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

11 SUPERIOR COURT OF THE STATE OF CALIFORNIA
12 FOR THE COUNTY OF SANTA CRUZ

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14 ELYZABETH SILVAH, individually, and) Case No. CV 145704
as Guardian Ad Litem for JAIAH)
15 SILVAH,) The Honorable Arthur Danner, III
16 Plaintiffs,) Complaint Filed February 14, 2003
17 vs.) **EXPERT DECLARATION OF**
18 NANETTE MICKIEWICZ, M.D., an) **ALASTAIR MUNRO, BSc FRCP (Edin)**
individual; HOWARD SALEM) **FRCR**
19 MAGARIAN, M.D., an individual;)
20 PLANNED PARENTHOOD, a business)
entity; GLAXOSMITHKLINE, a)
21 corporation and DOES 1 through 50,)
inclusive,)
22 Defendants.)

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24
25 I, Alastair Munro, BSc FRCP (Edin) FRCR, declare:

26 1. The matters set forth in this Declaration are true and accurate based upon my
27 own experience and personal knowledge. If called upon to do so, I could competently
28

1 testify to the following:

2 2. EDUCATION: I received my BSc (Honours, First Class) Medical Sciences
3 (Anatomy) from St. Andrews University in 1972. I also received my MBChB (with
4 Honours) from the University of Dundee in 1975. I am a full professor at the University of
5 Dundee, Ninewells Hospital and Medical School.

6 3. I am the Alastair Munro, Professor of Radiation Oncology, who wrote the
7 book *Modern Oncology, An A-Z of Key Topics*, published by Greenwich Medical Media
8 Limited, 2001.

9 4. I participated in and am familiar with the language in that book, the basic
10 medicine and science from which the statements in the book were drawn, and the meaning
11 of the language in that book.

12 5. Under the section entitled "Cytotoxic Drugs" (pp. 84-85), I made the
13 statement: "Conversely, there is the concern that some discarded compounds may have
14 been inappropriately rejected: AZT, now a major component in antiretroviral therapy for
15 AIDS, started out as a cancer drug that was considered too toxic for clinical use." I
16 intended this statement to convey the same meaning as the more commonly phrased
17 statement that AZT was considered ineffective for cancer chemotherapy. In cancer
18 chemotherapy, there is a "therapeutic index" which oncologists use to determine the
19 efficacy of a particular agent in comparison to the drug's "toxicities." If the drug must be
20 given at very high doses to be effective, then there is always the risk that the toxicities at
21 that high dose will outweigh the advantage of the drug's efficacy.

22 6. Such was the case in the early work with AZT prior to its development as an
23 antiretroviral medication. Experiments done *in vitro* (i.e. in the test tube) to evaluate the
24 drug's ability to kill cancer cells ("cytotoxicity") showed that AZT was ineffective at any
25 concentrations that would correlate to human doses that could be given without undue
26 acute (immediate and transient) toxicities, largely related to anemia and gastrointestinal
27 effects. Accordingly, the comments in my book relative to AZT were intended to convey
28 the fact that the ineffectiveness of the drug in killing human cancer cells rendered the

1 compound inappropriate as a cancer chemotherapeutic agent since the human doses that
2 would have been required to achieve cytotoxic efficacy (much larger than doses given to
3 treat HIV) would have caused unacceptable acute toxicities. That having been said, its
4 should be noted that the reason for my discussion of AZT was not to describe it as a cancer
5 agent, but to observe that empirically, some compounds are initially rejected for use in one
6 disease, as AZT was for cancer, only to be "rediscovered" as an important therapy for
7 other conditions.

8 7. Under the section entitled: "Second Malignancies" (pp. 280-281), I made the
9 statement: "Second malignancies are one of the most unpleasant consequences of
10 successful treatment for cancer. One of the ironies of the non-surgical treatment of cancer
11 is that both radiation and chemotherapy are mutagenic: they have the potential to produce
12 the very disease they are used to treat." While certain anticancer agents are associated with
13 the development of secondary malignancies (most prominently the class known as
14 "alkylating agents"), one cannot categorically state that all cancer chemotherapy drugs
15 carry that risk. Some drugs used to treat cancer are not associated with such malignancies.
16 Others have risks that vary from negligible to significant. Other factors that must be taken
17 into account include the types of cancers being treated, the dose and duration of treatment,
18 and the concomitant use of radiation therapy.

19 8. AZT is not an alkylating agent, and has not been shown to cause cancer in
20 humans, especially at the doses used to treat HIV/AIDS. I am not aware of any evidence
21 that AZT is associated with secondary malignancies in humans.

22 I declare under penalty of perjury under the laws of the State of California that the
23 foregoing is true and correct.

24 Executed this 31st day of March, 2005 in Rand., Great Britain.



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27 ALASTAIR MUNRO, BSc FRCP (Edin) FRCR