Profile of Hoffmann-LaRoche, Inc.

www.rocheusa.com

Hoffman-La Roche (Roche) Ltd. was founded in the 1890's, is presently headquartered in Basle, Switzerland on the scenic Rhine, and informs us of its proud tradition. We have been unable to document a criminal history of Roche prior to 1973, and the era of the late 1990s seems the most interesting. In *United States v.Hoffman-La Roche Ltd. and Udo Haas*, cause number CR 97-00083 before the U. S. District Court in San Francisco, the government charged Hoffman- La Roche Ltd. of Basle, the parent of Hoffman-La Roche Inc. in New Jersey, with violating the Sherman Anti-Trust Act (15 U S C sec. 1) by means of price fixing and conspiracy to fix and maintain prices of citric acid. On March 26, 1997, Roche pleaded guilty and agreed to pay a fine of $14 million dollars, plus a $200, special assessment.

Two years later, Roche was again charged in U. S. District Court in Dallas, cause number 3-99-CR-184, with violating the Sherman Anti-Trust Act for combination and conspiracy to fix prices and allocate market shares of Vitamin A, E, B2, B5, Vitamin C, Beta Carotene, and vitamin pre-mixes. Roche again pleaded guilty and was fined $500 million dollars, plus a $400, special assessment – a then record fine for anti-trust violations. Some co-conspirators were also fined. This 1999 case had other repercussions.

Releases from European news services state that Roche and some of its fellow conspirators paid many millions of dollars in fines to the European Union, Canada, and Australia as well. Some countries gave cease and desist orders. Private lawsuits and some state anti-trust suits resulted as well. A former Roche executive once in charge of vitamins was incarcerated for four months and was fined $100,000 dollars for making untruthful statements to federal investigators. A media conference called by Roche in Basle on 05-21-99 implied that only former executives were involved, none of them top level.

In 1973, Roche's world product manager secretly informed the E E C that Roche was engaged in price fixing, market sharing with supposed competitors, and otherwise preventing rivals from expanding into the vitamin market. Roche would end up being assessed some 600 million Swiss Francs in fines. This episode seems to have occasioned a probe by the U K Monopoly Commission which learned that Roche's U K subsidiary was required to pay fifty times the price for Roche tranquilizers that was paid in Italy. The Commission required 60% price reduction and other measures.

In the 1960s, Roche tranquilizers, Librium and Valium, yielded generous profits. With those patents expiring in the 1980's, Roche turned its attention to vitamins. With fear and an unestimated danger of avian influenza (bird flu), it corners another market- Oseltavamir (brand name Tamiflu)- by purchasing the rights to its manufacture from its originating company. The Philippine Health Minister has accused Roche of monopolizing the principal antiviral drug for combating that disease by concentrating its availability in First World countries rather than Third World countries in S. E. Asia presently affected. Some skeptics fear Roche will charge all the traffic can bear. The future course of bird flu remains unpredictable as do any anti–trust consequences for Roche.

Hoffman-La Roche Inc. (Roche U S) has sometimes less than a stellar record of giving adequate product warnings to doctors and consumers as well. Roche's acne medication Accutane is said to have serious side effects noted in a 1998 F D A letter to doctors: depression, psychosis, rarely suicidal

ideation, suicide attempts, and suicide. The F D A also found Accutane promotional advertisements to contain false and misleading information. It took an F D A letter for Roche U S to strengthen its warnings. http://www.accutane-side-effects.net

This episode does not stand alone. On 01-05-98 the F D A New Jersey District Director informed the President and C E O of Roche U S that it was not submitting Adverse Drug Experience reports within the required fifteen working days while noting a 2 year to over 8 year delay for 13 of its products, some 5 years for Bactrim. A 05-29-03 letter from the F D A Director of the Division of Drug Marketing , Advertising, and Communications to the president and C E O of Roche U S complained of Roche's direct to consumer promotional materials for Xeloda, an anti-cancer drug, that was misleading as it failed to present risk information as to serious potentially life threatening risks while making unsubstantiated efficacy claims as well.

It seems that what a serious "Black Box Warning" gave, promotional material for consumers took away. A video reportedly downplayed adverse events through patient testimonials minimizing the severity and importance of risks. The letter requested that Roche U S cease dissemination of these and similar materials, formulate a plan of action to disseminate accurate and complete information to audiences who received the violative materials, and send a written statement of intent to comply. http://www.fda.gov/foi/warning_letters/g4059d.htm