Protecting Consumers from Health Scams

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Mariani Wine (1875)
“Coca wine”
Hastens convalescence
Especially after influenza
Fortifies, strengthens,
Stimulates and refreshes
Pope Leo XIII carried it everywhere

Spanish Flu Remedies: 1918

- 50 million deaths worldwide
- People were scared and would try anything that might help.
- Folk treatments:
  - Onions (with every meal)
  - Salt placed in nostrils
  - Smoke from sulfur, brown sugar
    on hot coals

Avian Flu Remedies: 2005

“Take any sort of product, irresponsibly claim it works and you are a millionaire, that’s for sure.” “Some of the cures are so ridiculous and dangerous.”
Edzard Ernst, Univ. of Exeter

FDA Health Fraud Definition

The deceptive promotion, advertisement, or sale of products as being effective to diagnose, prevent, cure, treat, or mitigate disease, or to provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes.

may be deliberate, or done without adequate knowledge or understanding of the product
FDA Health Fraud Definitions

- **Direct health hazard**: product is likely to cause injury, death or other serious adverse effect when used as directed

- **Indirect health hazard**: product poses no direct hazard, but consumer is likely to delay or discontinue appropriate medical treatment by relying on product.

Identifying Health Fraud

- Treats serious, chronic and/or incurable diseases
- Effectiveness is established through personal testimonials
- Claims to cure many diseases
  - One product “does it all”

Red Flag: “Cure-all” Claims

- 12 types of cancer
- Bacterial, viral infections
- Parasites, worms, lice
- High blood pressure
- Depression
- Anticonvulsant

Graviola Max
True Renewal Warning Letter, 1/6/2009

Identifying Health Fraud

- Marketing Terminology
  - “new discovery”
  - “ancient remedy”
  - “scientific breakthrough”
  - “secret formula”
- Pseudo-scientific terminology and product ingredients
Red Flag: Jargon

- Neutralizes negative "thought-forms" & stagnant energy patterns;
- Eliminates blockages by re-polarizing cells;
- Complete photobiotic nutrition at the cellular level

Skilling Institute Warning Letter: May 14, 2009

Photon Genie - $3000

Agents Against Swine Flu

- Proteins from garlic
- Garlic, onion, ginger

Ingredients: Fanciful names

- 3-hydroxy-4-trimethylaminobutyric acid 2200mg
- Carboxymethylcellulose acid 1600mg
- Sanguinaria sanguinaria acid 500mg
- Ribose acid 450mg
- 3, 5-diaminopyruvic acid 300mg
- 1-carboxylic acid 300mg
- N-carboxyphthaleinester 3-mercapto-N-carboxymethylpropanesulfonic acid 100mg
- Quilliamamycin acid 50mg

* Absolutely no interferences or negative effects when taken with other medicines.

Identifying Health Fraud

- Money back guarantee
- "all-natural" = safer than conventional treatments
- "Quick fixes" (especially for weight loss, H1N1 flu)
- Conspiracy Theories

Identifying Health Fraud

- Requires to stop taking prescribed medications
- Fake medical and scientific credentials

Cancer Control Targets and Destroys Your Cancer Cells

"The most important reason why I recommend Cancer Control is my patient's in the fact that Cancer Control is more effective than chemotherapy but with minimal side effects. In fact, most patients feel better as they continue to receive treatment. This non-invasive, minimally invasive treatment is designed to target and destroy cancer by stimulating the body's own immune system and allowing the body to naturally fight and destroy cancer cells."

Rita Shidky, MD, PhD
Red Flag: Fake Medical Credentials

* Dr. Kennedy Ross, real name Gregg Kell
* Gregg Kell is a web designer and advertising agent
* Gregg Kell made $45,000 just from the cancer site.

Thousands of Dollars

Greed Motivates These Practices!

Billions of Dollars

The Modern Con-Artist

Rapid Growth of Internet

Over 215 million people in the U.S. use the Internet

2000 = 46% American adults had internet access (5% broadband)

2008 = 74% (57% broadband)

The Social Life of Health Information, S. Fox, Pew Internet & American Life Project, June 11, 2009
Health Information & the Internet

- 61% of American adults look online for medical help
- 60% say the information affected a decision about how to treat an illness,
- ~50% searched on behalf of someone else
- 35% say search influenced decision to see MD

The Social Life of Health Information, S. Fox, Pew Internet & American Life Project, June 11, 2009

Health Information & the Internet

- Health topics searched by internet users:
  - 66% - a specific disease
  - 55% - a specific treatment
  - 45% - Rx or OTC drugs
  - 35% - Alternative treatments or meds
  - 20% - Experimental treatments or meds or medicines

The Social Life of Health Information, S. Fox, Pew Internet & American Life Project, June 11, 2009

Global Marketplace

- www.internet.com
- Credit card and online billing
- International commercial carriers
- Multilevel marketing
- SPAM and text messages: internet, fax, and cell phone
- TV and radio (infomercials, etc.)

MOISTUROIL

Importation of FDA Regulated Products

- 150 countries are exporting FDA regulated goods to US
  - 130,000 US importers of record
  - 300,000 foreign manufacturers
The Risks

- Fraudulent claims
- Adulterated products
- Counterfeit drugs
- Unapproved HIV tests
- Dangerous, addictive drugs without Rx
  (NAPB 5-09 survey >1300 internet sites: 88% no Rx)

“Health scam whack-a-mole”

- Stream of new products & claims;
- Instantaneous response to emerging health threats
  (SARS, Anthrax, Avian flu, MRSA, H1N1 Flu)
- Old standbys
  (Ozone, Colloidal silver, Laetrile, Hoxsey formula, Zapper)

Ozone Therapy

OZONE

GENERATOR

THE AIDS TREATING MACHINE

THE AIDS TREATING MACHINE de-activates pathogens, viruses and the most resilient spore, Bacillus subtilis, within 60 seconds by electrolyzing HzO and NaCl solution in the solution treating proprietary electrolytic chamber and patented anodes.

Laboratory data available upon written request only.

SOLUTION “A” may be administered intramuscularly, intravenously, orally, via enema, or a combination.

The quantity, method and frequency of application depends upon the patient’s condition as determined by a qualified physician.

After completing the 7-day efficacy test as follows, compare blood analysis “before” and “after” treatment.

HERE IS THE 7-DAY EFFICACY TEST:

LA WATTS TREATING MACHINE

DIET DURING 7-DAY EFFICACY TEST:

- Avoid all illegal drugs, liquor and tobacco
- Avoid raw or cooked vegetables and fruits
- Avoid meat, beans, pasta, dairy products, and drink plenty of water.

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Strategies for Combating Health Fraud

- Enforcement Actions
- Collaboration
- Public Outreach and Education

Health Fraud Enforcement Strategy

- Direct health hazard: highest priority

Health Fraud Enforcement Strategy

- Indirect health hazards: case-by-case
  - Significance of claims (H1N1 flu cures)
  - Vulnerability of user group (elderly, children, etc)
  - Number of users affected
  - Economic impact (cost, etc)
Enforcement Actions

• Untitled and Warning Letters
  • More is better
• Import alerts
• Seizures
• Injunctions
• Debarment
• Criminal Prosecution

Outreach and Education

• Consumer Updates with major initiatives
• Press calls and interviews
• WebMD partnership – 49 million visitors/mo.
• MedWatch
• WL’s on Google search

Recent Health Scam Enforcement Initiatives

• H1N1 Flu Fraud
• Cancer fraud
• Adulterated “supplements”

2009 H1N1 Flu Fraud Initiative

• April 26: Public health Emergency declared
• Consumer Protection Team convened
  • Health Fraud Action Plan
    • Process to target H1N1 fraudulent flu products
    • Press release and consumer message
    • Proposed enforcement strategy
    • Collaboration with Federal Trade Commission

2009 H1N1 Flu Fraud Initiative

• Template warning letter
  • accelerated OCC review
  • email issue & 48-hour response
  • Immediate posting, searchable database
• Daily “surfs” by Centers, report to OE
• Flu fraud web page
• “One-stop” online reporting form
• Contacted e-bay, Amazon, Shopzilla, Paypal, etc
• Press releases

http://www.fda.gov/ICECI/CriminalInvestigations/ucm162855.htm
**H1N1 Flu Fraud Searchable Database**

<table>
<thead>
<tr>
<th>Category</th>
<th>URL</th>
<th>Brand or Manufacturer</th>
<th>Product Name</th>
<th>Description</th>
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<td>SilicaCore</td>
<td>Anti-Flu</td>
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**2009 H1N1 Flu Fraud Initiative**

- 54 Warning letters
- 72% Compliance to date
- Press releases: 5-1 and 6-15
- Extensive press coverage

**Fraudulent H1N1 Flu Claims**

- Exterminates the flu before you notice any symptoms. “We’ve been overwhelmed with orders”
- “Stop swine flu in its tracks”
- 100x more effective at killing flu virus than most potent prescription anti-viral
- 1 capsule kills “whole body viral infection” in 4-8 hours

**CANCER FRAUD INITIATIVE – 2008**

- Trilateral Initiative ~30 “surfers” from FDA
- 40 warning letters to US and 2 foreign firms
- Widespread coverage (CNN, Medical journals, Telemundo, Korean TV)

**Dangerous Drugs Found in “Dietary Supplements”**

- Intentionally Added Adulterants
- Many are imported products and ingredients

**Adulterated “Slimming” Products**

- Survey of foreign consumer alerts (i.e., Asia, Europe, Canada, Middle East)
- Complaints, press reports
- Internet surf by OE and CDER
- 25 undercover buys
- Over 80 products and counting
APIs detected in weight-loss "supplements"

- Sibutramine (Meridia-Schedule IV)
- Fenproporex (amphetamine analog)
- Phenytoin (Dilantin)
- Fluoxetine (Prozac)
- Bumetanide (Bumex)
- Furosemide (Lasix)
- Rimonabant (not approved)
- Cetilistat
- Phenolphthalein (carcinogen)

Sibutramine Adverse Effects

- Increased blood pressure (severe in some individuals) and heart rate
- Dangerous interaction with other drugs; should not be taken with other stimulants
- Should not be used in patients with renal impairment

ED “Supplements” Adulterated with APIs

- Common in men with diabetes, high blood pressure, high cholesterol.
- Often prescribed nitrates (such as nitroglycerin).
- FDA-approved ED drugs (Viagra, Levitra, etc) may interact with nitrates to cause a dangerous drop in blood pressure
- Men may seek alternative “all natural” supplements because they can’t take FDA-approved ED drugs

ED Drugs

- Internet
- Mail order
- Retail stores: Adult and liquor stores, Gas stations, “Vitamin and nutrition stores” (GNC, etc)
- Ads in newspaper, mags.
- Spam
ED DRUGS

Xiadafil VIP (by SEI)
Contains analog of sildenafil (Viagra)
--Florida issued “stop sale” 5-12 and over $8 million inventory detained
--Firm refused to recall
--FDA requested recall 5-27-08

“RIZE 2 THE OCCASION” and “ROSE 4 HER”
Innovative Health Products
Largo, FL
•Contains sildenafil analog

Dangerous Drugs Intentionally Added to “Supplements”
• Erectile Dysfunction Drugs
• Weight loss supplements
• Diabetes Drugs
• Steroids and hormones
• Cosmetic eyelash products
Consumer Outreach and Education

- Health Scams brochure available
  - Office of Women’s Health/OE

Coming:
- Health fraud website
- Components for a campaign including:
  - Video ~ 3 minutes
  - Portable Banner Display

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