Thomas M. Moore (Bar No. 116059)
Mario Horwitz (Bar No. 110965)
DRINKER BIDDLE & REATH LLP
333 South Grand Avenue, Suite 1700
Los Angeles, CA 90071-1504
Telephone: (213) 253-2300
Facsimile: (213) 253-2301

Brian P. Johnson (admitted *pro hac vice*)
JOHNSON, SPALDING, DOYLE,
WEST & TRENT, LLP
910 Travis, Suite 1700
Houston, Texas 77002
Telephone: (713) 222-2323
Facsimile: (713)222-2226

Attorneys for Defendant
SmithKline Beecham Corporation
(erroneously sued and served as Glaxosmithkline)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SANTA CRUZ

ELYZABETH SILVAH, individually, and as Guardian Ad Litem for JAIAH SILVAH,

Plaintiffs,

vs.

NANETTE MICKIEWICZ, M.D., an individual; HOWARD SALEM MAGARIAN, M.D., an individual; PLANNED PARENTHOOD, a business entity; GLAXOSMITHKLINE, a corporation and DOES 1 through 50, inclusive,

Defendants.

Case No. CV 145704

Complaint Filed February 14, 2003

Trial Date May 23, 2005

Honorable Arthur Danner, III

~~[Proposed]~~ Order Granting SmithKline Beecham Corporation's Motion For Summary Judgment

On April 27, 2005, the Motion for Summary Judgment or, alternatively, Summary Adjudication ("Motion") filed by defendant SmithKline Beecham Corporation ("SKB") came on regularly for hearing. Thomas M. Moore and Ronald T. Labriola of Drinker Biddle & Reath, and Thomas N. Griffin of Grunsky, Ebey, Farrar & Howell appeared for SKB. Lynne G. Stocker of the Law Offices of Robert J. Glynn appeared for defendants

Planned Parenthood and Howard Salem Magarian, M.D. Randy Romero of McCormick, Barstow, Sheppard, Wayte & Caruth appeared for defendant Nanette Marie Mickiewicz, M.D. D. David Steele of the Law Offices of D. David Steele appeared for plaintiffs Elyzabeth Silvah and Jaiah Silvah.

The Court considered SKB's Motion, plaintiffs' Opposition, SKB's Reply, the evidence submitted in support of each, and the arguments that counsel for SKB and plaintiffs, respectively, presented orally at the hearing. The Court thereafter took the Motion under submission and directed counsel to appear on April 28 for a final ruling. On April 28, the Court orally issued its decision and **GRANTED** SKB's Motion for Summary Judgment.

The Court finds that SKB is entitled to summary judgment on three separate grounds. First, the liability of SKB for its purported failure to adequately warn about certain risks attendant to the use of Retrovir® and Epivir® is precluded under the doctrine of "conflict preemption." Second, SKB's warnings for Retrovir® and Epivir® concerning the risks relevant to this case were adequate as a matter of law. Third, SKB's alleged failure to warn was not the proximate cause of plaintiffs' alleged injuries

Conflict Preemption. Conflict preemption is a distinct and "[t]hird form of preemption" in which state laws, including tort actions, are preempted "[w]here it is impossible for a private party to comply with both state and federal requirements, or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Dowhal v. SmithKline Beecham Consumer Health Care* (2004) 32 Cal.4th 910, 924. As relevant here, the Food and Drug Administration ("FDA") has authority to prohibit even "truthful" statements on a prescription drug label if the FDA concludes that such statements could "scare consumers into foregoing use of a product that in most cases will be to their benefit." *Id* at 931, 933.

Here, plaintiffs allege that SKB should have warned that Retrovir® (aka AZT) does and/or can cause cancer in humans. However, the FDA clearly stated in its March 17, 2004, letter to California Office of Environmental Health Hazard Assessment ("FDA

Letter") that any such warning would directly conflict with FDA regulations and public health objectives: "It is also FDA's position that because the addition of a cancer warning would misbrand the products under federal law, the state law requiring the warning would be preempted." FDA Letter, p. 3.

Plaintiffs also allege that SKB should have warned that the generic form of Retrovir® had been originally investigated as an anticancer agent and that it continues to be studied for that purpose. However, the FDA has not approved Retrovir® to treat cancer and federal regulations explicitly prohibit SKB from discussing unapproved (i.e., "off-label") uses of a prescription drug on the drug's label. *See*, 21 C.F.R. § 201.56; 21 C.F.R. § 201.57(b)(1); *Washington Legal Foundation v. Henney* (2000 D.C.) 202 F. 3d 331, 332-333 ("a manufacturer illegally 'misbrands' a drug if the drug's labeling includes information about its unapproved uses.").[1]

Plaintiffs also allege that SKB should have included a "skull and bones" warning on the Retrovir® label. However, the FDA explicitly prohibits a prescription drug manufacturer from including on a prescription drug label "any intervening written, printed, *or graphic matter*, except the proprietary names of ingredients...and such statements as "'Warning – May be habit forming' that are specifically required for certain ingredients by the act or regulations in this chapter." 21 C.F.R. § 201.10(a) (Emphasis added.)

Plaintiffs also allege that SKB should have warned on the Retrovir® label that the medical community disputes whether HIV causes AIDS. However, the "etiologic" relationship between HIV and the development of AIDS is recognized by both the federal and state governments. *See*, *e.g.*, 42 U.S.C. § 300 ff-76(8) ("HIV means infection with the etiologic agent for Acquired Immune Deficiency Syndrome"); Health & Safety Code § 120775 ("HIV means the etiologic virus of AIDS"). Finally, referencing such a "dispute"

[1] The Court also notes that the medical condition for which a physician uses a prescription drug is not a "risk" against which a prescription drug manufacturer must warn. *See*, *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116.

on the Retrovir® label is prohibited by law and would misbrand Retrovir® as "misleading." 21 C.F.R. § 1.21(c)(1) and (2).

For the foregoing reasons, the Court finds that plaintiffs' allegations that SKB failed to adequately warn (1) about the risk of cancer allegedly associated with Retrovir®, (2) development and off-label use of Retrovir®, and (3) the alleged dispute about whether HIV causes AIDS are conflict preempted.

Adequacy of SKB's Warning. "FDA precludes drug manufacturers from warning about every conceivable adverse reaction; they may warn only if there exists significant medical evidence of a possible health hazard. They are also specifically prohibited from warning of adverse reactions when differences of opinions exist within the medical community with regard to potential adverse reactions." *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1114

The Court finds that the warnings and other safety information disseminated by SKB to the medical community as contained in the package inserts for Retrovir® and Epivir® were comprehensive and, as a matter of law, adequately imparted upon prescribing doctors those risks "known or scientifically knowable" by SKB at the time of distribution, including the conditions that the minor plaintiff Jaiah Silvah allegedly experienced (e.g. nausea, jaundice, etc.).

Here, plaintiffs have not demonstrated that the "prevailing best scientific evidence" shows that Retrovir® or Epivir® cause cancer in humans. Indeed, the FDA "[h]as determined that the scientific data in this case **do not support a cancer warning in the approved labeling for nucleoside analogs**." FDA Letter, p. 3 (Emphasis added.)

Plaintiffs also claim that SKB failed to warn that Retrovir® and Epivir® can suppress white blood cells. However, SKB warns about this risk in a "black box" warning, which is the strongest type of warning allowed by the FDA. *See*, 21 C.F.R. § 201.57(e).

Plaintiffs claim that the warnings for Retrovir® were inadequate because they did not indicate that the generic form of the drug had been originally investigated as an anticancer agent and that it continues to be studied for that purpose. The Court finds that

this claim has no merit. A drug manufacturer must warn of *risks* associated with its product. The fact that Retrovir® has been studied as a potential anticancer drug in addition to its approved use in HIV/AIDS therapy does not constitute a "risk" about which SKB is obligated to warn.

For the foregoing reasons, the Court finds that SKB's warnings for Retrovir® and Epivir® concerning the risks relevant to this case are adequate as a matter of law.

Proximate Cause. Proximate cause is "not determined by a linear projection from a 'but for' premise. Instead, it is expressed in terms of 'foreseeability' and is limited by the policy that cause must be 'proximate.'" *Brewer v. Teano* (1995) 40 Cal.App.4th 1024, 1030. Indeed, the issue of proximate cause "[i]s not primarily one of causation at all, since it does not arise until cause-in-fact is established. It is rather one of the policy as to imposing legal responsibility." *Id.* Resolution of these policy considerations in light of the undisputed facts are "the exclusive function of the court." *Id.*

Here, Dr. Magarian was not aware of the identity of the medications that Dr. Mickiewicz prescribed to plaintiff Jaiah Silvah, nor their potential side effects, and Dr. Magarian never read the package insert for Retrovir®. Similarly, Dr. Magarian's report to Child Protective Services ("CPS") was not predicated on SKB's warnings and as a matter of law was not a "normal consequence of a situation created by [SKB's]...conduct." *Brewer v. Teano, supra* at 1031. Accordingly, SKB's alleged failure to warn concerning Retrovir® and Epivir® could not have influenced Dr. Magarian's actions one way or the other.

Even an actual threat by CPS could not have been proximately related to SKB's warnings. Dr. Mickiewicz was not involved in the report to CPS and there is no evidence that CPS was aware of the identity of the medications that Dr. Mickiewicz prescribed to plaintiff Jaiah Silvah. Thus, any alleged defects in SKB's warnings could not have influenced CPS.

The stated policy of California is to limit the liability of prescription drug manufacturers to cases where the manufacturer fails to warn the prescribing physician

about known or knowable risks. *Brown v. Superior Court* (1988) 44 Cal.3d 1049. A finding of proximate cause between SKB's alleged failure to warn and plaintiffs' alleged injuries under the circumstances of this case would contravene this public policy. Consequently, the Court finds that there is no proximate cause between any alleged deficiencies in SKB's warnings for Retrovir® and/or Epivir® and plaintiffs' alleged injuries.

In conclusion, the Court **GRANTS** SKB's Motion for Summary Judgment and **ORDERS** that plaintiffs' Third Amended Complaint against SKB is summarily adjudicated in SKB's favor and that judgment on the Third Amended Complaint shall be entered against plaintiffs and in favor of SKB.

Dated: 6-14, 2005

ARTHUR DANNER III

Honorable Arthur Danner, III
Santa Cruz County Superior Court Judge

APPROVED AS TO FORM:

Dated: May _____, 2005

LAW OFFICES OF D. DAVID STEELE

By: _____

D. David Steele
Attorneys for Plaintiffs