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P R E S S R E L E A S E

OFFICE OF THE UNITED STATES ATTORNEY

SOUTHERN DISTRICT OF CALIFORNIA

San Diego, California

March 16, 1992

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NEWS RELEASE SUMMARY

The United States Attorney for the Southern District of California, William Braniff, the Commissioner of the Food and Drug Administration, Dr. David A. Kessler, M.D., and the Commissioner of the United States Customs Service, Carol B. Hallett, announced today a major federal indictment exposing an international black market in smuggled unapproved "fountain of youth" drugs.

According to Braniff, the indictment alleges that a criminal organization centered in California illegally smuggled more than 15 tons of dangerous unapproved new drugs, valued in the millions of dollars, into the United States over the last five years. These so-called fountain of youth drugs were then illegally distributed nationwide as part of a burgeoning \$2 billion anti-aging black market. A black market described by Congress as the fastest growing and perhaps most profitable segment of the \$10 billion "quackery scandal."

According to the indictment the defendant, David M. Halpern of Pebble Peach, Calif., formed various companies to conceal and disguise his importation of the illegal drugs. Utilizing these

corporations and mail drops in the names of fictitious individuals, Halpern had been illegally importing fountain of youth drugs from Germany and England since at least 1983.

These drugs had been promoted as curing everything from depression to diabetes, and rheumatoid arthritis to radiation damage. In total, they claimed to be able to treat scores of medical conditions related to aging and the variety of physical and psychological problems that accompany the aging process. Three basic types of drugs -- various cell therapies, procaine hydrochloride derivatives, and sexual tonics -- were included.

In cell therapy, ribonucleic acid (RNA) is isolated from the organs and tissues of young sheep or cattle, or the fetuses of these animals. Once isolated, the "organospecific" RNA is placed in injectable bottles or ampules to allow individuals to inject the animal proteins. This therapy is now being promoted in this country by black marketeers for over 100 different medical conditions ranging from acne to sterility.

"In trumpeting miracle cure-alls, the literature is reminiscent of the medicine shows of the last century," said FDA Commissioner David A. Kessler, M.D. "Despite these claims of a miracle panacea, no one has ever submitted to the FDA any well controlled clinical investigations which demonstrate either the effectiveness or safety of cell therapy for any medical purpose."

According to the FDA, use of these products may result in serious adverse reactions, including allergic complications, anaphylactic shock and even death. Moreover, since animal tissues

are being used, animal viruses and microbes could be transmitted to patients. In this manner, individuals utilizing these prohibited drugs run the real risk of contracting, among other diseases, brucellosis and Q-Fever, and perhaps, even bovine spongiform encephalitis (also known as "mad cow disease").

Gerovital H3, a procaine hydrochloride product, is touted as the most popular rejuvenation product in the world. Despite lavish claims, controlled trials have reportedly failed to demonstrate any improvement in the physical or mental status of elderly patients. According to the FDA, procaine hydrochloride's only recognized medical use in the United States is as a local anesthetic. No manufacturer has demonstrated that Gerovital H3 has any value whatsoever in retarding the aging process, or for the treatment or prevention of any disorder in the elderly. If and to the extent procaine hydrochloride products were relied upon as a remedy for the many conditions associated with increasing age that are amenable to management with good medical care, they would adversely affect the patients' health and waste resources.

According to the Indictment, David Halpern also illegally imported large quantities of Zumba Forte, billed as a "sexualtonic" by its manufacturer, codefendant Zumba Vertriebsgesellschaft Pharmazeutischer Erzeugnisse GmbH. According to its promotional literature, Zumba Forte is based on vegetable substances discovered by primitive native inhabitants of tropical jungles.

The vegetable components in Zumba Forte include the unapproved substance yohimbine. Medical authorities are particularly

concerned with the abuse of this drug in older men seeking rejuvenation because its recognized contraindications include renal disease. In addition to Yohimbine, Zumba Forte contains the anabolic steroid, methyltestosterone. The FDA has limited the use of this substance due to well documented adverse side effects. Due to these side effects, methyltestosterone is also specifically contraindicated for use by the elderly

As alleged in the Indictment, David Halpern set up a number of corporations overseas to cover his illegal purchases of procaine hydrochloride related products. He then arranged for a U.K. citizen to run the British side of his operation. Orders were divided to avoid suspicion, falsely declared and sent to mail drops throughout southern California. Similarly, Halpern arranged with codefendant Maximillian Schmidt to utilize his German firm, defendant Zumba GmbH, to illegally ship fountain of youth drugs from Germany.

Halpern, who claimed sales about \$1 million per year from the operation, also engaged various family members to assist with collecting the illegal shipments. Between 1986 and 1990, his family collected over 13 tons of smuggled fountain of youth drugs. After collection, the drugs were repackaged to disguise the fact that they had been illegally imported, and then shipped to customers.

According to Assistant U.S. Attorney Phillip L.B. Halpern (no relation to the defendants), who directed the prosecution, the defendants specialized in sales to black market wholesale

distributors, health food stores, chiropractors, gyms, natural food stores, nutrition centers and individual consumers. They sold millions of dollars of the drugs to thousands of customers located in 43 states, Canada, Guam, and the Virgin Islands. Combined orders to a single customer exceeded over \$400,000 during the course of the conspiracy. The defendants even accepted payment by major credit cards.

As recognized in a report issued by the Chairman of the House Select Committee on Aging (May 31, 1984), man has always "hoped to find the fountain of youth, the magic potion or secret substance that will forestall aging and maintain the vigor associated with youth." Playing into this universal yearning, the purveyors of quackery utilize a "conscious deceit and the absence of, and, in most cases, total disregard for scientific proof." As a result, in addition to the billions spent on these useless, and potentially dangerous drugs, it is impossible to quantify the cost in human terms, "measured in disillusion, pain relief forsaken or postponed. All too frequently, the purchaser pays with his life."

Braniff praised the efforts of the FDA and Customs Service for their work on this complex investigation. "Without their dedication, this multi-year, international investigation would not have been possible," he said. "Today's indictment demonstrates that the problems posed by these unapproved fountain of youth drugs can be successfully combatted by serious law enforcement efforts."

DEFENDANTS

1. David M. Halpern
4081 Los Altos Drive
Pebble Beach, California
Age: 38
2. Frances H. Wellgood
33166 Frog Pond Road
Little River, California
Age: 37
3. Edward Sollisch
33166 Frog Pond Road
Little River, California
Age: 62
4. Frances D. Halpern
12269 Carmel Vista (no. 166)
San Diego, California
Age: 65
5. Maximillian Schmidt
Bernauer Strasse 17
8000 Munchen 80
Munich, Germany
Age: 26
6. Emanon, Inc.
18603 N. Highway 1
Fort Bragg, California
7. Tudor Trading Co.
90 Hale Drive
Mill Hill, London
England
8. Sharefirst, Ltd.
90 Hale Drive
Mill Hill, London,
England
9. Big Ben Export Co.
P.O. Box 146
Mill Hill, London
England
10. Zumba Vertriebsgesellschaft
Pharmazeutischer Erzeugnisse GmbH
Bernauer Strasse 17
8000 Munchen 80
Munich, Germany

SUMMARY OF CHARGES

Indictment No: 92-0298-G

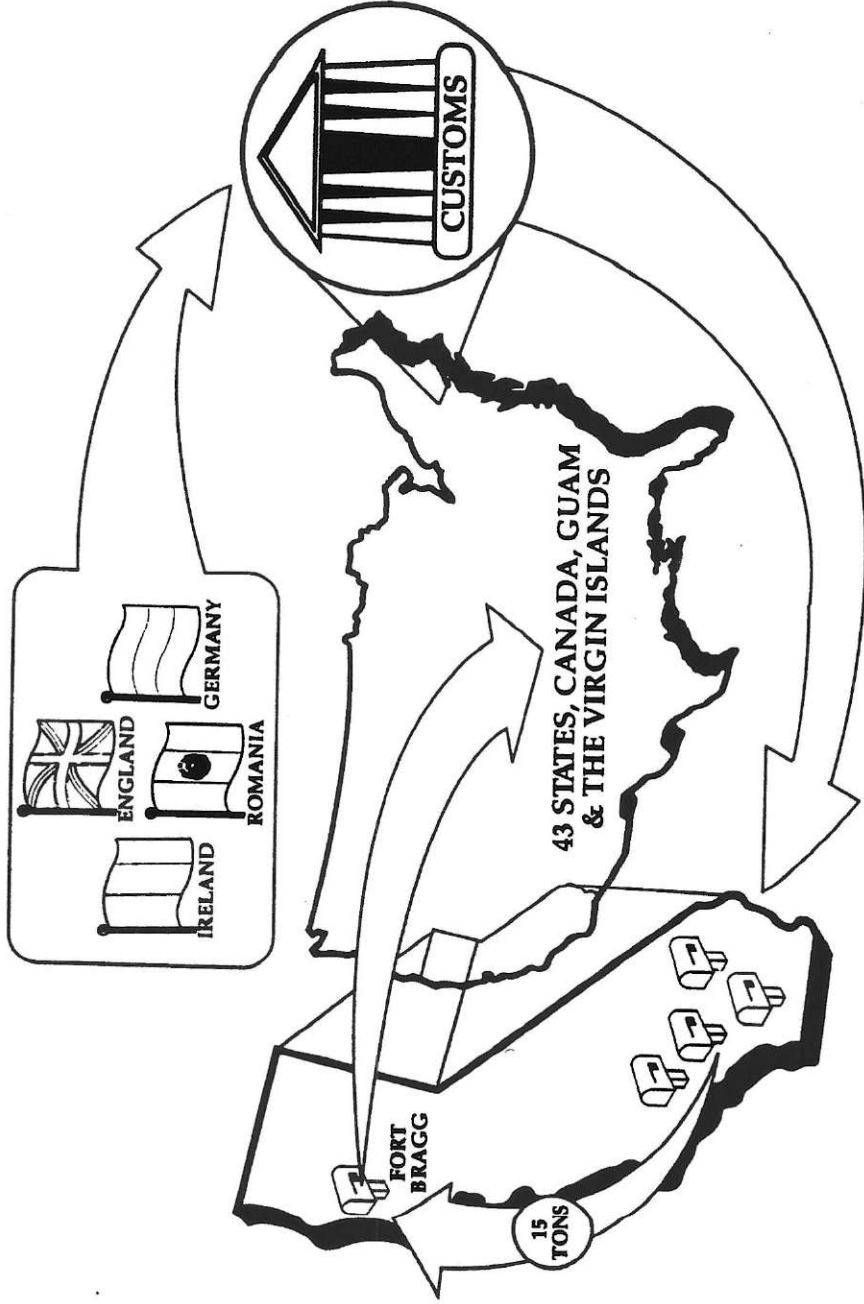
No. of Defendants: 10

No. of Counts: 198

Violations & Maximum Penalties:

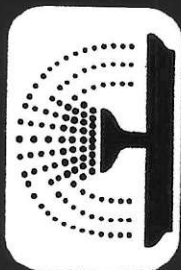
- Count 1: Conspiracy To Defraud The United States
5 years and/or a \$250,000 fine
All Defendants
- Counts 2-105: Introducing Unapproved Drugs in Commerce
3 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Maximillian Schmidt,
Emanon, Inc., and Zumba GmbH
- Counts 106-122: Introducing Unapproved Drugs in Commerce
3 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Emanon, Inc., Tudor
Trading Co., Big Ben Export Co., and
Sharefirst Ltd.
- Counts 123-134: Entry of Goods by False Documents
2 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Frances D. Halpern,
Emanon, Inc., Tudor
Trading Co., Big Ben Export Co., and
Sharefirst Ltd.
- Counts 135-160: Entry of Goods by False Documents
2 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Frances D. Halpern,
Maximillian Schmidt, Emanon, Inc., and
Zumba GmbH
- Counts 161-172: Smuggling Unapproved Drugs into the U.S
5 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Frances D. Halpern,
Emanon, Inc., Tudor Trading Co., Big Ben
Export Co., and Sharefirst Ltd.
- Counts 173-198: Smuggling Unapproved Drugs into the U.S
5 years and/or a \$250,000 fine
David M. Halpern, Frances H. Wellgood,
Edward Sollisch, Frances D. Halpern,
Maximillian Schmidt, Emanon, Inc., and
Zumba GmbH

**"FOUNTAIN OF YOUTH" DRUGS
MANUFACTURING AND DISTRIBUTION SEGMENT**



BLACK MARKET:

**Health Food Stores, Chiropractors, Gyms, Natural Food Stores,
Nutrition Centers and Various Black Market Companies and Individuals.**



“FOUNTAIN OF YOUTH” DRUGS THE “CURE-ALL” FALLACY



BOGUS ANTI-AGING CLAIMS

- ANTI-AGING**
- Mental Exhaustion
 - Physical
 - Sexual
 - Circulation
 - Senility
 - Arthritis
 - Hypertension
 - Arteriosclerosis
 - Pneumonia
-
- DISEASES**
- Heart Problems
 - Liver Problems
 - Prostate Problems
 - Anemia
 - Osteoporosis
 - Diabetes
 - Cataracts
 - Parkinson's Disease
 - Colitis



POTENTIAL HIDDEN DANGERS

- Allergic Complication
- Anaphylactic Shock
- Brucellosis
- Q-Fever
- Bovine Encephalitis
- Septic Arthritis
- Hypotension
- Convulsions
- Liver Disease
- Cancer
- Death

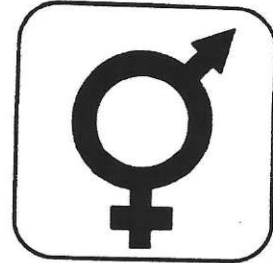
"FOUNTAIN OF YOUTH" DRUGS



**CELL
THERAPY**



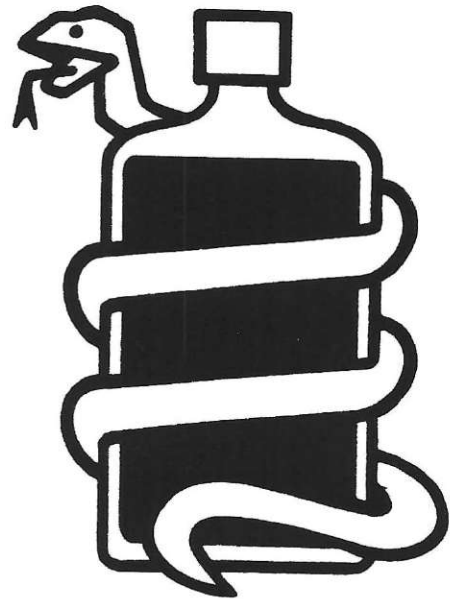
**PROCAINE
HYDROCHLORIDE
DERIVATIVES**



**SEXUAL
TONICS**

UNKNOWN FACTORS

- Safety
- Identity
- Quality
- Purity
- Potency



NO QUALITY CONTROL

- NO FDA Approval
- NO Scientific Proof
- NO Controlled Clinical Investigations
- NO Demonstration of Safety
- NO Demonstration of Effectiveness
- NO Manufacturing Information