which we publish here:

	COCA (100 grs)	Average nutrients of 30 food plants (100 grs)
Calories	305	279
Proteins	19.9 g.	11.4 g.
Fats	3.3 g.	7.9 g.
Carbohydrates	44.3 g.	37.9 g.
Calcium (mg)	1749	99
Phosphorus (mg)	637	270
Iron (mg)	26.8	3.6
Vitamin A (iu)	10000	135
Vitamin B1 (mg)	0.58	0.58
Vitamin PP (mg)	3.7	2.2
Vitamin C (mg)	1.4	13.0
Vitamin B2 (mg)	1.73	0.18

#### FOODS USED FOR COMPARISON PURPOSES:

#### **10 CEREALS**

Amaranthus caudatus, Oriza sativa, Avena sativa, Chenopodium pallidicaule, Chenopodium quinoa, Hordeum vulgare, Secale cereale, Coix lachryma jobi, Zea mays and Triticum aesticum.

#### **10 VEGETABLES**

Canna edulis, Capsicum spp., Allium sativum, Arracacha xanthorriza, Ipomoea batatas, Cyclanthera pedata, Cucurbita maxima, Allium cepa, Brassica oleracea and Tropacolum tuberosum,

#### **10 FRUITS**

Persea americana, Ananas cosmosus, Musa sapientum, Cocos nucifera, Passiflora mollissima, Annona cherimolia, Prunus persica, Fregaria spp., Annona muricata, and Ficus carica.































### People, Land and Culture of Coca Leaf



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### SUGAR v. COCA TEA

V.





hundreds of grams v.



hundreds of micrograms



coca leaves. In 1903, the U.S. version of this product removed the alcohol, but retained the coca leaves. In 1903, the U.S. version of this product removed the coca leaves, because of false racist fears that black men were raping white women after drinking the U.S. version of this product. Coca leaves are replaced (ironically) with sugar (cocaine wasn't made illegal until 1914). The resulting deadly product?

fppt.com



### A killer of 25,000 Americans a year



and can contain 0.1 micrograms of cocaine alkaloid



Sugary drinks linked to 180,000 deaths a year [globally]", Gitanjali Singh et al., *Circulation, June 2015* <u>http://circ.ahajournals.org/content/early/2015/06/25/CIRCULATIONAHA.114.010636</u>

Con and	Relative Coca Tea Safety Coca tea has a bit of risk. Compared to WHAT?									
ſ	Much ConsumedSubstanceAddictiveness		Deaths (U.S., per year)	Lethality	Treatment Costs (U.S., per year)	Social Harm				
	Nicotine	Most Addictive DSM-5	<b>480,000</b> (2007, CDC)	Most Deadly	<b>\$300+ billion</b> (2014, CDC)	Most Harmful				
	Alcohol	↓ DSM-5	<mark>88,000</mark> (2008, CDC)	$\downarrow$	<b>\$223 billion</b> (2006, CDC)	$\downarrow$				
	Sugar *	↓ DSM-6??	<b>69,000</b> (diabetes) (2000, ADA)	$\downarrow$	<b>\$245 billion</b> (2013, ADA)	<b>50,000+</b> (LE Amputations) (2007, ADA)				
	Sugary Drinks	$\downarrow$	<b>25,000</b> (2015, Tufts)	$\downarrow$		$\downarrow$				
	Oxycontin & other legal opioids	↓ DSM-5	<b>16,000</b> (2013, CDC)	↓ DEA II	<b>\$25 billion</b> (2007, CDC)	$\downarrow$				
	Cocaine *	↓ DSM-5	5,000 (2010, NIH)	↓ DEA II	< \$5 billion (est, DoJ.)	$\downarrow$				
	Caffeine	↓ DSM-5	<100 (2013, CDC)	$\downarrow$	< \$1 million (est.)	$\downarrow$				
	Coca Leaf Tea	NOT Addictive	NONE – globally	DEA II NOT Deadly	NONE – globally	NOT Harmful				
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Years since onset of dependence

Worry for the chocolate industry -- where is the sugar curve? Closer to the cocaine curve? Or closer to the alcohol curve? There is no curve for coca tea, because it causes no dependence.

Curve from: "**Probability and predictors of remission from lifetime nicotine, alcohol, cannabis or cocaine dependence**", *Addiction, March 2011, v106(3), 657-669*, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3227547/



### Sugar: Toxin Worse than Cocaine



"Intense sweetness surpasses cocaine reward", M. Lenoir, et al., *PLoS ONE, August 2007* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0000698

"Food addictions to fat and sugar similar to cocaine and heroin in brain response", National Monitor, Beth Balen, *12 December 2014 (referencing article in the Am. Journal of Clinical Nutrition* http://natmonitor.com/2014/12/12/food-addictions-to-fat-and-sugar-similar-to-cocaine-and-heroin-in-brain-

response/

fppt.com

"Differences in bingeing behavior and cocaine reward following intermittent access to sucrose, glucose or fructose solutions", JM Rorabaugh et al., *Neuroscience, June 2015, 213-220* 

http://www.ncbi.nlm.nih.gov/pubmed/26079112

Evidence for sugar addiction: behavioral and neurochemical effects of intermittent, excessive sugar intake", N. Avena et al., *Neurosci Biobehav Review*, 2008 v1, 20-39 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2235907/

"Animal models of sugar and fat bingeing: relationship to food addiction and increased body weight", N. Avena et al., *Methods Mol Biol, v 829, 2012, 351-65* http://www.ncbi.nlm.nih.gov/pubmed/?term=22231826

Sugary drinks linked to 180,000 deaths a year", Gitanjali Singh et al., *Circulation, June 2015* <u>http://circ.ahajournals.org/content/early/2015/06/25/CIRCULATIONAHA.114.010636</u>



### Sugar: Toxin Worse than Cocaine







### Chocolate: 4+ million tons of sugar and fat a year



#### When you read:

<u>"Sugary drinks linked to 180,000 deaths a year"</u> Washington Post, 29 June 2015

and

"High sugar diet can impair learning and memory" Huffington Post, 24 June 2015

THINK!



Tobacco tort lawyers ... Asbestos tort lawyers ... **"ADDED SUGAR" MASS TORTS – "PUBLIC NUISANCE"** The lawyers are hungry – for your chocolate profits!!!

See: "Lawyers pitching state attorney generals ... to make food industry pay for soaring obesity-related health care costs", Politico, Feb. 2014 http://www.politico.com/story/2014/02/food-industry-obesity-health-care-costs-103390.html



## Chocolate inherits sugar's higher addictiveness than cocaine



#### Partial extinction of a conditioned context enhances preference for elements previously associated with cocaine but not with chocolate

Physiological Behavior, August 2013, v120, pg. 1-10

http://www.ncbi.nlm.nih.gov/pubmed/23831243

Abstract:

fppt.com

Drug-associated stimuli are crucial to reinstatement of drug-seeking after periods of abstinence, representing a central problem in treatment of addiction. The present study investigated the influence of partial extinction of the conditioned context on the expression of conditioned place preference (CPP). Mice of the inbred DBA/2J strain were conditioned with cocaine or chocolate in a context identified by multiple elements (A+B) and subsequently CPP expression was evaluated in a context containing only one element (A or B) or both (A+B). Cocaine- and chocolate-conditioned mice showed CPP in presence of the original compound stimulus. However, <u>cocaine-conditioned mice did not show CPP when tested in A or B</u> context, while chocolate-conditioned mice did show CPP to single element context.

Or, as the BBC asks, "**Can people learn to curb their chocolate cravings?**", <u>http://www.bbc.com/news/magazine-33690211</u>, 29 July 2015



### Chocolate: 4+ million tons of sugar and fat a year



In 2003, Kraft Foods was sued for using unsafe and easily replaceable trans fats in Oreos, by consumer lawyer Stephen Joseph in the San Fran Bay Area county court system. Lawsuit was shortly thereafter dropped:

Lawsuit dropped as Oreo looks to drop the fat

CNN Law Center, 14 May 2003

http://www.cnn.com/2003/LAW/05/14/oreo.suit/

Twelve years later, FDA rules trans fats are not GRAS, and orders their removal from <u>all</u> foods:

The FDA takes steps to remove artificial trans fats in processed foods

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm451237.htm, 16 June 2015

The chocolate industry will have less than 12 years to remove sugar when the FDA rules that full coca leaf extracts are GRAS.



### "Added Sugar" Mass Tort Troll Insurance Policy



An insurance policy for the chocolate industry being designed in conjunction with Intellectual Property Insurance Services Corp. (Louisville, KY). Will cover litigation costs and damages due to tort troll lawsuits arising from health costs caused by public consumption of added sugar (a "public nuisance"?) in food products.

An assessment is done for past, present and future uses of added sugar in your products, especially fructose.

Health actuarial models are used to calculate resulting deaths and social health costs due to the added sugar, discounted for past future availability of alternatives to added sugars and sweeteners.

Premiums based on expected deaths and costs of added sugars. Models are prepared for slight price increases to cover costs of insurance. Consultations provided for damages avoidance.

For more information, contact IPISC at <u>www.patentinsurance.com</u>, 800-537-7863.



Other IPISC Insurance Products for the Chocolate Industry



<u>Abatement/Pursuit</u> – an insurance policy that covers the costs of asserting your IP (patents, copyright, trademarks) against infringer

<u>**Defense**</u> – an insurance policy that covers the costs of defending your company from IP infringement lawsuits, one variant being protection against patent trolls plaguing other industries

<u>**ABIPI**</u> – an insurance policy that insures your IP (especially patents) to then use the IP as collateral for a loan

For more information, contact IPISC at <u>www.patentinsurance.com</u>, 800-537-7863.







<u>Industry Threat</u> – pharmaceutical industry better positioned to commercialize cacao/coca as a medical/health product, given its size and greater experiences with the FDA, NIH, and DEA

<u>Chocolate Patent Pool</u> – patent pools are vital in many industries with similar concerns (such as telecom), a united defense that the chocolate industry can easily create to ward off pharmaceutical industry competition, while reaping a variety of tax benefits

<u>Chocolate Patent Pool Insurance</u> – an insurance policy can be acquired from IPISC for the pool that can provide up to \$100 million in patent enforcement and defense costs





### **Current Activities**



KukaXoco - our nutraceutical start-up - Boston IICC – our InterAndean Institute of Coca sCiences – La Paz www.cienciadelacoca.org

GRAS – filing GRAS application for full coca leaf with FDA
KickStarter – raising funds for Institute and GRAS filing
Cacao/Coca Industry Laboratory - in La Paz, seeking funding

Winter 2016 Tour – Organizing hands-on learning tour in January to Bolivia for chocolate industry UNGASS – Spring 2016 Special Session of UN General Assembly on World Drug Problem – helping coca delegations – <u>https://www.unodc.org/ungass2016/</u>



### Commercialization



First Market – South America and Mexico (GDP \$6.5 trillion)

currently coca/cacao is sellable unregulated by drug authorities, just need food safety agency approvals (e.g., SENASAG in Bolivia has approved multiple coca products, as well as chocolates) based in Bolivia (MercoSur, ALADI) and Peru (Pacific Alliance) -

Second Market – China (GDP \$9.2 trillion)

currently quite interested in importing coca tea, more so coca/cacao **Third Market – Europe** (GDP \$18.4 trillion) will open market to coca products – if good science is shown

**Fourth Market – U.S. and Canada** (GDP \$18.5 trillion) can enter now, and will do so with funding, otherwise enter gradually after educational and legal campaign



### False Precedent of the 2009 Ban of Red Bull in Germany



- In 2009, the German consumer protection agency banned one version of
  Red Bull, after it was found to contain 0.13 micrograms of coca alkaloid.
  Why is this not a deterrent for KukaXoco acceptance?
- Red Bull has no health benefits with its 28 grams of sugar, especially with nutrients already obtained elsewhere in the diet
- Sugar increasingly recognized in U.S. as more dangerous than coca alkaloid
- Growing U.S. acceptance of marijuana, more dangerous than coca alkaloid (and U.S. tolerance for legalized heroin [Oxycodone] and legalized amphetamine [Adderall], both far more dangerous than coca alkaloid)
- European Union willingness to accept a proven-safe, proven-beneficial, use of coca alkaloid in consumer products.



### EU Promise to Open Markets



**Declaraciones de Andris Piebalgs, Comisario de la Unión Europea para el Desarrollo** (published in La Razon, Bolivia, 31 August 2013)



"Bolivia debe hacer esfuerzos para que en la UE no se asocie la coca con la cocaína y **también llevar adelante estudios para** <u>demostrar que</u> <u>los productos de coca no son dañinos</u>."

Ante la pregunta ¿La UE puede convertirse, a largo plazo, en un mercado para productos industrializados de la coca, como el mate, bebidas, etc?

- "No lo excluiría, pero <u>requeriría de muchos estudios científicos que</u> <u>demuestren</u> clara e innegablemente <u>que éstos productos no tienen consecuencia</u> <u>negativa</u> alguna para el consumidor."



### Helping End Drug War in South America



US and European governments are encouraging coca leaf farmers in South America to switch from coca leaf to cacao, to reduce supplies of coca leaf for drug traffickers:

#### USAID invests \$60 million in Peru's alternative development and deforestation programs

Peru This Week, 09 July 2014

Efforts are struggling due to inadequate profits for the farmers:

Push for Colombians to stop farming coca falls short

New York Times, 02 June 2015

The chocolate industry can help here, working with government agencies – offering farmers higher prices for mixtures of coca leaf extract and cacao powder – the best of both worlds for farmers, government, and chocolate makers.

### Chocolate: Candy – Sugar = Medicine MILK CHOCOLATE NET WI 155 07 (430) Now: 7 ounce / 200 grams candy bar \$2.00 (which government now discourages)

remove sugar, some fat (save many pennies) add a bit of coca leaf (cost a few pennies)

Future: 7 ounce / 200 grams medical product\$4.00(which government could now subsidize)\$4.00

\$100 billion/year market ====> **\$200 billion/year market** 



### CONTACTS:



Vice Ministry of Coca (VCDI) and Coca Industrialization Agency (DIGCOIN) – Government of Bolivia, La Paz <u>http://www.vcdi.gob.bo</u>

National Service for Agricultural and Food Safety (SENASAG) – Government of Bolivia, La Paz <u>http://www.senasag.gob.bo</u>

CocaCoquita S.R.L (supplier of organic coca leaves and extracts) – Alejandro Revilla <u>cocacoquita.srl@cienciadelacoca.org</u>, La Paz

National Coca Business (ENACO), Lima, Peru – government agency for coca industrialization, <u>www.enaco.com.pe</u>

Commercial Section, U.S. Embassies:

La Paz: <u>commercelapaz@state.gov</u> Lima: econlima@state.gov





### THANK YOU!



Thank You, and if nothing else, please visit South America, and experience for yourself their culture, their hospitality, their cacao and their coca tea.

