EXPERT PANEL REPORT ON THE POTENTIAL RISK OF ORAL CANCER FROM HYDROGEN PEROXIDE IN TOOTH WHITENING PRODUCTS

EXECUTIVE SUMMARY

The Tooth Whitening Products (TWP) Task Force of COLIPA, The European Cosmetics Industry Association, is currently working with the European Commission to clarify the legal classification of TWP (strips, gels, varnishes) containing hydrogen peroxide up to a level of 6.0%. At the request of the Tooth Whitening Products (TWP) Task Force, a panel of independent international experts was convened to evaluate all data pertaining to the potential risk of oral cancer from the presence of hydrogen peroxide (HPO) in TWP.

The Panel was provided with an industry-prepared summary of data pertaining to the safety of HPO and TWP. The Expert Panel carefully reviewed the data and other relevant published and unpublished studies. Following assessment of the data, the TWP Task Force presented four (4) questions to the Expert Panel. These questions and the Panel's responses are provided below.

What relevance do the non-clinical data on genotoxicity, tumor promotion, and carcinogenicity of HPO have to the risk assessment of HPO in TWP?

The genotoxicity data indicate that while HPO is predictably genotoxic *in vitro* under conditions that allow oxidative attack on DNA (*i.e*., high concentrations and lack of detoxification systems), such activity is not expressed *in vivo*. Taking into consideration the foregoing, the genotoxic risk of exposures of the oral mucosa to HPO encountered from TWP under recommended conditions of use is likely to be vanishingly small.

The available carcinogenicity, tumor initiation-promotion, and studies involving concomitant exposures to other carcinogenic chemicals, are not appropriate for assessment of oral cancer risk in humans. Although HPO is weakly tumourigenic in catalase-deficient strains of mice, and shows activity in initiation-promotion and combined exposure studies following long-term dosing at high-concentrations, these data do not denote a human carcinogenic risk.

Overall, it can be concluded that the available experimental data pertaining to the carcinogenicity of HPO, are of limited relevance to the risk assessment of HPO exposure from use of TWP and where relevant, do not raise any concern for cancer risk of HPO exposure from use of TWP.

What is the nature of adverse effects in users of TWP?

The clinical data, including the results from studies of 6-months duration involving continuous exposure to HPO from the use of TWP, only show evidence of mild, transient gingival irritation and tooth sensitization and no evidence of any visible pathological changes that could be associated with the development of preneoplastic or neoplastic oral lesions.

Does exposure to TWP containing peroxide, under the recommended/intended use conditions, represent a risk factor for developing oral cancer?

The evaluation of the potential oral cancer risk associated with HPO exposure from TWP under the intended/recommended conditions requires a critical analysis of both the clinical and animal toxicology studies. First, it was noted that there were no findings of any pre-neoplastic or neoplastic changes in the oral cavity/oesophagus under high-level continuous HPO exposures in any the animal studies, including those employing an "initiation" phase with a potent carcinogen.

Secondly, the animal carcinogenicity data, including the initiation-promotion and combined exposure studies, were considered to be of limited relevance to the assessment of oral cancer risk from TWP in humans as discussed above. In contrast to the animal studies in which the few tumourigenic effects of HPO were mediated through sustained, chronic, high-level exposures, the recommended use patterns for TWP are for short-term exposures (up to 14 days) that are intermittent in nature (2 to 3 times per year).

Beyond the different exposure patterns, to TWP, an HPO exposures following application of the TWP are very low (*i.e.*, a peak of 0.03% in saliva within 1 minute) and decline to undetectable values within 15 to 60 minutes of application. Finally, there have been no published reports of TWP abuse at levels and durations that could approach exposure levels that could plausibly be associated with the development of oral cancer, the Expert Panel concurs that exposure to HPO from TWP under the recommended/intended conditions of use is not a risk factor for the development of oral cancer.

Is there a significantly increased risk of developing oral cancer in smokers and drinkers through use of TWP containing peroxide under intended or exaggerated use conditions?

Increased cancer risk from combined exposures can arise when one exposure and other concomitant exposures each convey a cancer risk. For example, combined smoking and asbestos exposures, which individually present cancer risks, present greatly increased risks for lung cancer. Since there is no established cancer risk from TWP, there is no basis to postulate that there would be an increased risk from use by individuals with exposure to products associated with risk of oral cancer. Furthermore, the clinical studies on TWP, many of which included smokers, provide no evidence to indicate that the rate or severity of the adverse effects of TWP, namely mild, transient gingival irritation and tooth sensitivity are significantly different from non-smokers. The exposures to HPO received by the oral cavity, including areas associated with development oral cancer due to excessive smoking/drinking, are exceedingly low and cannot plausibly pose a risk for promotion of initiated cells or for co-carcinogenic effects with cigarette smoke carcinogens or with alcohol. In addition, the few rodent tumourigenic effects of HPO were mediated through sustained, chronic, high-level exposures, not representative of any use pattern of TWP. Based on these data, the Expert Panel concluded that use of TWP, under either recommended or exaggerated use condition, poses no significantly increased risk for the development of oral cancer in alcohol abusers and/or heavy cigarette smokers.

The Expert Panel concludes that TWP are safe for all members of the population.

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INTRODUCTION

The Tooth Whitening Products (TWP) Task Force of COLIPA, The European Cosmetics Industry Association, is currently working with the European Commission to clarify the legal classification of TWP (strips, gels, varnishes) containing hydrogen peroxide up to a level of 6.0%. At the request of the Tooth Whitening Products (TWP) Task Force, a panel of independent international experts was convened to evaluate all data pertaining to the potential risk of oral cancer from the presence of hydrogen peroxide (HPO) in TWP. The members of the Expert Panel and their *curriculum vitae* are presented in Appendix 1.

The Panel was provided with an industry-prepared summary of data pertaining to the safety of HPO, including *in vitro* and *in vivo* genotoxicity studies, experimental animal studies, clinical tolerance studies involving TWP and human pharmacokinetic studies. These data had been previously submitted to the Scientific Committee on Consumer Products (SCCP). The Expert Panel carefully reviewed the data provided by industry along with relevant original published and unpublished reports pertaining to the potential carcinogenicity of HPO.

The TWP Task Force presented four (4) questions to the Expert Panel. These questions and the Panel's responses are provided below.

Question 1

What relevance do the non-clinical data on genotoxicity, tumor promotion, and carcinogenicity of HPO have to the risk assessment of HPO in TWP?

The Expert Panel reviewed the data on the genotoxicity of HPO, both *in vitro* and *in vivo*, including the data in the evaluation conducted by the International Agency for Research on Cancer (IARC, 1999).

HPO generates reactive hydroxyl radicals that can oxidize lipid (Kanner *et al*., 1987; O'Brien, 1988) and produce oxidative DNA damage (Williams and Jeffrey, 2000; Cadet *et al*., 2003). The hydroxyl radical also can reacts with deoxyguanosine to form 7, 8-dihydro-8-oxo-2'-deoxyguanosine (8-oxo-dG) DNA adducts (Rosen *et al*., 1996). The 8-oxo-dG adducts are potentially promutagenic adducts and mispair during DNA replication to yield point mutations. However, for mutagenicity to occur, the DNA adducts must escape the effective DNA repair process, which negates endogenous DNA oxidation (Asagoshi *et al*., 2000; Slupphaug *et al*.,

2003). In mammalian cells, the scavenging of hydroxyl radicals formed from HPO is expected to be highly efficient due to the activities of peroxidase and catalase enzymes and the presence of cellular stores of nucleophiles such as glutathione (Griffith and Mulcahy, 1999). In addition, any 8-oxo-dG adducts that may be formed as a result of exceeding the free radical scavenging capacity of the cells, including cells of the oral mucosa, are known to be eliminated by DNA repair enzymes. In particular, in humans 8-oxo-dG adducts are readily repaired by such enzymes to the point that these adducts are not easily converted into a mutagenic lesion (Asagoshi *et al*., 2000; Lunec *et al*., 2002). The 8-oxo-dG DNA adduct is considered to be only weakly promutagenic (Kamiya, 2003).

As expected, the *in vitro* genetic toxicity data clearly show genotoxic effects of HPO. In the Ames test, positive results have been reported in *Salmonella typhimurium* strains TA102 and TA104, strains that are known to be sensitive to oxidative DNA damage (Levin *et al*., 1982; De Flora *et al*., 1984; Carlsson *et al*., 1988; Glatt, 1989; Kensese and Smith, 1989; Abu-Shakra and Zeiger, 1990; Wilcox *et al*., 1990; Li *et al*., 1992; Nakayama *et al*., 1993).

Most mammalian gene mutation assays were negative (IARC, 1999).

HPO has been reported to induce sister-chromatid exchanges (SCE) in several mammalian cell types, including Chinese hamster V-79 cells (Bradley *et al*., 1979; MacRae and Stich, 1979; Sasaki *et al*., 1980; Speit *et al*., 1982; Estervig and Wang, 1984; Mehnert *et al*., 1984a; Mehnert *et al*., 1984b; Speit, 1986; Tucker *et al*., 1989; Diaz-Llera *et al*., 2000;). *In vitro* exposures to HPO have also been associated with single stranded DNA breaks (Bradley *et al*., 1979; Cantoni *et al*., 1986; Prise *et al*., 1989; Kleiman *et al*., 1990; Djuric *et al*., 1993), chromosomal aberrations (*e.g*., Hanham *et al*., 1983; Estervig and Wang, 1984; Ishidate *et al*., 1984; Oya *et al*., 1986; Fenech *et al*., 1999), and the induction of micronuclei (Sasaki *et al*., 1980; Stich and Dunn, 1986).

The *in vitro* mutagenicity and clastogenicity data must be interpreted in light of the fact that these test systems do not contain the enzymes responsible for the detoxification of HPO. For example, the inclusion of catalase enzymes in the test preparations prevented the appearance of clastogenic effects (Hanham *et al*., 1983; Estervig and Wang, 1984; Stich *et al*., 1978; Tsuda, 1981). Moreover, in a number of cases, clastogenic effects of HPO were only noted at cytotoxic concentrations. Finally, the inclusion of a metabolic activation system in the *in vitro* assays had the effect of reducing or negating the effects of HPO (summarized in IARC, 1999). This is due to either the direct detoxification of HPO or the reaction of hydroxyl radicals with the protein content of the metabolic activation.

In *in vivo* studies, including a SCE assay in Chinese hamsters (Li *et al*., 1993), UDS assay (Regnier *et al*., 1997), and a mouse bone marrow assay (Regnier *et al*., 1996), no genotoxic activity of HPO was reported.

Overall the genotoxicity data indicate that while HPO is predictably genotoxic under conditions that allow oxidative attack on DNA (*i.e*., high concentrations and lack of detoxification systems), such activity is not expressed *in vivo*. Taking into consideration the foregoing, the genotoxic risk of exposures of the oral mucosa to HPO encountered from TWP under recommended conditions of use is likely to be vanishingly small.

Data to assess the carcinogenicity of HPO in rodents include several dermal skin painting assays (Klein-Szanto and Slaga, 1982; Kurokawa *et al*., 1984), results of high-dose administration to strains of mice deficient in catalase activity (Ito *et al*., 1981a, b, 1982, 1984), data from a classical initiation-promotion study in rats (Takahashi *et al*., 1986), and the results of an unpublished study of the carcinogenicity of HPO in F344 rats (Takayama, 1981). Of these studies, only the Ito *et al*. series of studies and the Takahashi *et al*. (1986) study reported results indicative of weak carcinogenic activity. It was noted that the protocols of these studies were deficient in several ways, in particular the lack of analysis of the stability of HPO in the dosing media. Nevertheless, HPO is reportedly stable in aqueous solutions (based on Material Safety Data Sheet information) and clearly was present at biologically effective doses in those studies reporting treatment-related effects**.**

Administration of HPO to groups of 48-50 male and female C57BL/6J mice (Ito *et al*., 1981a, b, 1982) at 0, 0.1, or 0.4 % (w/v) in the drinking water (approximately 0, 250, or 1000 mg/kg/day) for 2 years yielded a slight increase in the incidence of duodenal adenocarcinomas, but only when the results for both sexes were combined (5/99, males and females) (p=0.05). The study authors concluded that the oral administration of HPO to mice induced gastric erosion, duodenal hyperplasia, and, at the high dose, duodenal carcinoma. These results must be interpreted with caution, as C57BL mice have low levels of catalase and may therefore be especially susceptible to HPO (Ito *et al*., 1984). This fact was highlighted by the finding in further studies (Ito *et al*., 1984) that preneoplastic/neoplastic lesion development in the duodenum following HPO treatment was inversely correlated with the catalase activity of each strain of mouse tested; mice with the highest catalase activity developed a low incidence of duodenal tumors. No pathological findings in the oral cavity or in the oesophagus were reported despite the oral administration of high HPO concentrations. The relevance of the Ito *et al*. studies to humans is limited because healthy humans are likely to have sufficient peroxidase/catalase activity in saliva and in the oral mucosa to deal with the extremely low amounts of HPO released from TWP.

In an initiation-promotion experiment in rats, in which one of the study arms included a non-initiated control group dosed with 1.0% HPO in the drinking water for 32 weeks, forestomach papillomas developed in 5/10 of the treated rats as compared to 0/10 in the non-initiated controls not administered HPO (Takahashi *et al*., 1986). Again, no tumors of the oral cavity or oesophagus were reported. The significance of forestomach tumors is questionable given the fact that humans have no corresponding organ. In the rat, the forestomach acts as a storage

organ rather than a digestive one. As a result, locally high exposures to forestomach epithelium/mucosa would be expected. For this reason, tumors of the forestomach, especially if related to chronic tissue irritation, are generally considered to be of little relevance to human carcinogenic risk (Wester and Kroes, 1988; Grasso *et al*., 1991; Wurtzen, 1993; IARC, 2003). Moreover, the exposures to HPO in the Takahashi *et al*. (1986) study do not resemble those likely to occur in human oral mucosa under the recommended conditions of use (*e.g.,* short-term exposure periods of up to 14 days 2 or 3 times per year), or even under more exaggerated use conditions (up to 6 months continuous as in the treatment of tetracycline dental stains). Also, in the Takahashi *et al*. (1986) study, exposures were of a continuous nature to 1.0% in the drinking as compared to peak whole mouth salivary HPO concentrations of 0.03% 1 minute post-application (Slezak *et al*., 2002), with concentrations declining to near undetectable levels within 15 to 60 minutes of application of the TWP containing up to 6% HPO (Slezak *et al*., 2002; Mahony *et al*., 2003).

In contrast to the results reported by Takahashi *et al*. (1986), Takayama (1981) treated F344 rats (50 per sex per group) with hydrogen peroxide in the drinking water at dose levels of 0, 0.3 (195 to 306 mg/kg/day) or 0.6% (433 to 677 mg/kg/day) for 18 months, followed by a six-month recovery period. This study was well conducted and collected data pertaining to mortality, serum biochemistry, as well as the histopathology of all key organs (skin, mammary glands, pituitary, thyroid, lung, pancreas, liver, adrenal, kidney, small intestine, testis, muscle, peritoneum, eye spleen, stomach, uterus, vagina, lymph nodes). There were no statistically significant differences in tumor incidence between treated and control animals for animals that died on study or for animals killed at the end of the recovery period. The authors concluded that hydrogen peroxide was not carcinogenic to F344 rats. Findings of reduced body weight gain of about 6 and 10% in the 0.3 and 0.6% HPO groups indicate that an adequate, near MTD dose, was utilized in the study.

HPO has been evaluated in a classical initiation-promotion study in rats (Takahashi *et al*., 1986), in initiation-promotion studies using skin painting of mice (Shamberger, 1972; Bock *et al*., 1975; Klein-Szanto and Slaga, 1982; Kurokawa *et al*., 1984) and in 2 combined exposure studies, one in rats (Hirota and Yokoyama, 1981) and one in the hamster cheek pouch model (Weitzman *et al*., 1986). The last 2 studies, although often cited as initiation-promotion type studies are in fact more complex studies of the interactive effects of HPO and potent carcinogens since in these 2 cases there was overlap between the periods during which the carcinogens and HPO were administered.

The skin painting initiation-promotion studies using the pre-treatment of mice with DMBA followed by treatment with HPO failed to elicit any clear evidence of a tumor promoting effect. Although the dermal studies were negative, it should be acknowledged that mouse skin, although a standard assay (Enzmann *et al*., 1998), is not a perfect surrogate for oral mucosa. Both are squamous epithelia, but mouse skin has a greater degree of keratinisation as

compared to the oral mucosa. Thus oral mucosa could be more sensitive due to a greater degree of HPO absorption. The gingiva, however, is more highly keratinized than the floor of the mouth, and thus is more similar to mouse skin. In any case, the studies generally used acetone as the dosing vehicle for HPO. This vehicle, based on data available for benzoyl peroxide (Binder *et al*., 1997) likely increased the absorption of HPO into the skin. Thus, these studies do provide some evidence for a lack of initiating activity of HPO.

Tumor promotion was reported in the Takahashi *et al*. (1986) study in which rats were pre-treated with MNNG and sodium chloride, and then exposed to 1.0% HPO in the drinking water for 32 weeks; the HPO-treated rats had a 100% incidence of forestomach papillomas compared to 0% in the initiated control group. However, the incidence of adenocarcinoma of glandular stomach and duodenum was not increased by HPO in comparison to initiation-only controls. The incidence of adenomatous hyperplasia in the glandular stomach was increased in the initiated and HPO-treated group (8/21 or 38%) compared to the initiated controls (0%). These data indicate that HPO has promoting activity on the forestomach tumors and can enhance preneoplastic lesion development in the glandular stomach of rats pre-treated with a strong alkylating agent such as MNNG. As indicated in the earlier discussion, the relevance to humans of tumors in the forestomach is uncertain due to the lack of a human correlate for this organ. Despite the use of a strong alkylating agent and high concentrations of HPO over a 32-week span, no tumors or other adverse effects were reported to occur in tissues proximal to the forestomach (*i.e*., the oesophagus and the oral cavity). Strong alkylating agents and other carcinogens have been shown to produce tumors of the oral cavity and oesophagus, thus indicating that these sites in rodent respond to genotoxic insult (Gold *et al*., 2001). Also it is important to note that initiation-promotion type studies are typically conducted to address mechanisms of carcinogenesis and are generally not included or used in carcinogenic risk assessments conducted by regulatory authorities (Kraus *et al*., 1995). Finally, it is also well known, and experimentally demonstrated with phenobarbital (reviewed in Whysner *et al*., 1996), that for promoters to be effective they require continuous long-term sustained high-level exposures. Interruption of the exposure generally results in the lack of initial development of preneoplastic/neoplastic lesions or regression of any lesions formed (Burns *et al*., 1976; Williams and Whysner, 1996). As result, under conditions of expected use of TWP, tumor promotion would not be anticipated. This conclusion is consistent with the existing literature indicating that there is no known tumor promoter for the oral cavity (Kraus *et al*., 1995).

In another rat experiment, Hirota and Yokoyama (1981) studied the interactive effects of methylazoxymethanol acetate (MAM) treatment in conjunction with HPO. Male Fischer 344 rats were exposed to 1.5% HPO in the drinking water for 8 or 21 weeks, during which time MAM was administered by i.p. administration (25 mg/kg) in weeks 4, 6, and 8 of the study. No GI tract tumors were observed in rats treated with HPO alone for 21 weeks or in untreated controls. Treatment of rats with HPO for 8 weeks (during which time MAM was administered), and for a further 25 weeks resulted in a 100% incidence of duodenal carcinomas. In rats exposed only to

HPO during the first 8 weeks plus the MAM treatments, a 25% incidence of duodenal carcinomas was reported. The lack of an MAM only initiation control group limits the interpretation of the study; however, the data are suggestive of an enhancing effect of HPO treatment on the development of duodenal tumors following co-treatment with MAM. In a small group (n=3) of rats given only HPO, no tumors were recorded. As in the other oral studies, including carcinogenicity (Ito *et al*., 1981a, b, 1982, 1984) and initiation-promotion protocols (Takahashi *et al*., 1986), no evidence of any tumors in the upper GI tract was reported in rats treated with HPO and MAM, or HPO alone.

In the hamster cheek pouch assay, the buccal pouches were painted with 0.25-0.5% DMBA 2-5 times per week for 16-22 weeks followed by hydrogen peroxide up to 5 times per weeks over the same period of time (HPO treatment the day following treatment with DMBA) (Marshall *et al*., 1996; Weitzman *et al*., 1986). Weitzman *et al.* (1986) reported a marginally significant (p=0.054) increase in the trend for cheek carcinoma incidence in hamsters treated with DMBA and 30% HPO (5/5 = 100%) *versus* DMBA alone (3/7=43%). These results are uncertain given the low numbers of animals used in the experiment and the marginal nature of the results. Co-treatment of the buccal pouches with DMBA and 3% HPO did not increase the incidence of carcinoma (6/11 = 55%) in comparison to the DMBA only controls. Also, no tumors were seen in hamsters (n=9) treated with 30% hydrogen peroxide alone. Treatment at the high-concentration of 30% HPO in uninitiated controls resulted in clear evidence of tissue irritation and toxicity as shown by the observation of chronic inflammation and cellular dysplasia. In a later study, Marshall *et al.* (1996) presented HPO in dentifrice formulations (single or dual phase) or mixtures with sodium bicarbonate at a maximum concentration of 3%. In these studies, cheek pouch carcinoma incidence was close to 100% in the DMBA-only groups (0.25 to 0.5% DMBA), leaving no chance for the detection of any promoting effects if they existed.

Beyond the limitations of the studies with respect to human relevance (*e.g*., forestomach tumor development, conduct of mechanistic studies to assess initiation-promotion and or interaction effects with other genotoxic chemicals), the results of these studies must be interpreted in light of the exposure conditions experienced by humans using TWP under the recommended conditions of use. In fact, clinical data from the 6-month continuous use of TWP to treat tetracycline stains show no increased incidence or severity of the mild, transient gingival irritation reported in the shorter-term studies. Based on available data, salivary concentrations of HPO following application of a TWP rapidly decline to near undetectable levels within 15 to 60 minutes (Slezak *et al*., 2002; Mahony *et al*., 2003). Moreover, based on a surface area exposure analysis (to account for the fact that effects in the human oral mucosa would, if they were to occur, be associated with site of contact concentrations, not systemic mg/kg body weigh/day exposure rates), exposures in the carcinogenicity/tumor promotion/interaction studies are orders magnitude higher than would be experienced by humans using TWP. Specifically, based on information in a submission filed for evaluation by the SCCP in 2003, exposure of the floor of the mouth to HPO from TWP use was calculated to be >400-fold lower than the dose

used in mouse dermal tumor initiation-promotion skin painting studies (Shamberger, 1972; Bock *et al*., 1975; Kurokawa *et al*., 1984), in which no carcinogenic effects were observed, and >100-fold lower than the dose used in a hamster check pouch tumor initiation and promotion studies in which no carcinogenic effects were observed (Marshall *et al*., 1996).

A comparison of the maximal drinking water HPO concentrations of 0.4%, 1.0%, and 1.5% utilized in the Ito *et al*. (1981a, b, 1982, 1984) mouse studies, in the Takahashi *et al*. (1986) rat initiation-promotion study, and in the Hirota and Yokoyama (1981) combined exposure (with MAM) study, respectively, with HPO concentrations in saliva after application of TWP also reveals large differences in exposure. The above drinking water HPO concentrations (continuous exposure) are from 13-fold to 33-fold-greater than the peak concentrations of HPO in the saliva of 0.03% (representative data) achieved 1 minute after application of TWP (Slezak *et al.*, 2002). Given the rapid disappearance of HPO in the saliva (undetectable within 15 to 60 minutes), daily exposures in the animal studies were in fact likely 1000s of fold greater than exposure to HPO from TWP since during the time that the animals consumed water, and during residency time in the stomach and duodenum, HPO concentrations would remain near the nominal concentrations used in each study (*i.e*., constant exposure to 0.4 to 1.0% HPO concentrations during periods of water consumption and storage/transit through the stomach and duodenum).

In addition to the low rates of exposure of the human oral mucosa to HPO from the use of TWP, exposures are generally short-term and intermittent in nature (*e.g.,* exposure periods of up to 14 days 2 or 3 times per year). As a result, the weak carcinogenic, promoting and or enhancing effect of repeated or sustained exposures to much higher concentrations of HPO on the development of duodenal, gastric and forestomach tumors is not considered to denote any potential risk to humans.

In summary, the Panel concludes that HPO is genotoxic, as would be expected, under conditions that allow oxidative attack on DNA (*i.e*., high concentrations and lack of detoxification systems). However, such activity is not expressed *in vivo*. HPO at high concentrations is weakly carcinogenic to the duodenum of mice, especially those that are catalase deficient. This model is of limited relevance to humans. Similarly, the relevance of forestomach tumors induced by high drinking water concentrations of HPO in rats is highly questionable given the lack of a human correlate for this organ and the typical requirement for chronic tissue irritation over a sustained chronic period (Wester and Kroes, 1988; Grasso *et al*., 1991; Wurtzen, 1993; Kraus *et al.*, 1995; IARC, 2003).

Results of initiation-promotion protocols (Takahashi *et al*., 1986) and of studies evaluating the interactive effects of HPO with alkylating substances (Hirota and Yokoyama, 1981) cannot be extrapolated directly to the assessment of carcinogenic risk of HPO to the human oral mucosa due to the fact that such studies are mechanistic investigations and are not appropriate for risk

assessment (Binder *et al*., 1995; Kraus *et al*., 1995). Moreover, enhancing, and especially promoting, action requires long-term sustained high-dose exposure for effects to be manifest This does not resemble the recommended use pattern for TWP. Evidence for the fact that long-term high-dose exposures are required with HPO comes from the hamster buccal pouch assay (Weitzman *et al*., 1986) in which exposure to DMBA and 30% HPO appeared to enhance carcinoma development, while 30% HPO alone produced no tumors, but clear evidence of tissue irritation. The HPO dosing regimen used in these studies is not representative of the intermittent exposures experienced by users of TWP. That initiation-promotion type studies, and any associated positive results, are not necessarily indicative of human carcinogenic risk, is highlighted by the fact that many common food ingredients (Table 1) and other substances have been reported to be tumor promoters (Kraus *et al*., 1995).

Table 1. Some Common Materials and Dietary Components That Have Been Reported to Have Rodent Tumor Promoting Activity

Substance	Site of Promoting Activity	Reference
Ascorbic acid	Bladder	Fukushima *et al.* (1983)
Butylated hydroxyanisole	Bladder, forestomach,	Imaida *et al.* (1983); Williams (1986)
Butlyated hydroxytoluene	Bladder, liver, lung	Imaida *et al.* (1983); Maeura and Williams (1984)
Chili extract, (capsaicin)	Liver, stomach	Agrawal *et al.* (1986)
Ethyl alcohol	Esophagus, liver	Driver and McLean (1986)
Glycerin	Lung	Inayama (1986)
L-Leucine and L-isoleucine	Bladder	Nishio *et al.* (1986)
Linoleic acid	Breast	Ip *et al.* (1985)
Orange oil	Skin	Elegbede *et al.* (1986)
Polysorbates 60 and 80	Skin	Setala (1956)
Sodium chloride	Stomach	Shirai *et al.* (1984)
Sucrose	Liver (foci)	Hei and Sudilovosky (1985)

In conclusion, the available genetic toxicity and animal toxicology data do not indicate that HPO poses a carcinogenic risk to the human oral mucosa. This conclusion is further bolstered by the results of the dosimetric exposure analyses from TWP users (data contained in a submission filed for evaluation by the SCCP in 2003), showing margins-of-safety on the order of 100s to 1000s of fold between no effect levels in animal studies and peak HPO concentrations in saliva at the floor of the mouth. Moreover, HPO concentrations are highest in the gingival, a site where oral cancer is rarely found. Floor of the mouth and lateral area of the tongue are

common oral cancers, yet HPO concentrations in these areas are low relative to the gingival concentrations.

Overall, it can be concluded that the available experimental data pertaining to the carcinogenicity of HPO are of limited relevance to the risk assessment of HPO exposure from use of TWP, and where relevant, do not raise any concern for cancer risk of HPO exposure from use of TWP.

Question 2

What is the nature of adverse effects in users of TWP?

There are over 100 published and unpublished clinical studies, comprising approximately 4000 subjects in total, that have been conducted on HPO-containing (5.33 to16%) TWP. In addition, there exists in the scientific literature a 7.5-year follow-up study on a small group of TWP users (Leonard *et al.*, 2003). In this follow-up study of 15 subjects who received 6-months of continuous HPO treatment for tetracycline stains, no evidence of adverse effects in the oral cavity were noted in 9 of the 15 who agreed to a clinical examination. None of the 15 participants in the study reported any side effects that they believed to have been treatment-related. Studies have evaluated the effects of TWP under recommended use conditions (1 to 2 weeks) and under conditions of extended (up to 6 months) and exaggerated use (4 times application per day). A summary of the clinical data, arranged by duration of use, is provided in the tables appended to this report (Appendix 2).

The incidence of adverse effects incidence, while quite variable, is in all cases mild and transient and limited to gingival irritation and tooth sensitization. These effects resolve within a few days of ending product use.

Mild gingival irritation is not a known risk factor for the development of oral cancer. Moreover, the gingiva is a very rare site for the development of oral cancers. The most common sites, the floor of the mouth and the lateral edge of the tongue have not been reported to be adversely affected in any of the clinical studies on TWP. Also, at these sites, salivary concentrations [maximum concentration of 0.03% 1-minute post application (Slezak *et al*., 2002)] of HPO are very low in comparison to HPO concentrations achieved on the gingiva [maximum median concentrations of 0.65% within 5 minutes of application of 10% HPO TWP strips] (unpublished clinical trial, summarized in a 2003 submission to the SCCP), the site adjacent to the application of TWP. Even the highly variable incidence of gingival irritation reported in the clinical studies may not entirely be the result of HPO since many TWP contain dehydrant vehicles such as glycerol. In addition, subjects in clinical trials, often traumatize gingival tissues through over zealous brushing prior to dental visits.

Bleaching procedures involving HPO have been used extensively under the close supervision of dental professionals for the last 15 years. In addition over the last 4 to 5 years, millions of tooth whitening kits have been sold directly to consumers, yet no published reports of preneoplastic or neoplastic lesions have appeared in the scientific literature to date. In the 7.5-year follow-up study no evidence of adverse effects in the oral cavity were noted in 9 of the 15 who agreed to a clinical examination. None of the 15 participants in the study reported any side effects that they believed to have been treatment-related (Leonard *et al*., 2003).

In summary, the clinical data only show evidence of mild, transient gingival irritation and tooth sensitization and no evidence of any visible pathological changes that could be associated with the development of preneoplastic or neoplastic oral lesions.

Question 3

Does exposure to TWP containing peroxide, under the recommended/intended use conditions, represent a risk factor for developing oral cancer?

The extensive clinical data available on HPO-containing TWP provides no indication that mild transient effects that include gingival irritation could plausibly be associated with the development of oral cancers, especially given the fact that oral cancer develops most commonly in the floor of the mouth and in the lateral portion of the tongue; areas that receive the lowest HPO exposures during then use of the TWP.

A critical analysis of the non-clinical data, including *in vitro* and *in vivo* genotoxicity, carcinogenicity, tumor initiation-promotion, and combined exposure studies, leads to the conclusion that exposure to HPO from the use of TWP under recommended use conditions is not a significant risk for the development of oral cancer.

The key bases for this conclusion include:

- The lack of finding of any pre-neoplastic or neoplastic changes in the oral cavity/oesophagus under high-level continuous exposures in the animal studies, including those reporting tumourigenic effects in the duodenum, glandular stomach, or forestomach (*e.g*., Hirota and Yokoyama, 1981; Ito *et al*., 1981a, b, 1982, 1984; Takahashi et al., 1986).

- Duodenal adenocarcinomas reported in mice (Ito *et al*., 1981a, b, 1982, 1984) were found to be inversely correlated to the catalase activity present in each strain. In humans peroxidase/catalase activity of saliva would protect against the effects of HPO in the oral cavity.

- In an initiation-promotion study (Takahashi *et al*., 1986), HPO induced forestomach papillomas. These tumors are not considered relevant to humans (Wester and Kroes, 1988; Grasso *et al*., 1991; Wurtzen, 1993; IARC, 2003) given the lack of the human tissue correlate and the requirement for prolonged high-exposure to HPO likely to be associated with chronic tissue irritation.

- The initiation-promotion study (Takahashi *et al*., 1986) and in combined exposure studies (Hirota and Yokoyama, 1981; Weitzman *et al*., 1986), discussed above in the response to Question 1, are mechanistic investigations not appropriate for risk assessment (Binder *et al*., 1995; Kraus *et al*., 1995).

- Tumors that develop in initiation-promotion experiments (Takahashi *et al*., 1986) and to a lesser extent in combined exposure studies (Hirota and Yokoyama, 1981; Weitzman *et al*., 1986) require long-term sustained high-dose exposure, usually to the point of producing clear evidence of antecedent tissue damage, for neoplastic lesions to develop. Without such exposure, lesions either initially fail to develop or regress (Burns *et al*., 1976; Williams and Whysner, 1996). With HPO exposure alone, 30% concentrations in a hamster buccal pouch assay (Weitzman *et al*., 1986) failed to induce tumors despite evidence of tissue injury (chronic inflammation).

- The exposure data provided demonstrated that within 15 to 60 minutes the concentrations of HPO in the saliva was reduced to very low levels; thus use under the recommended conditions dose not duplicate the chronic, sustained high-dose exposures reported in the animal studies. The exposure pattern described in the animal studies renders these studies of little relevance in the assessment of human carcinogenic risk from the use of TWP.

- There have been no published reports of TWP abuse at levels and durations that could approach exposure levels that could plausibly be associated with the development of oral cancer.

- A recent unpublished meeting abstract (Burningham *et al*., 2004) suggested a possible association between the development of oral cancer and use of TWP in younger adults (<45 years of age). The study had several methodological flaws. Firstly, it contained only 19 subjects. Moreover, the reported association could arise simply by chance. In addition, the 2 cases of tongue cancer in young adults who had used TWP involved patients who reported using TWP 2 to 3 years prior to diagnosis; that is not a sufficient interval for tumor development. The unpublished article from Burningham *et al*. (2004) provides no biologically plausible basis for any potential association between the use of TWP and the 2 cases of tongue cancer. This is further supported by the fact that in extensive clinical trials, the only soft tissue effect is mild, transient gingival irritation, and,

in addition, that in the 7.5-year follow-up study in subjects who received 6 months of continuous TWP treatment, no evidence of adverse effect in the oral cavity was noted in all 9 of the 15 subjects who agreed to a clinical examination (Leonard *et al*., 2003). Moreover, in no clinical studies have adverse effects on the tongue been reported to occur.

- Salivary HPO exposure data demonstrate rapid decline of HPO levels within 15 to 60 minutes. As a result, exposure of the human oral mucosa is orders of magnitude below no-effect levels reported in the animal studies.

Based on the foregoing, the Expert Panel concludes that TWP use is not a risk factor for oral cancer.

Question 4

Is there a significantly increased risk of developing oral cancer in smokers and drinkers through use of TWP containing peroxide under intended or exaggerated use conditions?

Increased cancer risk from combined exposures can arise when one exposure and other concomitant exposures each convey a cancer risk. For example, combined smoking and asbestos exposures, which individually present cancer risks (IARC, 1977, 2002), present greatly increased risks for lung cancer (IARC, 1977). Since there is no established human cancer risk from TWP or HPO, there is no basis to postulate that there would be an increased risk from use by individuals with exposure to products associated with risk of oral cancer. With the lack of any established risk from the use of TWP, there is no basis to assume that TWP would increase cancer risk in smokers and/or heavy drinkers. Any attempt to do so involves a high degree of speculation.

The clinical studies on TWP, many of which included smokers, provide no evidence to indicate that the rate or severity of the adverse effects of TWP, namely mild, transient gingival irritation and tooth sensitivity are significantly different from non-smokers. Although, there is no long-term follow-up (*e.g*. greater than 10 years) in smokers and non-smokers, no visible pathological changes that could plausibly be related to future preneoplastic or neoplastic lesion development were seen in any of the subjects in the over 100 clinical trials.

The theoretical risk from the use of TWP, even under exaggerated use conditions, to smokers and/or heavy drinkers must be put in perspective with the fact that even under conditions of smoking and heavy alcohol consumption, human risks for oral cancers are significantly increased only after prolonged and sustained high-level usage. Secondly, the exposures to HPO received by the oral cavity, including areas associated with development oral cancer due

to excessive smoking/drinking, are exceedingly low. After application of TWP, salivary concentrations in the floor of the mouth decline to levels of 0.0001% or less within 15 to 60 minutes (Slezak *et al*., 2002; Mahony *et al*., 2003). Such exposures (*i.e*., low concentrations of HPO that exist for less than 60 minutes per application) cannot plausibly pose a risk for promotion of initiated cells or for co-carcinogenic effects with cigarette smoke carcinogens or with alcohol.

The available tumor initiation-promotion (Takahashi *et al*., 1986) and combined exposure studies (Hirota and Yokoyama, 1981; Weitzman *et al*., 1986) on HPO document that for promoters to be effective they require continuous long-term sustained high-level exposures, interruption of which generally results in the lack of initial development of preneoplastic/neoplastic lesions or regression of any lesions formed (Burns *et al*., 1976; Williams and Whysner, 1996). Similarly, such exposures typically produce clear signs of tissue injury at the affected site [*e.g.*, forestomach (Wester and Kroes, 1988; Grasso *et al*., 1991; Wurtzen, 1993; IARC, 2003) and skin (summarized in Kraus *et al.*, 1995)]. No evidence of tissue injury in areas prone to develop oral cancer have been reported, even following long-term continuous use of TWP for 6-months to treat tetracycline stains. Therefore, the results of initiation-promotion or combined exposure studies, generally not originally designed for use in human risk assessment, cannot be extrapolated to suggest a potential risk of HPO to the oral mucosa of heavy smoker and/or drinkers from TWP under recommended, exaggerated or extended, conditions of use. This conclusion is also supported by the fact that there are many common tumor promoters, including food ingredients such as sodium chloride, butylated hydroxylanisole, glycerine, and sucrose, but very few, if any, known human tumor promoters (Kraus *et al*., 1995).

In summary, based on the low transient concentrations of HPO received by users of TWP, even under conditions of exaggerated or extended use, the lack of any established risk for oral cancer from the use of TWP or from HPO, the lack of relevance of the available tumor initiation promotion (Takahashi *et al*., 1986) and combined exposure studies (Hirota and Yokoyama, 1981), and the results of the clinical studies demonstrating only transient, mild gingival irritation, a rare site for the development of oral cancer, even after 6-months of continuous exposure, the Expert Panel concludes that use of TWP, under either recommended or exaggerated use conditions, poses no increased risk for the development of oral cancer in alcohol abusers and/or cigarette smokers.

CONCLUSION

The Panel concludes that HPO is predictably genotoxic under conditions that allow oxidative attack on DNA (*i.e*., high concentrations and lack of detoxification systems). However, such activity is not expressed *in vivo*, at least at exposures that do not overwhelm detoxification mechanisms. HPO at high concentrations is weakly carcinogenic to the duodenum of mice that

are catalase deficient. Similarly, the relevance of forestomach tumors induced by high drinking water concentrations of HPO in rats is highly questionable given the lack of a human correlate for this organ and the typical requirement for chronic tissue irritation over a sustained chronic period of time (Wester and Kroes, 1988; Grasso *et al*., 1991; Wurtzen, 1993; Kraus *et al.*, 1995; IARC, 2003). Results of initiation-promotion protocols (Takahashi *et al*., 1986) and of studies evaluating the interactive effects of HPO with alkylating substances (Hirota and Yokoyama, 1981) cannot be extrapolated directly to the assessment of carcinogenic risk of HPO to the human oral mucosa due to the fact that such studies are mechanistic investigations and, therefore, are not appropriate for risk assessment. Moreover, enhancing, and especially promoting, action require long-term, sustained high-dose exposure for effects to be manifest. This pattern of exposure is unlike the recommended use pattern of TWP. Concentrations of HPO achieved in the saliva in contact with the floor of the mouth, one of the more common sites for oral cancers in the general population, are very low within 15 (0.0001%) to 60 (<0.00007%) minutes of the application of TWP (Slezak *et al*., 2002; Mahony *et al*., 2003). Moreover, any effects of HPO from TWP use, even over 6-month continuous exposure, are mild, transient, and involve only gingival irritation and tooth sensitivity, both of which resolve within a few days after use of the product is stopped. The gingiva, in contrast to the floor of the mouth, is a very rare site for the development of oral cancer.

On the basis of the foregoing evidence the Expert Panel concludes that TWP are safe for all members of the population. In fact there are no published reports of abuse of TWP, in either normal individuals or in heavy smokers and/or alcohol abusers, to the extent that there could plausibly be a risk. Use of TWP by alcohol abusers and heavy smokers also does not pose an increased risk for the development of oral cancer, since although smoking and alcohol use are risks for oral cancer development, especially when combined together, no cancer risk has been established for HPO from the use of TWP. Tumor promotion or co-carcinogenesis studies, require sustained, long-term, high-level exposures to agent that's commonly cause clear evidence of tissue damage. Use of TWP, by any member of the human population, is intermittent, and of relatively short-term duration. In addition, HPO concentrations achieved in the oral cavity are so low that no plausible risk exists.

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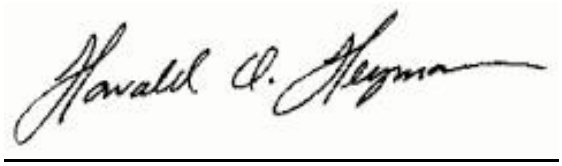
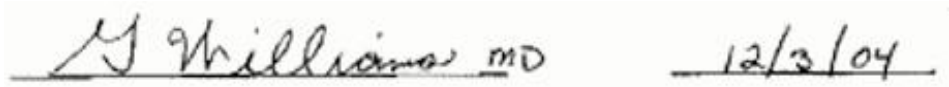
Expert Panel Report on the Potential Risk of Oral Cancer from Hydrogen Peroxide in Tooth Whitening Products



Harald O. Heymann, DDS, M.Ed.
Professor and Graduate Program Director
Department of Operative Dentistry
School of Dentistry
University of North Carolina
Chapel Hill, NC 27599-7450 USA

Date



Gary M. Williams, M.D.
Professor of Pathology
Dept. of Pathology
New York Medical College
- Basic Science Building, Room 413
Valhalla, NY 10595 USA

Date

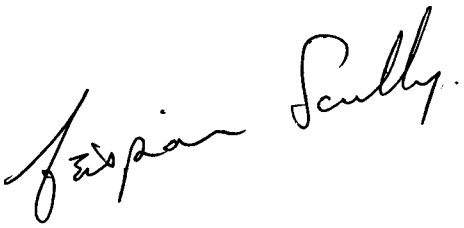
Robert Kroes, DVM, Ph.D.
Director Inst. for Risk Assessment Sciences
Utrecht University
PO Box 80176
Nl-3508 TD Utrecht
The Netherlands

Date

Ian C. Munro, Ph.D., F.A.T.S., FRCPath
President
CANTOX Health Sciences International

Date

2233 Argentia Road, Suite 308
Mississauga, Ontario L5N 2X7 Canada



Crispian Scully, CBE, M.D., Ph.D., MDS, MRCS, FDSRCS, FDSRCPS, FFDRCSI, FDSRCSE, FRCPath, FMedSci
Dean and Director of Studies and Research
Eastman Dental Institute for Oral Health Care Sciences, and International Centres for Excellence in Dentistry
University College London
University of London
256 Gray's Inn Road
LONDON WC1X 8LD
UK

Date

Volker Beck, Ph.D.
Coordinator for Cancer Prevention
in the German Cancer Society, Frankfurt/Main
(my signature does not yet reflect an official position or statement of the German Cancer Society at this time)

Date

APPENDIX 1

CURRICULUM VITAE FOR EACH EXPERT PANEL MEMBER

CURRICULUM VITAE
GARY MURRAY WILLIAMS, M.D.

BORN:	Regina, Saskatchewan, Canada
CITIZENSHIP:	Naturalized U.S. Citizen, 1966
PERSONAL:	Married 1966; Children born 1969, 1973, 1979
ADDRESS:	8 Elm Road, Scarsdale, New York 10583
EDUCATION:	Washington and Jefferson College, Washington, Pa. B.A. 1963; Magna Cum Laude
	University of Pittsburgh School of Medicine, Pittsburgh, Pa. M.D., 1967

SUBSEQUENT TRAINING AND POSITIONS;

1967-1969	Intern and Resident in Pathology, Department of Pathology, Massachusetts General Hospital and Instructor in Pathology, Harvard University Medical School, Boston, Massachusetts.
1969-1971	Staff Associate, National Cancer Institute, Experimental Pathology Branch, Chemical Carcinogen Screening Unit, Bethesda, Maryland.
1971-1972	Visiting Scientist, Wenner-Gren Institute, Department of Cell Physiology, Stockholm, Sweden.
1971-1975	Assistant Professor, Department of Pathology, and Member, Fels Research Institute, Temple University School of Medicine, Philadelphia, Pennsylvania.
1975-1979	Chief, Division of Experimental Pathology, American Health Foundation; and Research Associate Professor, Department of Pathology, New York Medical College, Valhalla, New York.
1979-1980	Chief, Division of Pathology and Toxicology, American Health Foundation; and Research Professor, Department of Pathology, New York Medical College, Valhalla, New York.
1980-1987	Associate Director and Chief, Division of Pathology and Toxicology, American Health Foundation; Research Professor, Department of

	Pathology, New York Medical College, Valhalla, New York.
1987-1997	Director of Medical Sciences and Chief, Division of Pathology and Toxicology, American Health Foundation; Research Professor, Department of Pathology, New York Medical College, Valhalla, New York.
1997-1998	Director, Naylor Dana Institute and Chief, Division of Pathology and Toxicology, American Health Foundation; Research Professor, Department of Pathology, New York Medical College, Valhalla, New York; Visiting Lecturer, Graduate School of Health Sciences, New York Medical College, Valhalla, New York.
1999 - present	Professor of Pathology, Department of Pathology, Director of Environmental Pathology and Toxicology, Head, Program on Medicine, Food and Chemical Safety, New York Medical College, Valhalla, New York; Affiliated Faculty, Graduate School of Health Sciences, New York Medical College, Valhalla, New York.

CERTIFICATIONS:

1974	American Board of Pathology
1975	Physician, State Education Department, State of New York
1981	American Board of Toxicology, Recertified, 2002.
1984	Expert in Toxicology, Ministere des Affaires Sociales et de la Solidarite Nationale, Direction de la pharmacie et du medicament, Republic Francais
2000	Fellow in Toxicologic Pathology, International Academy of Toxicologic Pathology

AWARDS AND HONORS:

1963	Phi Beta Kappa, Washington and Jefferson College
1967	Sheard-Sandford Award, American Society of Clinical Pathologists
1967	Alpha Omega Alpha, University of Pittsburgh School of Medicine
1971	Research Training Fellowship, International Agency for Research on Cancer
1980	Association of University Pathologists
1981	Invited Contributor, Special Issue Food and Cosmetics Toxicology,

	9:557, 1981, dedicated to Leon Goldberg
1982	Arnold J. Lehman Award, Society of Toxicology
1984	Invited Contributor Hommage au Professeur Rene Truhaut
1987	Citation Classics: Cancer Lett. 1:231, 1976 and Cancer Res. 37:1845, 1977. Institute for Scientific Information, Current Contents, Vol. 30, No.36, September 7, 1987
1988	Citation Classics: In Vitro 12:521, 1976; 12:821, 1976; 13:809, 1977, 14:824, 1978. Institute for Scientific Information. Current Contents, Vol. 32, No. 9, February 27, 1989
1989	Featured on cover of Cancer Research, Volume 49, November 1
1995	Featured on cover of Cancer Research, Volume 55, April 15
1996	Awards Lecture, Society of Toxicology
1997	Invited Contributor, Special Issue Cancer Letters, 118:1, 1997, dedicated to Phillipe Shubik
1998	Top 10 Most Frequently Cited Articles in 25 years of Toxicologic Pathology Toxicologic Pathology 10:3-10, 1982; Toxicologic Pathology 26:452, 1998
2001	Ambassador in Toxicology Award, Mid-Atlantic Chapter of the Society of Toxicology.
2002	Enhancement of Animal Welfare Award, Society of Toxicology.

RECOGNITION:

1996-01	Who's Who in American/50th-56th Editions
1996-00	Who's Who in the East/26-28th Editions
1996-03	Who's Who in Science and Engineering/3rd-6th Editions
1997/1998	American Men and Women of Science Directory of American Research & Technology
1998-00	Official American Board of Medical Specialties Directory of Board Certified Medical Specialists 30th-33rd Editions

SOCIETIES:

1974	American Association for Cancer Research
1978	Society of Toxicology
1981	Society of Toxicologic Pathologists
1991	International Society of Regulatory Toxicology and Pharmacology

EDITORIAL RESPONSIBILITIES:

1980	Co-Editor, Differentiation and Carcinogenesis in Liver Cell Cultures. Vol. 349. New York Academy of Sciences.
1980-1981	Consulting Reviewer, Oncology Overviews, International Cancer Research Data Bank.
1980-1986	Reviewing Editor, In Vitro.
1980	Co-editor, The Predictive Value of In Vitro Short-term Screening Tests in Carcinogenicity Evaluation. Elsevier/North Holland Biomedical Press.
1981-1983	Editorial Board, Fundamental and Applied Toxicology.
1981-1989	Editorial Board, Toxicology and Applied Pharmacology.
1981-1999	Editorial Board, Nutrition and Cancer.
1981	Meeting Report: Carcinogenesis and Gene Expression in Liver Cultures. Cancer Research 42:2462-2464, 1982.
1982	Consulting Reviewer, Oncology Overview, International Cancer Research Data Bank Program, National Cancer Institute.
1982-1993	Editorial Board, Mutation Research, Genetic Toxicology Testing Section.
1983	Co-Editor, Colon Carcinogenesis. CRC Press.
1983	Co-Editor, Cellular Systems for Toxicity Testing. Vol. 407. New York Academy of Sciences.
1983	Co-Editor, Tests Courts de Cancerogenese/Short-term Tests for Carcinogenesis, Elsevier Science Publishers BV, Amsterdam.
1983-1992	Editorial Board, Chemico-Biological Interactions.
1983-1996	Editorial Board, Toxicologic Pathology.

1984-present Founding Editor, Cell Biology and Toxicology.

1987 Meeting Report: Causative and Modifying Factors in Digestive Tract Cancer. Cancer Research 47:922-923, 1987

1988-present Editorial Board, Archives of Toxicology

1988 Editor, Sweeteners: Health Effects, Princeton Scientific Publishing Company.

1989 Editorial Board, Complex Mixtures and Cancer Risk, IARC Scientific Publications, International Agency for Research on Cancer

1990 Meeting Report: American Health Foundation 20th Anniversary International Symposium on Causes and Prevention of Cancer. Preventive Medicine, in 20:534-547, 1991

1991-present International Advisory Board, European Journal of Cancer Prevention

1992 Proceedings of the Second International Conference on Longevity and Aging: Environmental and Nutritional Influences on Aging and Cancer Experimental Gerontology, Volume 27, Special Issue, 1992

1993 Editor-in-Chief, Antioxidants Chemical, Physiological, Nutritional and Toxicological Aspects, Princeton Scientific Publish. Co.

1994-present Area Editor for Carcinogenesis, Drug and Chemical Toxicology.

1997 Co-Editor, Reducing Dietary Fat: Putting Theory into Practice, Journal of The American Dietetic Association, Volume 97, Supplement 1, 1997

2001 Co-Editor, Toxicology, Special Issue, Volume 166, Number 3, Festschrift J.H. Weisburger.

MEETINGS ORGANIZED:

1980 Conference on Differentiation and Carcinogenesis in Liver Cell Cultures. New York Academy of Sciences. New York, NY.

1980 Workshop on the Predictive Value of in vitro Short Term Screening Tests in the Evaluation of Carcinogenicity. Scientific Council of the Netherlands Cancer Society. Dalen, The Netherlands.

1982 Quo Vadis Symposium on Short Term Tests in Carcinogenesis and Mutagenesis. Research Center Clin-Midy. Montpellier, France.

1983 Conference on Carcinogenesis and Gene Expression in Liver Cultures

United States-Japan Cooperative Cancer Research Program. Honolulu, Hawaii.

1984 Conference on Cellular Systems for Toxicity Testing, New York Academy of Sciences, New York, NY.

1986 Conference on Causative and Modulating Factors for Digestive Tract Cancer
United States-Japan Cooperative Cancer Research Program. Tokyo, Japan.

1986 International Conference on Cancer Research. Theories of Carcinogenesis. The Norwegian Cancer Society, Oslo, Norway.

1986 Conference on Non-Mutagenic Carcinogens: How Much Risk to Man?
The Robens Institute, University of Surrey, Guildford, England.

1987 Conference on Sweeteners: Health Effects. American Health Foundation,
New York.

1987 International Symposium in Genetic Toxicology, National Science
Foundation (U.S.) and Council of Scientific and Industrial Research (India), University of Calcutta, Calcutta, India.

1988 International Symposium on Causes and Prevention of Cancer, American Health Foundation in cooperation with American Cancer Society and
National Cancer Institute, New York, NY.

1989 International Conference on Environmental and Nutritional Influences on
Aging and Cancer, American Health Foundation in cooperation with National Institute on Aging, New York, NY.

1990 Conference on Cancer Prevention for Black Americans, Metropolitan Life Insurance, Company, New York, NY.

1991 International Conference on Antioxidants: Chemical, Physiological, Nutritional and Toxicological Aspects, American Health Foundation, Tarrytown, NY.

1991 Second International Conference on Theories of Carcinogenesis. Norwegian
Cancer Society, Oslo, Norway.

1992 1st International Short Course on Preclinical Drug and Chemical Safety,

Tarrytown, NY.

1993 2nd International Short Course on Preclinical Drug and Chemical Safety, Tarrytown, NY.

1993 American Health Foundation, 25th Anniversary Conference and Celebration, Toward Optimal Health: Examining Goals for Nutrition and the Environment, Tarrytown, NY.

1994 3rd International Course on the Safety Assessment of Pharmaceuticals, Tarrytown, NY.

1995 International Congress on Hepatocytes-Applications in Cell Biology, Toxicology and Medicine, Tubingen, Germany.

1996 Conference, Reducing Dietary Fat: Putting Theory Into Practice, American Health Foundation, New York, NY.

1996 4th International Course on the Safety Assessment of Pharmaceuticals, Part I, White Plains, NY.

1996 4th International Course on the Safety Assessment of Pharmaceuticals, Part II, San Francisco, CA.

1997 5th International Course on the Safety Assessment of Medicines, Part I, White Plains, NY.

1998 6th International Course on the Safety Assessment of Medicine. Basic and Regulatory Aspects, White Plains, NY.

2000 7th International Course on the Safety Assessment of Medicine. Basic and Regulatory Aspects, White Plains, NY.

2001 8th International Course on the Safety Assessment of Medicine. Basic and Regulatory Aspects, White Plains, NY.

2002 International Symposium on Antimutagenesis and Anticarcinogenesis, New York Medical College, Valhalla, NY

NATIONAL AND INTERNATIONAL RESPONSIBILITIES

1975 Consultant, Pesticides, Toxic Substance and Solid Waste Management, United States Environmental Protection Agency.

1975-1978 Member, Epidemiology Committee, Breast Cancer Task Force, NationalCancer Institute.

1976-1977	Member, Program Committee, American Association for Cancer Research.
1976	Member, Working Group on Evaluation of Carcinogenic Risk of Chemicals to Man: Some Miscellaneous Pharmaceutical Substances, International Agency for Research on Cancer.
1976-1978	Co-Chairperson, Subcommittee on Rat Liver Tumors, Committee on Histologic Classification of Laboratory Animal Tumors, Institute of Laboratory Animal Resources, National Research Council.
1977-1978	Member, Panel on Kepone/Mirex, Scientific and Technical Assessments of Environmental Pollutants, Environmental Studies Board, Commission on Natural
1979-1980	Member, Panel on Unscheduled DNA Synthesis, Gene-Tox Program, U.S. Environmental Protection Agency.
1980-1981	Member, Panel of Experts Associated with Technical Report Review Subcommittee, National Toxicology Program, Department of Health and Human Ser
1980	Member, Working Group on Evaluation of Carcinogenic Risk of Chemicals to Man-Antineoplastic and Immunosuppressive Drugs, International Agency for Research on Cancer.
1980-1986	Panel of Reviewers, Netherlands Cancer Foundation.
1981	Advisor, Technical Committee, Society of Toxicology.
1981-1982	Member, Task Group on the Differentiation Between Genotoxic and Epigenetic Carcinogens, International Commission on Protection Against Environmental Mutagens and Carcinogens.
1982	Member, Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Chemicals and Industrial Processes Associated with Cancer in Humans, IARC Monographs Volumes 1 to 29, International Agency for Research on Cancer.
1982-1983	Consultant, Office of Health and Environmental Assessment, Reproductive Effects Assessment Group, U.S. Environmental Protection Agency.
1982-1983	Member, International Expert Committee to the Nutrition Foundation on the Relevance of Mouse Liver as a Model for Assessing Carcinogenic Risk, Nutrition Foundation, Incorporated.

1982-1983	Coordinator, Assays of DNA Damage, Collaborative Study on Short-Term Tests for Genotoxicity and Carcinogenicity. International Programme on Chemical Safety, World Health Organization.
1983	Member, Working Group on the Mechanisms of Chemical Carcinogenesis, International Agency for Research on Cancer.
1983-1984	Member, Expert Committee on Pathology/Toxicology and Expert Committee on Short-Term Testing, International Life Sciences Institute.
1984-1987	Assessor, National Health and Medical Research Council Panel of Independent Assessors, National Health and Medical Research Council, Commonwealth of Australia.
1984-1985	Member, Committee on the Carcinogenicity of Cyclamates, Food and Nutrition Board, Commission on Life Sciences, National Research Council.
1984-1985	Member, Task Group of DNA Repair, Subcommittee on Genetic Toxicology, American Society for Testing and Materials.
1985-1987	Member, Toxicology Study Section, National Institutes of Health.
1985	Vice-Chairman, Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Some Naturally Occurring Substances, Food Additives and Amino Acid Pyrolysates in Food, International Agency for Research on Cancer.
1985-1986	Member, Awards Committee, Society of Toxicology.
1986	Member, Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Genetic and Related Effects: An Updating of Selected IARC Monographs from Volumes 1 to 42, International Agency for Research on Cancer.
1987	Member, Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, International Agency for Research on Cancer.
1988	Participant, Tox-90s Conference, Society of Toxicology.
1989	Organizing Committee, Workshop on the Effects of pesticides on Human Health, Task Force on Environmental Cancer and Heart and Lung Disease.

1989	Chairman, Working Group and Chairman, Subgroup on Animal Carcinogenicity, Working Group on Evaluation of Carcinogenic Risk of Chemicals to Humans: Some Pharmaceutical Drugs, International Agency for Research on Cancer.
1989	Participant and Member of Editorial Board, Workshop on Complex Mixtures and Cancer Risk, International Agency for Research and Cancer.
1989	Participant, Working Group on Short-Term In Vitro and In Vivo Tests, Workshop on Research to Improve Predictions of Long-Term Chemical Toxicity, National Research Council.
1990-present	Member, Committee of Education on Toxicologic Pathology, International Federation of Societies of Toxicologic Pathologists.
1991	Member, Working Group on Approaches to Classifying Carcinogens According to Mechanisms of Action, International Agency for Research on Cancer.
1992-1993	Member, Expert Panel on Interpretive Review of the Potential Adverse Effects of Chlorinated Organic Chemicals on Human Health and the Environment, CanTox, Inc.
1993-1999	Member, Committee on Evaluation of the Research Program "Cancer Risk Factors and Prevention," German Cancer Center.
1993-present	Member, Board of Trustees, International Life Sciences Institute, Health and Environmental Sciences Institute. Chair, Membership Development Committee, 2002.
1993-1999	Member, Cellular Telephone Advisory Committee, Harvard Center for Risk Analysis, Harvard School of Public Health.
1993-1999	Wireless Technology Research Peer Review Board.
1993-present	Member, Subcommittee on Carcinogenicity, International Federation of Societies of Toxicologic Pathologists.
1995-1998	Member, International Committee on Wireless Communication Health Research (ICWCHR).
1995-1997	Member, Committee on Research Opportunities and Priorities for EPA, Commission on Geosciences, Environment, and Resources, National Research Council.
1996	Reviewer, U.S. Environmental Protection Agency (EPA), PCBs: Cancer

Dose-Response Assessment and Application to Environmental Mixtures.

1996 Participant, Developmental Planning for Office of Dietary Supplements (ODS), National Institutes of Health.

1996-1997 Member, Advisory Board to the Calcium Channel Blockers/Cancer Study, Boston University School of Medicine, Slone Epidemiology Unit.

1997 Member, Working Group on Short/Medium Term Carcinogenicity Tests and Genetic and Related Effects. International Agency for Research on Cancer.

1998 Member, Working Group - Re-evaluation of Some Industrial Chemicals. International Agency for Research on Cancer.

1999-present Member, Subcommittee on Upper Limits, Committee on Reference Levels of Nutrients, National Academy of Sciences, Institute of Medicine.

1999 Member, Working Group on Predictive Value of Gastric Neuroendocrine Tumours and Forestomach Tumours in Rodents for Carcinogenic Hazard Identification. Co-Chairperson, Forestomach Tumors. International Agency for Research on Cancer.

2000 Member and Report Coordinator, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel. U.S. Environmental Protection Agency.

2001 Reviewer, Office of Dietary Supplements, National Institutes of Health. Annual Bibliography of Significant Advances in Dietary Supplement Research - 2000.

2001-present Member, Accreditation Committee, International Academy of Toxicologic Pathology.

2002 Peer Review Member, U.S. Environmental Protection Agency "Perchlorate Environmental Contamination: Toxicological Review and Risk Assessment."

2002 WHO Temporary Adviser, 59th Meeting of the Joint Expert Committee on Food Additives (JECFA).

2/02

June 1, 2004

CURRICULUM VITAE: HARALD OTTO HEYMANN

PERSONAL HISTORY

Born	Date: August 13, 1952 Place: Frankfurt A/M, Germany Citizenship: United States
Family	Married: Karen Bost Heymann Children: Gavin Christopher Heymann 2/24/79 Wesley Benjamin Heymann 1/12/83
Office Address	302C Brauer Hall School of Dentistry CB#7450 University of North Carolina at Chapel Hill Chapel Hill, North Carolina 27599-7450 (919) 966-2770 FAX 966-5660 email: harald_heymann@dentistry.unc.edu
Home Address	330 Chapel View Drive Apex, North Carolina 27502 (919) 387-7585

EDUCATION

Institution and Location	Degree	Date Conferred	Degree Major
UNC School of Education Chapel Hill, NC	M.Ed.	1980	Education
UNC School of Dentistry Chapel Hill, NC	D.D.S.	1978	Dentistry
Appalachian State Univ. Boone, NC	B.A. (Summa Cum Laude)	1974	Biology

STATE LICENSE

1978	North Carolina (#4490)

ACADEMIC OR PROFESSIONAL APPOINTMENTS

July 2000-present	Graduate Program Director
January 1995-present	Professor
January 1990-June 2000	Chair Department of Operative Dentistry UNC School of Dentistry
July 1988-December 1989	Interim Chair Department of Operative Dentistry UNC School of Dentistry
July 1988-December 1994	Associate Professor Department of Operative Dentistry UNC School of Dentistry
July 1981-June 1988	Assistant Professor Department of Operative Dentistry UNC School of Dentistry
July 1978-June 1981	Instructor Department of Operative Dentistry UNC School of Dentistry (while pursuing M.Ed degree)
January 1978-July 1978	Graduate Teaching Assistant Department of Operative Dentistry UNC School of Dentistry

DENTAL PRACTICE

September 1981-present	Operative Department Dental Faculty Practice UNC School of Dentistry
July 1978-September 1981	Generalist Department Dental Faculty Practice UNC School of Dentistry

SOCIETY MEMBERSHIPS

1974-present	American Dental Association
1974-present	North Carolina Dental Society
1975-present	Delta Sigma Delta Upsilon Upsilon Chapter
1975-1996	Academy of General Dentistry
1978-present	Omicron Kappa Upsilon Dental Honor Society
1978-present	Third District Dental Society
1978-present	Durham-Orange Dental Society
1978-present	American Association of Dental Schools (currently American Dental Education Assoc) Operative Dentistry Section Dental Materials Section
1978-1980	American Society of Dentistry for Children
1978-present	Academy of Operative Dentistry

SOCIETY MEMBERSHIPS (Continued)

1979-present	International Association of Dental Research Dental Materials Group

1982-2000	Conference on Operative Dentistry Education (C.O.D.E.)
1986-present	Academy of Dental Materials (Fellow)
1987-present	International College of Dentists (Fellow)
1987-present	American Academy of Esthetic Dentistry (Fellow)
1989-present	American College of Dentists (Fellow)
1990-1998	Federation Dentaire Internationale

HONORS AND AWARDS

Appalachian State University

1971-1974	Alpha Chi Honor Society Award for Highest Academic Achievement
1971-1974	Faculty Scholastic Award for Outstanding Academic Achievement
1973-1974	Alpha Chi Honor Society
1972-1974	Beta Beta Beta Biological Honor Society President, 1972-1974
1974	IRC Science Scholarship
1974	Graduated first in class, College of Arts and Sciences (3.98 GPA)

University of North Carolina School of Dentistry

As Dental Student

1976-1977	Junior Class President
1977-1978	Senior Class President
1978	Who's Who Among Students in American Colleges and Universities
1978	C. V. Mosby Scholastic Award
1978	Delta Sigma Delta Award - Highest Academic Achievement
1978	Academy of Operative Dentistry Award
1978	Omicron Kappa Upsilon Dental Honor Society
1978	Dwight Clark Memorial Award
1978	American Society of Dentistry for Children Award

University of North Carolina School of Dentistry

As Faculty Member

1980, 1985, 1988	Faculty Teaching Awards presented by Classes of 1980, 1985, and 1988
1980,1981	Outstanding Young Men of America Award
1982	Foreign Study Award - German Academic Exchange Service (DAAD)

HONORS AND AWARDS (Continued)

University of North Carolina School of Dentistry (continued)

As Faculty Member (continued)

1983	Walter Reed Certificate of Achievement presented by United States Army Dentac

1987	Fellowship in International College of Dentists
1987	Fellowship in Academy of Dental Materials
1987	Selected for membership - ADA Council on Dental Materials, Instruments, and Equipment (4-year term)
1988	Selected as guest editor, "Esthetic Dentistry: Ethics and Excellence", a special issue of J Am Dent Assoc
1988	Class of 1958 Dental Research Award
1989	Fellowship in American College of Dentists
1992	Turner-Newell Lecturer, Turner Dental School, University of Manchester, Manchester, England.
1996	Profiled in *Quintessance International 27:293*
1997	Raymond E. Meyers Memorial Lecturer University of Louisville
1997	Selected to be the Health Team Dentist/Correspondent, WRAL-TV, Raleigh NC
1997	Distinguished Alumni Award, Appalachian State University
1997, 1998, 1999, 2000, 2001, 2002, 2003	Selected to "Who's Who in Dental Continuing Education" by *Dentistry Today*
1999	Selected as one of twenty-five "Dental Visionaries" nationwide by American Student Dental Association
2000	Selected for inclusion in "Guide to America's Top Dentists"
2000	Selected as an Honorary Member of Milwaukee's Dental Forum
2000	Selected as an Honorary Member of the Thomas P. Hinman Dental Society (one of only 11 selected in history of Hinman)
2000	Handelman Lecturer, Eastman Dental Center, Rochester, NY
2002	Gordon J. Christensen Award for CE Excellence, awarded by the Chicago Dental Society
2002	Nick Marineau Memorial Lecturer, University of Oregon, School of Dentistry
2003	Fellowship in American Academy of Esthetic Dentistry
2003	Dean Ernest Jones Memorial Lecturer, University of Washington, School of Dentistry
2003	Designated Guest Eminent Scholar by University of Oklahoma, School of Dentistry
2003	Marvin Goldstein Memorial Lecturer (25th Anniversary), Medical College of Georgia
2003	William J. Gies Memorial Lecturer, Greater New York Dental Meeting

HONORS AND AWARDS (Continued)
University of North Carolina School of Dentistry (continued)
As Faculty Member (continued)

2004	Selected for inclusion in *The Best Dentists in America* (nominated by Dr. Leonard Abrams, University of Pennsylvania)

COMMITTEE APPOINTMENTS AND CONSULTANT POSITIONS
University of North Carolina School of Dentistry

1978	Search Committee for Oral Surgery Chair

1978-1979	Accreditation Task Committee on Finances

COMMITTEE APPOINTMENTS AND CONSULTANT POSITIONS (Continued)

University of North Carolina School of Dentistry (continued)

1979-1983	Developmental Dentistry Track
1980-1982	D.A.T.E. Admissions Committee
	Omicron Kappa Upsilon Dental Honor Society
1980-1981	Auditing Committee (Chair)
1981-1982	Membership Committee (Chair)
1992	Vice President
1993	President-Elect
1994	President
1980	Search Committee for Operative Dentistry Chair
1981-1985	Student - Faculty Liason Committee (Class advisor for class of 1985)
1982-1984	Learning Resources Center Advisory Committee
1982-1985	Restorative Track
1983-1986	Curriculum Revision Subcommittee on Clinical Sciences
1984	D.A.T.E. Admissions Committee
1984-present	Continuing Dental Education Committee
1985-1987	First Year Teaching Committee
1985-1988	Administrative Board
1985-1988	Interdisciplinary Teaching Committee for Preventive Dentistry
1987-1989	Strategic Planning Committee
1988-2000	Department Chair's Committee
1988-2000	Academic Performance Committee
1989-1990	Dental Assisting Program Committee
1990-1999	Curriculum Committee
1991-1994	Bicentennial Observance Committee
1993	Search Committee for Chair of Pediatric Dentistry (Chair)
1995	DAU-Type Program Committee (Chair)
1995-2002	Conflicts of Interest Committee
1999-2002	(Chair)
1995-1996	Accreditation Steering Committee
1996-2000	Strategic Planning Committee
2000-2001	Search Committee (Chair) for Orthodontics Chair
2000-present	Advanced Education Program Director's Committee
2003-2004	Ad Hoc Committee on PTAC Document Revision

University of North Carolina

1985-1987	Provost's Committee on Continuing Education

Appalachian State University

1997-present	ASU College of Arts and Sciences Advancement Council

Durham-Orange Dental Society

1981-1982	Program Committee (Chair)
1991-1992	Program Committee (Chair)

COMMITTEE APPOINTMENTS AND CONSULTANT POSITIONS (Continued)

Third District Dental Society

1980	Registration Committee
1980	"Mini-Clinics" Program Coordinator
1980-1981	Annual Meeting Committee (Chair)
1984-1985	Public Education Committee
1984-1985	Membership Committee

North Carolina Dental Society

1985-1986	Constitution and By-Laws Committee
1985-1987	Dental Education Committee (Chair)
1979-1980	Monitor's Committee
1980-1981	Member of the Board of Directors of the North Carolina Association of Professions representing the NCDS
1986-1988	Council on Dental Education and Professional Relations
1994-1995	Program Chair, 1995 NCDS Annual Session

National

1982	Conference on Operative Dentistry Education (recording secretary)
1983-1988, 1993	Conference on Operative Dentistry Education (representing UNC)
1984-present	Reviewer for *General Dentistry*
1984-present	Reviewer, *Journal of Dental Education*
1986-present	Reviewer, *Dental Materials*
1987-1998	Advisory Panel Member, *Dental Abstracts*
1987-1997	Section Editor (Operative Dentistry), *Quintessance International*
1987-present	Member, ADA Speaker's Bureau
1987-1991	Member, ADA Council on Dental Materials, Instruments and Equipment (4 year term)
1989-1991	Vice-Chair, ADA Council on Dental Materials, Instruments, and Equipment
1988-2003	Reviewer, *Journal of the American Dental Association*
1990-1993	Member, Editorial Advisory Board for *Cosmetic Dentistry*
1990-1997	Member, Executive Committee, AADS Section on Operative Dentistry
1993-1994	Secretary
1994-1995	President-Elect
1995-1996	President
1991-1995	Consultant, ADA Council on Dental Materials, Instruments and Equipment
1991-1996	Member, Editorial Board, *Dental Study Club*
1991-present	Reviewer, *American Journal of Dentistry*
1989-present	American Academy of Esthetic Dentistry (Fellow)
1989-1990	A.V. Committee (Chair)
1990-1991	Scientific Investigations Committee

COMMITTEE APPOINTMENTS AND CONSULTANT POSITIONS (Continued)

National (continued

1990-1994	Awards Committee
1991-1999	Research Committee (Chair)
1993-2002	Grant Reviewer for AAED Grant in Esthetic Dentistry
1993-present	Strategic Planning Committee
1994-present	Member, Executive Council
1999-2001	Secretary
2000	Program Chair, 25th Anniversary Membership Meeting
2001-2002	Vice-President
2002-2003	President-Elect
2003-2004	President
2002	General Chair, Annual Membership Meeting
2002-2004	2004 Esthetic Update Meeting (Chair)
2002-present	Past Presidents Advisory Committee
2000-present	Editorial and Publications Committee (Chair)
2002-present	Nominations Committee (member)

1991-1996 & 1997-1999	Member, Board of Directors, Charles L. Pincus Foundation
1992-present	*Journal of Esthetic and Restorative Dentistry*
1992-1998	Member, Editorial Advisory Board
1995-1998	Associate Editor
1998-present	Editor-in-Chief
1992-1998	Grant Reviewer for American Fund for Dental Health
1993	Member, NIDR Study Section for review of Center Grants in Preventive and Operative Dentistry (April 22-23, 1993, Bethesda, MD).
1994-present	Member, Editorial Board, *Operative Dentistry*
1995-present	Consultant, ADA Council on Scientific Affairs
1995-present	Member, Editorial Board, *American Journal of Dentistry*
1996-1999	Omicron Kappa Upsilon (National) Liason with Component Chapters Committee
1988	Academy of Operative Dentistry
1998-present	Research Committee
1999-2000	Awards Committee
1996-present	Reviewer, *Journal of Dental Research*
2000- present	Member, Editorial Board, *Dental Traumatology*
2002- present	Member, Editorial Board, *Dimensions of Dental Hygiene*

International

1987-1991	Member, TAG (Technical Advisory Group) of ISO (International Standards Organization) /TC106
1989-present	Member, Editorial Executive Board , *Journal of Dentistry*
1989-1998	FDI Commission on Dental Products
	Member, Working Group 1 on Clinical Research and Testing Protocols
	Consultant to Commission
	FDI Speaker's Bureau

PRESENTATIONS

1980-present	Over 700 presentations made as invited lecturer, seminarian, television speaker, or featured clinician before local, state, national, and international dental goups. (See Addendum for detailed citations.)

SCIENTIFIC PAPERS/SYMPOSIA

State

February 22, 1989	-Presented paper entitled "Two-Year Clinical Study of Dentinal Adhesives in Class V Cervical Lesions," Dental Research in Review, UNC School of Dentistry, Chapel Hill, NC.
February 22, 1989	-Symposium speaker, "Clinical Utilization of CEREC® CAD/CAM System", Dental Research in Review, UNC School of Dentistry, Chapel Hill, NC.
February 21, 1990	- Session Chair, Dental Materials, Dental Research in Review, UNC School of Dentistry, Chapel Hill, NC.
February 26, 1992	-Presented paper entitled "Two-Year Clinical Performance of CEREC CAD/CAM-Generated MGC Inlays," Dental Research in Review, UNC School of Dentistry, Chapel Hill, NC.
February 19, 1998	-Presented poster entitled "Six Month Clinical Study of a New Carbamide Peroxide Bleaching Agent," Dental Research in Review, UNC School of Dentistry, Chapel Hill, NC.

National

March 27, 1979	-Presented paper entitled, "Project ACORDE: Applied Evaluative Research," Section on Educational Research, American Association of Dental Schools, New Orleans, LA.
March 22, 1980	-Presented paper entitled "Systematic Instruction in a Pre-clinical Operative Technique Course: An Evaluative Investigation," Section on Behavioral Science - Educational Research, American Association of Dental Research, Los Angeles, CA.
March 14, 1981	-Co-director (with Dr. B. Machen) of seminar entitled "Clinical Evaluation," Learning Resources Section, American Association of Dental Schools, Chicago, IL.
March 16, 1982	-Presented paper entitled "A Systematic Approach to Curriculum Review and Development Through the Use of A Mailed Questionnaire," Section on Educational Research - New Programs, American Association of Dental Schools, New Orleans, LA.
November 19-22, 1986	-Symposium coordinator and speaker presenting "Current Concepts in Conservative Esthetic Dentistry" (half-day), Interdisciplinary Symposium on Dental Esthetics, Williamsburg, VA, sponsored by Medical College of Virginia, University of Maryland, Georgetown, and Howard University.
January 12, 1989	-Guest speaker and panelist presenting "The Artistry of Conservative Esthetic Dentistry" at ADA sponsored symposium entitled "Esthetic Dentistry: A New Direction," Denver, CO.
February 17, 1989	-Guest speaker, "CAD/CAM for Inlays: CEREC® System," Symposium on CAD/CAM in Dentistry, Academy of Dental Materials Annual Meeting, Chicago, IL.

SCIENTIFIC PAPERS/SYMPOSIA (Continued)

National (Continued)

March 17, 1989	-Presented paper entitled "Two-Year Clinical Study of Dentinal Adhesives in Class V Cervical Lesions," Section on Dental

Materials, American Association of Dental Research, San Francisco, CA.

March 17, 1989 -Session Chair, Dental Materials-Composites: Clinical Studies, AADR Annual Meeting, San Francisco, CA.

October 11, 1990 -"Clinical Evaluation of CAD/CAM Restorations: Preliminary Findings," First Annual CEREC® Symposium, Cape Cod, MA.

October 25, 1991 -Lecturer presenting "CAD/CAM Advances in Restorative Dentistry" and panelist, Symposium on "The Amalgam Controversy: Options and Alternatives," sponsored by the University of Southern California, Los Angeles, CA.

November 12, 1991 -Lecturer presenting "Dentin Adhesion Factors," and panelist, ADA-NIH sponsored "Symposium on Esthetic Restorative Materials," Chicago, IL.

March 13, 1992 -Presented paper entitled "Two-Year Clinical Performance of CEREC CAD/CAM-Generated MGC Inlays," Section on Dental Materials, American Association of Dental Research, Boston, MA.

September 26, 1992 -Guest speaker presenting "Practical Applications of Bleaching Methods," at Symposium on Achieveing Practical Esthetics in Dentistry- A Tribute to Dr. Ralph Phillips, sponsored by the University of Texas-San Antonio.

March 8, 1993 -Presented paper entitled "Incorporation of New Esthetic Dentistry Technologies into the Dental Curriculum: Problems and Potential for the Future" Operative Dentistry Section, American Association of Dental Schools, Chicago, IL.

June 5, 1993 -Lecturer presenting "Computer-Generated Ceramic Restorations" and panelist, Symposium on High-Tech Advances in Dentistry, Annual Meeting of the New Jersey Dental Association, Atlantic City, New Jersey.

January 21, 1995 -Panelist at Symposium on "Current Developments in Restorative Dentistry", Yankee Dental Congress, Boston, MA.

March 13, 1995 -Moderator of AADS Operative Dentistry Section program, "Clinical Decision Making in Restoration Replacement", San Antonio, TX.

March 24, 1995 -Panelist, "Adhesive Dentistry Update", Thomas P. Hinman Dental Meeting, Atlanta, GA.

February 9, 1996 -Lecturer presenting "Conservative Concepts in Achieving Anterior Esthetics", at Symposium entitled, "Ultra Conservative Advanced Clinical Treatments in Restorative Dentistry", sponsored by Medical College of Georgia, Atlanta, GA .

SCIENTIFIC PAPERS/SYMPOSIA (Continued)

National (Continued)

November 15, 1996 -Lecturer presenting "Conservative Concepts in Achieving Anterior Esthetics", at Symposium entitled, USC First Annual Restorative Dentistry Symposium," University of Southern California, Los Angeles, CA.

September 25, 1997 -Lecturer presenting "Tooth Flexural Effects on Restorations and Teeth", at Symposium entitled, "Boston University Symposium on Modern Restorative Materials and Techniques", Boston, MA.

March 7, 1998 -Presented poster entitled "Six Month Clinical Study of a New Carbamide Peroxide Bleaching Agent," Section on Dental Materials, American Association of Dental Research, Minneapolis, MN.

March 20, 1998 -Panelist and guest speaker presenting "Current Concepts in Dentin Bonding" at Symposium on Adhesvie Dentistry and Cements, VA (sponsored by Northern District Dental Society)

January 5, 2000 -"Repairing Dental Tissues: From Science to Practice," NIDCR Symposium, "Building a Healthy Millennium – From the Laboratory to the Operatory," Ann Arbor, MI.

August 22, 2003 -Participant, "Color Measurement Symposium," Medical College of Georgia, Augusta, GA.

October 23, 2003 -Moderator of panel discussion, "Current Controversies in Vital Bleaching," ADA Annual Meeting, San Francisco, CA.

January 30, 2003 -Panelist, "Controversies in Esthetic Dentistry," Yankee Dental Congress, Boston, MA.

February 8-9, 2004 -Participant, "Adhesion Dentistry 2004 Symposium." Presented, "Adhesive Dentistry: Separating Fact from Fiction," and "Whiter and Brighter: Keys to Smile Enhancement," Maui, HI (two, half-day courses).

February 21, 2004 -Panelist, "Contemporary Materials and Techniques: How Well do They Work?" Chicago Midwinter Meeting, Chicago, IL.

March 26-27, 2004 -Moderator and Meeting Chair, "AAED Esthetic and Restorative Update," Seattle, WA.

International

March 17, 1984 -Presented paper entitled "Two-Year Clinical Study of Composites in Posterior Teeth," Section on Dental Materials, International Association of Dental Research, Dallas, TX.

December 13, 1984 -Guest speaker, presenting "Indirect Resin Veneers" First International Symposium on Laboratory Applications of Light-Cured Composites, Philadelphia, PA.

January 26-28, 1986 -Panelist, International Symposium on Present and Future of Chairside Polymers, Boca Raton, FL. (3-day symposium)

SCIENTIFIC PAPERS/SYMPOSIA (Continued)

International

October 10-11, 1986 -Panelist and guest speaker presenting "Current Concepts in Veneering Techniques with Composite Resins," and panelist at International Symposium on Laminate Systems, Philadelphia, PA. (2-day symposium)

February 22-24, 1987 -Panelist and guest speaker presenting "Current Concepts in Resin Veneering Techniques," International Symposium on Dental Esthetics sponsored by GC International, Scottsdale, AZ.

March 14, 1987 -Presented paper entitled "Six-Month Clinical Study of Dentinal Adhesives in Class V Eroded Lesions," Section on Dental Materials, International Association of Dental Research, Chicago, IL.

July 19-21, 1988 -Panelist at Research Forum on Dentin Bonding and Ceramics, Santa Maria, CA. (3-day symposium)

September 1-2, 1988	-Guest lecturer presenting "Introducing a Posterior Composite Teaching Program," at International Symposium on Posterior Composites, Cambridge University, Cambridge, England.
June 7-10, 1992	-Panelist and guest speaker presenting "Clinical Co-Variables in Dentin Adhesion" at International Symposium on Resin Adhesives and Glass Ionomers, La Costa, CA.
September 16, 1992	-Turner-Newell Lecturer presenting paper entitled "CAD/CAM Advances in Restorative Dentistry," Turner Dental School, University of Manchester, Manchester, England.
September 17, 1992	-Presented paper entitled "Future Trends in Operative Dentistry Education," to British Association of Teachers of Conservative Dentistry, Manchester, England.
September 2, 1993	-Guest speaker presenting "Clinical Research Update on Dentin Adhesion and Light-Cured Glass Ionomers", Symposium on "The New Restorative Dentistry", FDI World Dental Congress, Gothenburg, Sweden.
August 24, 1996	-"New Age Concepts in Vital Bleaching," to Thirteenth Annual Quintessance Symposium, Sydney, Australia.
August 28, 1996	-Invited research lecturer, "Tooth Flexural Effects on Restorations and Teeth," University Dental Hospital of Melbourne, Melbourne, Australia.
September 25-26, 1996	-Moderator, International Symposium on the Non-Restorative Treatment of Discolored Teeth, Chapel Hill, NC.
September 27, 1998	-Panelist and speaker presenting "Future Restorative Needs in Light of Tooth Biodynamics" at Symposium on Adhesive and Restorative Dentistry, Munich, Germany.
July 16, 1999	-"Tooth Flexural Effects on Restorations and Teeth," QI's 16th International Symposium on Adhesive Dentistry, Orlando, FL.
January 5, 2000	-"Reparing Dental Tissues: From Science to Practice," at NIDR Symposium on "Building a Healthy Millenium: From Laboratory to Operatory," Ann Arbor, MI

SCIENTIFIC PAPERS/SYMPOSIA (Continued)

International

May 5-6, 2000	-Chair and Moderator, Second International Symposium on Adhesive Dentistry, Philadelphia, PA.
March 10, 2002	-"Conservative Concepts for Improving Anterior Esthetics," Dorado Beach Esthetics Symposium, Dorado Beach, Puerto Rico (half-day course).
September 28, 2002	-"Adhesive Dentistry: Proven Solutions vs. Opinion and Hype," Adhesive Dentistry Symposium, Bermuda (half-day course).
February 21-22, 2003	-"Non-Carious Cervical Lesions: Etiology and Considerations for Successful Treatment," and "Whiter and Brighter: Facts and Fallacies of Vital Bleaching," International Restorative Dentistry Symposium, Vancouver, BC, Canada.
May 27, 2004	-Session Chair, International Federation of Esthetic Dentistry Annual Meeting, Venice, Italy.

MAJOR TEACHING/ADMINISTRATIVE RESPONSIBILITIES

University of North Carolina

Teaching

Fall, 1979- present	-Faculty member, Clinical Operative Dentistry, Dent. 232, 332, 432 (2d, 3d, and 4th years)
Spring and Summer, 1978	-Core faculty, Dental Science I
Fall, 1978	-Core faculty, Dental Science II
Spring and Summer, 1979	-Core faculty, Dental Science I-A and I-B
Fall, 1979	-Core faculty, Dental Science II-A
Fall, 1979	-Faculty member, Advanced Operative Elective, 179R
Spring and Summer, 1980	-Core faculty, Dental Science I-A and I-B
Fall, l980	-Core faculty, Dental Science II-A
	-Co-director, Advanced Operative Elective, 179R
Spring and Summer, 1981	-Core faculty, Dental Science I-A and I-B
Fall, 1981	-Core faculty, Dental Science II-A
	-Co-director, Advanced Operative Elective, 179R
1982-present	-Invited Lecturer: Auxiliary Programs, Graduate Programs, General Practice Residency Program
Spring and Summer, 1982	-Assistant Director, Dental Science I-A and I-B
Fall, 1982	-Co-director, Advanced Operative Elective, 179R
Spring and Summer, 1983	-Course Director, Dental Science I-A and I-B (260 hrs)
Fall, l983	-Co-director, Advanced Operative Elective, 179R
Spring and Summer, 1984	-Course Director, Dental Science I-A and I-B(260 hrs)
Fall, 1984	-Director, Advanced Operative Elective 179R
Spring and Summer, 1985	-Course Director, Dental Science I-A and I-B (260 hrs)
Fall, 1985	-Faculty member, Advanced Operative Elective 179R
Spring, 1986	-Course Director, Conservative OperativeDentistry 112 (154 hours)
Fall, 1986	-Faculty member, Restorative Didactic 302
Spring, 1987	-Course Director, Conservative OperativeDentistry 112 (154 hours)
	-Faculty member, Restorative Didactic, 313
Fall, 1987	-Faculty member, Graduate Prosthodontic Treatment Planning, 231-D
Fall, 1987	-Faculty member, Dental Anatomy, 105
	-Faculty member, Restorative Didactic, 302
1988-2000	- Course Director, Clinical Operative Dentistry, Dent. 232, 332, 432 (2d, 3d, and 4th years)
Spring, 1988	-Faculty member, Conservative Operative Dentistry 112 (Lecturer - 20 hours)
	-Faculty member, Restorative Didactic, 313
Fall, 1988	-Faculty member, Restorative Didactic, 302
Fall, 1988	-Faculty member, Graduate Prosthodontic Treatment Planning, 231-D
Spring, 1989	-Faculty member, Restorative Didactic, 313

MAJOR TEACHING/ADMINISTRATIVE RESPONSIBILITIES (Continued)

University of North Carolina

Teaching (continued)

Fall, 1989	-Faculty member, Restorative Didactic, 302
Fall, 1989	-Faculty member, Graduate Prosthodontic Treatment Planning, 231-D
Spring, 1990	-Faculty member, Restorative Didactic, 313
	-Faculty member, Restorative Didactic, 411

Fall, 1990	-Faculty member, Restorative Didactic, 302
Fall, 1990	-Faculty member, Graduate Prosthodontic Treatment Planning, 231-D
Spring, 1991	-Faculty member, Restorative Didactic, 313
	-Faculty member, Restorative Didactic, 411
Fall, 1991	-Faculty member, Restorative Didactic, 302
Fall, 1991	-Faculty member, Graduate Prosthodontic Treatment Planning, 231-D
Spring, 1992	-Faculty member, Restorative Didactic, 411
Summer, 1992	-Faculty member, Restorative Didactic, 313
Fall, 1992	-Faculty member, Restorative Didactic, 302
Spring, 1993	-Faculty member, Special Topics II, Orthodontics
Spring, 1993	-Faculty member, Restorative Didactic, 411
Summer, 1993	-Faculty member, Restorative Didactic, 313
Fall, 1993	-Faculty member, Restorative Didactic, 302
Spring, 1994	-Faculty member, Special Topics II, Orthodontics
Spring, 1994	-Faculty member, Graduate Prosthodontics Rest. Update
Spring, 1994	-Faculty member, Restorative Didactic, 411
Summer, 1994	-Faculty member, Restorative Didactic, 313
Fall, 1994	-Faculty member, Restorative Didactic, 302
Spring, 1995	-Faculty member, Special Topics II, Orthodontics
Spring, 1995	-Faculty member, Graduate Prosthodontics Rest. Update
Spring, 1995	-Faculty member, Restorative Didactic, 411
Summer, 1995	-Faculty member, Restorative Didactic, 313
Spring, 1996	-Faculty member, Special Topics II, Orthodontics
Summer, 1996	-Faculty member, Restorative Didactic, 313
Fall, 1996	-Faculty member, Dental Anatomy
	-Faculty member, Restorative Didactic, 302
Spring, 1997	-Faculty member, Graduate Prosthodontics Rest. Update
Fall, 1997	-Faculty member, Advanced Operative Dentistry
Fall, 1998	-Faculty member, Advanced Operative Dentistry
Fall, 1999	-Faculty member, Advanced Operative Dentistry
Fall, 2000	-Assistant Director, Advanced Operative Dentistry
Fall, 2001	-Assistant Director, Advanced Operative Dentistry
Fall, 2002	-Assistant Director, Advanced Operative Dentistry

MAJOR TEACHING/ADMINISTRATIVE RESPONSIBILITIES (Continued)

University of North Carolina

Teaching (continued)

Fall, 1997- present	-Graduate faculty (Program Director since July 2000) of Operative Dentistry Graduate Program: clinical and didactic courses including Operative Dentistry Seminar (Oper 201 A,B,C,D), Operative Dentistry Research (Oper 203 A,B,C), etc.

Administrative

1980-1983	-Director of Natural Tooth Dentiform Project
1980-1984	-Course Director, Advanced Operative Elective, l79R
1982-1985	-Course Director, Dental Science I-A & I-B (260 hours)
1984-1987	-Course Director, Conservative Operative Dentistry 112 (154 hours)
1984-present	-Director of Continuing Education for Department of Operative Dentistry

1988-1990 -Acting Chair, Department of Operative Dentistry1988-2000 -Course Director, Clinical Operative Dentistry 232,332, and 432 (2d, 3d, and 4th years).
1989-1996 -Director, Carolina Institute of CAD-CAM Technology
1990-2000 -Chair, Department of Operative Dentistry
UNC School of Dentistry
1998-present -Editor-in-Chief, *Journal of Esthetic and Restorative Dentistry*
2000-present -Graduate Program Director

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC

June 6, 1980	-"Polishable Composites," UNC School of Dentistry, Chapel Hill, NC.
September 6, 1980	-"Update of Anterior Restorative Materials and Techniques," to UNC School of Dentistry Alumni, UNC School of Dentistry, Chapel Hill, NC. (Alumni Day)
September 25, 1981	-"New Composite Materials and Techniques," UNC School of Dentistry, Chapel Hill, NC. (1 day course with Dr. C. L. Sockwell)
March 11-12, 1982	-"Tooth Colored Restorations", UNC School of Dentistry, Chapel Hill, NC. (2 day lecture/participation course with Dr. C. L. Sockwell)
December 11, 1982	-"Tooth Colored Restorations," UNC School of Dentistry, Chapel Hill, NC. (l day lecture/participation course with Dr. C. L. Sockwell)
March 5, 1983	-"Tooth Colored Restorations," UNC School of Dentistry, Chapel Hill, NC. (l day lecture/participation course with Dr. C. L. Sockwell)
March 26, 1983	-"Extended Uses of the Acid Etch Technique" to SNDA Alumni Association, UNC School of Dentistry, Chapel Hill, NC.
November 11, 1983	-"Acid-Etched Resin-Bonded Bridges," UNC School of Dentistry, Chapel Hill, NC. (l day lecture/participation course with Dr. C. L. Sockwell and others)
December 2, 1983	-"Clinical Applications of Light-Cured Materials," Dental Seminar Day, UNC School of Dentistry, Chapel Hill, NC.
December 16, 1983	-"Acid-Etched Resin-Bonded Bridges," UNC School of Dentistry, Chapel Hill, NC. (l day lecture/ participation course with Dr. C. L. Sockwell and others)
June 22-23, 1984	-"Clinical Applications of Light-Cured Materials" and "Resin-Retained Bridges" as part of "Operative Update 1984," sponsored by UNC and the Department of Operative Dentistry, Myrtle Beach, SC.
October 12, 1984	-"Acid-Etched Resin-Bonded Bridges," UNC School of Dentistry, Chapel Hill, NC. (l day lecture participation course with other restorative faculty)
November 2, 1984	-"Resin-Retained Bridges" to Area L AHEC, Wilson, NC. (half day course)
January 4-5, 1985	-"Current Concepts in Conservative Esthetic Dentistry," UNC School of Dentistry, Chapel Hill, NC. (one-day lecture/participation course with Dr. D. Brunson)
February 15, 1985	-"Esthetic Dentistry," Medical Issues Seminar, UNC School of Dentistry, Chapel Hill, NC.

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

June 19-22, 1985	-"Update of Anterior Restorative Materials" and "Current Concepts in Cosmetic Dentistry" as part of "Second Annual Dental Review," Myrtle Beach, SC.
September 5-6 and November 15, 1985	-Course director of "Current Concepts in Conservative Esthetic Dentistry," UNC School of Dentistry, Chapel Hill, NC. (3 days of

	lectures, slide presentations, and participation including in-office component approved for 33 hours of AGD credit)
September 27, 1985	-"Esthetic Bonding," to First District Dental Society Annual Meeting, Asheville, NC. (AHEC Sponsored half-day course)
December 6, 1985	-"Current Concepts in Veneering Techniques," Dental Seminar Day, UNC School of Dentistry, Chapel Hill, NC.
January 18, 1986	-"Esthetic Bonding," UNC School of Dentistry, Chapel Hill, NC. (half-day participation Course with Drs. D. Brunson & T. Roberson)
January 28, 1986	-"Update of Dental Materials," Blueridge Dental Society, Elkin, NC. (AHEC sponsored)
June 20, 1986	-"Current Concepts in Veneering Techniques," as part of "Third Annual Dental Review," Myrtle Beach, SC.
June 26, 1986	-"Update on Posterior Composites" to Foothills Dental Study Club, Morganton, NC. (AHEC sponsored)
October 3, 1986	-"Esthetic Veneering with Porcelain and Resin" as part of Continuing Eduction course entitled "Hot Topics in General Dentistry," UNC School of Dentistry, Chapel Hill, NC.
October 15, 1986	-"Current Concepts in Veneering Techniques" to Sandhills Dental Study Club, Southern Pines, NC. (AHEC sponsored)
April 14, 1987	-"Conservative Esthetic Bonding: New Materials and Devices" to Asheville-Buncombe Dental Society, Asheville, NC. (AHEC sponsored)
June 18, 1987	-"Resin-Retained Bridges: An Update," as part of "Fourth Annual Dental Review," Myrtle Beach, SC.
August 27, October 1,2,16 and December 11,12, 1987	-Course director of "Operative Dentistry Update" -A 72-hour lecture/participation course (including in-office component) approved for AGD Mastership credit.
October 28, 1987	-"What's New in Esthetic Dentistry" to Craven, Jones, Pamlico Dental Society, New Bern, NC (AHEC sponsored)
December 4, 1987	-Featured speaker, Dental Seminar Day "Advances in the Artistry of Conservative Esthetic Dentistry" (all-day course), UNC, Chapel Hill, NC
June 16, 1988	-"Advances in the Artistry of Conservative Esthetic Dentistry," Fifth Annual Dental Review, Myrtle Beach, S.C.
December 13, 1988	-"Bonded Ceramic Inlays and Onlays" to High Point Dental Society, High Point, NC. (AHEC sponsored)

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

January 5, 1989	-"Bonded Ceramic Inlays and Onlays" to Gateway Dental Society, Henderson, NC. (AHEC sponsored)
May 4, 1989	-"Computer-Generated Ceramic Inlays/Onlays" to Triangle Study Club, Chapel Hill, NC. (AHEC sponsored)
June 15-16, 1989	-"Computer-Generated Ceramic Inlays/Onlays" and "The Artistry of Conservative Esthetic Dentistry" to Sixth Annual Dental Review, Myrtle Beach, SC.
August 31, 1989	- "Computer-Generated Ceramic Restorations," to Butler-Ross Study Club, Durham, NC. (AHEC sponsored)

October 7, 1989	- "CAD/CAM and Dentistry," Fall Football Day, UNC School of Dentistry, Chapel Hill, NC.
October 19-21, 1989	- "Computer-Generated Ceramic Restorations" to Continuing Education participants, UNC School of Dentistry, Chapel Hill, NC (2 1/2 day lecture/participation course).
October 24, 1989	- "Computer-Generated Ceramic Restorations," to Guilford County Dental Society, Greensboro, NC. (AHEC sponsored)
January 4-6, 1990	-"Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2 1/2-day lecture/participation course).
April 25, 1990	- "CAD/CAM in Dentistry" to Mountain AHEC, Asheville, NC (half-day AHEC sponsored).
May 4, 1990	- "What's New in Conservative Esthetic Dentistry: A Potpourri" to Charlotte AHEC, Charlotte, NC (half-day AHEC sponsored).
June 14, 1990	- "Treating Discolored Teeth," to Seventh Annual Dental Review, Myrtle Beach, SC.
June 21, 1990	- "What's New In Conservative Esthetic Dentistry: A Potpourri" to Area L AHEC, Rocky Mount, NC (half-day AHEC sponsored).
July 19-21, 1990	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2 1/2 day lecture/participation course).
September 28, 1990	- "CAD/CAM in Dentistry" to Eastern AHEC, Greenville, NC (half-day AHEC sponsored).
October 16, 1990	-"The Artistry of Conservative Esthetic Dentistry" to Iredell County Dental Society, Statesville, NC. (AHEC sponsored).
November 8-9, 1990	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
November 20, 1990	-"Bleaching for Vital and Non-Vital Teeth" to Rockingham County Dental Society, Eden, NC (AHEC sponsored).
January 3-4, 1991	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
February 15, 1991	- "What's New In Conservative Esthetic Dentistry: A Potpourri" to Wilmington AHEC, Wilmington, NC (half-day AHEC sponsored).

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

March 27, 1991	-"Bleaching for Vital and Non-Vital Teeth" to Craven-Jones-Pamlico Dental Society, Eden, NC (AHEC sponsored).
June 19-20, 1991	-"Advances in High Tech Dentistry" and "Update in Nightguard Vital Bleaching" to Eighth Annual Dental Review, Myrtle Beach, SC.
July 25-26, 1991	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
October 9, 1991	-"Computer-Generated Ceramic Inlays/Onlays" to Foothills Dental Study Club, Hickory, NC (AHEC sponsored).
October 11-12, 1991	-"Computer-Generated Ceramic Restorations," Charlotte, NC, (2-day lecture/participation CE course).
November 1, 1991	-"Update on Porcelain Veneers" to UNC Prosthodontics Alumni Dental Study Club, Chapel Hill, NC.
November 6, 1991	-"Esthetic Dentistry Potpourri" to Mid-Town Dental Study Club, Charlotte, NC (AHEC sponsored).

December 5, 1991	-"Dentin Bonding: An Update" to Gaston County Dental Society, Gastonia, NC (AHEC sponsored).
January 2-3, 1992	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
January 9, 1992	-"Update on Posterior Composites" to Loblolly Dental Study Club, Goldsboro, NC (AHEC sponsored).
February 6, 1992	-"CAD/CAM in Dentistry: The CEREC System" to Mountain Region AHEC, Asheville, NC (AHEC sponsored).
March 24, 1992	-"CAD/CAM in Dentistry: The CEREC System" to Durham-Orange Dental Assistants Society, Chapel Hill, NC.
April 2, 1992	-"Update on Dentin Bonding and Esthetic Materials" to Prima Dental Study Club, Goldsboro, NC, (AHEC sponsored).
April 4, 1992	-Guest speaker presenting "Current Concepts in Adhesive Dentistry" to Harrell Syposium, UNC School of Dentistry, Chapel Hill, NC,
April 6, 1992	-"Update on Posterior Composites" to Southeastern Dental Society, Lumberton, NC (AHEC sponsored).
April 10-11, 1992	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
June 18-20, 1992	-"Current Concepts in Dentin Bonding", and "Esthetic Dentistry: Gems, Pearls, and Potpourri" to Ninth Annual Dental Review, Myrtle Beach, SC.
July 31-August 1, 1992	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
October 23, 1992	-"Conservative Esthetic Posterior Restorations" to Mid-Town Dental Study Club, Charlotte, NC. (AHEC sponsored).
November 6-7, 1992	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

November 17, 1992	-"Esthetic Dentistry Update" to Raleigh-Wake County Dental Society, Raleigh, NC (AHEC sponsored).
January 8-9,1993	- "Computer-Generated Ceramic Restorations," UNC School of Dentistry, Chapel Hill, NC, (2-day lecture/participation course).
January 21, 1993	-"Computer-Generated Ceramic Inlays/Onlays" to Roy Heath Dental Study Club, Chapel Hill, NC (AHEC sponsored).
February 11, 1993	-"Conservative Esthetic Dentistry: Gems, Pearls, and Potpourri" to Loblolly Dental Study Club, Goldsboro, NC (AHEC sponsored).
March 31, 1993	-"Esthetic Dentistry Update" to Craven-Jones-Pamlico Dental Society, New Bern, NC (AHEC sponsored).
April 8, 1993	-"Conservative Esthetic Dentistry: Gems, Pearls, and Potpourri" to Gaston County Dental Society, Gastonia, NC (AHEC sponsored).
June 3, 1993	-"Current Concepts in Dentin Bonding", Update in General Practice, UNC School of Dentistry, Chapel Hill, NC.
June 17-19, 1993	-"Current Concepts in Veneering Techniques", Tenth Annual Dental Review, Myrtle Beach, SC.
June 22, 1993	-"Esthetic Dentistry Update" to East Carolina Dental Society, Greeneville, NC (AHEC sponsored).

August 24, 1993 -"Current Concepts in Veneering Techniques" to Fayetteville Dental Society, Fayetteville, NC (AHEC sponsored).

September 23, 1993 -"Update in Vital Bleaching Techniques" to Coastal Dental Study Club, New Bern, NC (AHEC sponsored).

November 2, 1993 -"Current Concepts in Veneering Techniques" to Chatham County Dental Society, Siler City, NC (AHEC sponsored).

November 4, 1993 -"Current Concepts in Veneering Techniques" to Davidson County Dental Society, Highpoint, NC (AHEC sponsored).

December 7, 1993 -"What's New in Conservative Esthetic Dentistry?" to Fayetteville Area AHEC, Fayetteville, NC (AHEC sponsored).

January 18, 1994 -"Current Concepts in Dentin Bonding" to Durham-Orange Dental Society, Chapel Hill, NC (AHEC sponsored).

February 8, 1994 -"Conservative Esthetic Techniques" to Nash-Edgecomb Dental Society, Rocky Mount, NC (AHEC sponsored).

February 17, 1994 -"Conservative Esthetic Dentistry: Gems, Pearls, and Potpourri" to Sandhills Dental Study Club, Pinehurst, NC (AHEC sponsored).

April 29, 1994 -"Treating Discolored Teeth", New Horizons in Restorative Dentistry, Salisbury, NC.

May 17, 1994 -"Computer-Generated Ceramic Restorations", to Rockingham County Dental Society, Reidsville, NC (AHEC sponsored).

June 2, 1994 -"Cosmetic Veneers", Update in General Practice 1994, UNC School of Dentistry, Chapel Hill, NC.

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

June 18, 1994 -"Perio Splinting and Conservative Resin-Bonded Bridges", Eleventh Annual Dental Review, Myrtle Beach, SC.

August 25-26, Sept. 9-10, & Dec., 16-17, 1994 -Course Director and faculty member, "Operative Dentistry Update", a 72-hour AGD Mastership Course, UNC School of Dentistry.

October 5, 1994 -"Perio-Splinting and Provisional Resin-Bonded Bridges", to Four Corners Study Club, Kinston, NC.(AHEC sponsored).

November 3, 1994 -"Update in Etched Porcelain Veneers" to Triangle Dental Study Club, Durham, NC. (AHEC sponsored).

January 27, 1995 -"What's New in Conservative Esthetic Dentistry: A Potpourri", Greensboro, NC. (AHEC sponsored half-day course).

February 3, 1995 -"What's New in Conservative Esthetic Dentistry: A Potpourri", to Prima Dental Study Club, Goldsboro, NC. (AHEC sponsored).

March 20, 1995 -"Esthetic Dentistry Update", Bowman-Gray School of Medicine, Northwest AHEC, Winston-Salem, NC. (AHEC sponsored half-day course).

June 1, 1995 -"Adhesive Dentistry Update", Update in General Practice 1995 UNC School of Dentistry, Chapel Hill, NC.

June 15, 1995 -"Esthetic Porcelain Veneers" , Twelth Annual Dental Review, Myrtle Beach, SC.

September 19, 1995 -"Update in Posterior Composites", Wake County Dental Society, Raleigh, NC. (AHEC sponsored).

September 28, 1995 -"Conservative Esthetic Dentistry: A Potpourri", to Stanley County Dental Society, Albemarle, NC.(AHEC sponsored).

December 13, 1995 -"Conservative Concepts in Achieving Anterior Esthetics", to Mountain AHEC, Asheville, NC. (AHEC-sponsored half-day course)

June 15, 1996 -"Tooth Flexural Effects on Restorations and Teeth", Thirteenth Annual Dental Review, Myrtle Beach, SC.

July 15, 1996 -"Current Concepts in Adhesive Dentistry", Fayetteville AHEC (AHEC sponsored).

July 31, August 1 & 2, 1996 -"Tooth Flexural Effects on Restorations and Teeth", "Conservative Concepts in Anterior Esthetics", and "Esthetic Options in Perio Splinting" to CE course participants, Prosthodontics Update Course, Hilton Head, SC.

September 17, 1996 -"Esthetic Porcelain Veneers", to Raleigh-Wake County Dental Society, Raleigh, NC (AHEC sponsored).

October 7, 1996 -"Update in Dentin Bonding" video conference to Western NC Dental Society (AHEC sponsored).

October 18, 1996 -"What's New in Adhesive Dentistry", to Raleigh AHEC, Raleigh, NC (half-day course).

November 19, 1996 -"Keys to Successful Porcelain Veneers" to Durham-Orange Dental Society, Durham NC (AHEC sponsored).

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

January 31, 1997 -"Conservative Esthetic Dentistry: An Update" to Area L AHEC, Rocky Mount, NC (half-day course).

April 3, 1997 -"Conservative Esthetic Dentistry: A Potpourri" to Prima Dental Study Club, Greenville, NC (AHEC sponsored)

June 21, 1997 -"Vital and Non-vital Bleaching: What's the Word?" Fourteenth Annual Dental Review, Myrtle Beach, SC.

September 3, 1997 -"Successful Porcelain Veneers" to Lenoir County Dental Society, Kinston, NC (AHEC sponsored).

September 23, 1997 -"Current Concepts in Dentin Bonding" to Guilford County Dental Sociey, Greensboro, NC (AHEC sponsored).

October 9, 1997 -"New Age Concepts in Vital Bleaching" to Gaston County Dental Society, Gastonia, NC (AHEC sponsored).

November 7, 1997 -"What's New in Conservative Esthetic Dentistry" to Charlotte AHEC (AHEC sponsored half-day course).

November 21, 1997 -"Dentin Bonding: What's Hot and What's Not" to 43rd Annual Dental Seminar Day, UNC School of Dentistry.

February 27, 1998 -"Conservative Concepts for Achieving Anterior Esthetics," to Coastal AHEC. (1/2 day course)

August 18, 1998 -"Adhesive Dentistry Update," to Iredell-Alexander County Dental Society, Statesville, NC. (AHEC sponsored).

April 20, 1999 -"Treatment of Cervical Erosive Lesions of Teeth," to Jones-Craven-Pamlico Dental Society, New Bern, NC (AHEC course).

June 3, 1999 -"Keys to Successful Porcelain Veneers," to course participants of General Dentistry Update 1999, UNC School of Dentistry.

June 17, 1999 -"Tooth Sensitivity: Causes, Prevention and Treatment," to course participants of 16th Annual Dental Review, Myrtle Beach, SC.

October 12, 1999 -"Conservative Esthetic Dentistry: A Potpourri," to Mountain AHEC, Hendersonville, NC. (AHEC course)

October 19, 1999 -"Adhesive Dentistry: Proven Solutions vs. Opinions and Hype," to Iredell County Dental Society, Statesville, NC. (AHEC course)

October 20, 1999 -"Orthodontic Considerations in Esthetic Restorative Dentistry" to course participants, Ortho Mini-Residency, Chapel Hill, NC.

November 3, 1999 -"Adhesive Dentistry: Proven Solutions vs. Opinions and Hype" to Mountain AHEC, Asheville, NC. (half-day, AHEC course)

April 17, 2000 -"Update in Adhesive Dentistry, " to Alamance County Dental Society, Burlington, NC (AHEC course).

April 18, 2000 -"Adhesive Dentistry: Proven Solutions vs. Opinions and Hype" to Tar Heel Study Club, Boone, NC (AHEC course).

January 12, 2001 -"Perio Splinting and All-Porcelain Pontics," Hot Topics CE Course, Chapel Hill, NC.

February 13, 2001 -"Tooth Sensitivity: Causes, Prevention and Treatment" to Durham-Orange Dental Society, Durham, NC (AHEC course).

May 1, 2001 -"Update in Adhesive Dentistry," Wilmington Dental Society, Wilmington, NC (AHEC Course).

CONTINUING EDUCATION COURSES PRESENTED FOR UNC SCHOOL OF DENTISTRY/AHEC (Continued)

June 16, 2001 -"Clinical Considerations in Light Curing," 18th Annual Dental Review, Myrtle Beach, SC.

October 9, 2001 -"Artistry of Conservative Esthetic Dentistry," to Highpoint DS, Highpoint, (AHEC Course).

October 11, 2001 -"Tooth Sensitivity: Causes, Prevention and Treatment" to Gaston County Dental Society, Gastonia, NC (AHEC course).

November 6, 2002 -"Current Concepts in Veneering Techniques," to Iredell County Dental Society, Statesville, NC (AHEC).

November 29, 2002 -"Clinical Considerations in Light Curing," to Coastal AHEC, Wilmington, NC (Half-day AHEC course).

January 28, 2002 -"Tooth Sensitivity: Causes, Prevention and Treatment" to Alamance County Dental Society, Burlington, NC (AHEC course).

April 10, 2002 -"Artistry of Conservative Esthetic Dentistry," to Orthodontics Mini-Residency participants, UNC School of Dentistry.

June 27, 2002 -" Current Concepts in Veneering Techniques," and "All-Porcelain Bonded Pontics," to19th Annual Dental Review, Myrtle Beach, SC.

September 17, 2002 -"Artistry of Conservative Esthetic Dentistry," Coastal AHEC, Wilmington, NC (AHEC Course).

October 15, 2002 -"Esthetic Dentistry Update, 2002," Charlotte Dental Society (AHEC sponsored).

January 31, 2003 -"Facts and Fallacies of Vital Bleaching," as part of Hot Topics CE course, Chapel Hill, NC.

April 16, 2003 -"Whiter and Brighter: The Facts and Fallacies of Vital Bleaching," Highpoint Dental Society (AHEC sponsored).

May 7, 2003 -"Keys to Success with Etched Porcelain Veneers," Four Corners Dental Study Club (AHEC sponsored).

June 11, 2003 -"Keys to Success with Etched Porcelain Veneers," Area L AHEC (AHEC sponsored).

June 19, 2003 -" Adhesive Dentistry: Proven Solutions vs Opinion and Hype," to 20th Annual Dental Review, Myrtle Beach, SC.

September 3, 2003 -"Update in Conservative Esthetic Dentistry," Four Corners Dental Study Club, Greenville, NC (AHEC Course).

September 9, 2003	-"Esthetic Dentistry Update, 2003," Charlotte Dental Society (AHEC sponsored).
November 11, 2003	-"Esthetic Dentistry Update, 2003," Wilmington, NC (AHEC sponsored).
December 12, 2003	-"Adhesive Dentistry: Separating Fact from Fiction," Highpoint Dental Society (AHEC sponsored).
April 27, 2004	-"Update in Dentin Bonding," to Blueridge Dental Society, Elkin, NC (AHEC sponsored).
April 29, 2004	-"Esthetic Dentistry: An Update," to Stanley County Dental Society, Albemarle, NC (AHEC sponsored.)

THESES/STUDENT RESEARCH DIRECTED

1983	"Dental Auxiliary Utilization: Didactic and (degree date) Clinical Instruction," Masters Program (M.S. in Dental Auxiliary Teacher Education), Karen Lanier. (member of thesis committee)
1984	"A Comparison of Two Techniques Used for the Fabrication of Resin-Bonded Retainer Castings,"Masters Program (M.S. in Prosthodontics), William Gielincki, Jr. (member of thesis committee)
1986	"Cognitive Styles in Dental Students" Masters Program (M.Ed.), Linda Stewart (member of thesis committee)

THESES/STUDENT RESEARCH DIRECTED (Continued)

1986	"Liquid vs. Gel Etchants on Glass Ionomers: Effects on Bond Strengths and Surface Morphology" Steven Andreaus (student researcher) (Note: Mr. Andreaus presented paper at 1986 IADR, The Hague Netherlands, and won Dentsply International Student Clinician Award at 1986 A.D.A. Meeting based on this research.)
1986	"Effect of Etchant Viscosity on Resin/Enamel Bond Strength and Surface Morphology" Steven Andreaus (student research traineeship fellow) (Note: Mr. Andreaus selected among 10 finalists for IADR Edward H. Hatton Awards Competition, 1987 IADR Meeting, Chicago, IL.)
1996	"The Clinical and Microscopic Effects of Vital Bleaching and Enamel Micro-Abrasion on Surface Enamel", for Dr. L.S.M.Tong, University of Hong Kong (outside reviewer for Ph.D. dissertation)
1997	"Effects of Occlusion Type and Wear on Cervical Lesion Frequency". Masters Program (M.S. in Prosthodontics), Louis Marion (member of thesis committee).
1997	"In-vitro Analysis of Class V Retention Variables". Susanne Parkhurst, student research fellow.
1998	"Clinical Evaluation of CFA, OCA, FCA, PCA, and TBA for Posterior Composites" Masters Program (M.S. in Prosthodontics), Jacques Maurel (member of thesis committee).
2000	"Effects of Various Contaminants on the Bond Strengths of Resin to Enamel and Dentin," Masters Program (M.S. in Operative Dentistry), Bruno Rosa (Director of thesis committee).
2000	"Analysis of Collagen Cross Links and Dentin Bond Strengths as a Function of Acid-Etch, Re-Wetting Agents, and Adhesive Resins." Masters Program (M.S. in Operative Dentistry), Andre Ritter (member of thesis committee).

2001	"Curing Light Intensity Effects on the Structure and Mechanical Behavior of Polymer-Based Dental Composites", Masters Program (M.S. in Operative Dentistry), Annie St. Georges (member of thesis committee).
2001	"The Effect of Depth of Demineralization and Adhesive Composition on Microtensile Bond Strength to Human Dentin", Masters Program (M.S. in Operative Dentistry), Mauro Nunes (member of thesis committee).
2002	"Contamination Effects on Resin-to-Resin Microtensile Bond Strengths", Masters Program (M.S. in Operative Dentistry), Siggie Eiriksson (member of thesis committee).
2003	"Bond Strength of Self-Etching Primers to Enamel and Dentin Cut with Different Burs." Masters Program (M.S. in Operative Dentistry), Walter Dias (member of thesis committee).

THESES/STUDENT RESEARCH DIRECTED (Continued)

2003	"Effects of Prolonged Use of OTC Bleacing Materials on Enamel," Ricardo Walter, first year grad student (served as mentor).
2004	"Porosity and Marginal Integrity of a Novel Direct Ceramic Restorative Material." Masters Program (M.S. in Operative Dentistry), Jonas Geirsson (member of thesis committee).
2005	"In vitro Inhibition of Bacterial Growth and Carie Formation by Different Dental Materials." Masters Program (M.S. in Operative Dentistry), Ricardo Walter (member of thesis committee).
2006	Roongkit Leehacharoenkul: "Meta Analysis of xxx" (M.S. in Operative Denitstry- in progress), (member of thesis committee).
2006	Cristina Maresca, "Effect of Instrumentation on Enamel Surface Texture and Marginal Adaptation of Composite Restorations," (M.S. in Operative Denitstry- in progress), (member of thesis committee).

MAJOR RESEARCH INTERESTS

Current dental research interests are centered around clinical and *in vitro* research regarding esthetic restorative materials and techniques. Specific clinical research interests include long-term investigations of anterior and posterior composite resin restorations and also use of various proprietary dentin bonding agents in the treatment of Class V eroded lesions. Particular attention has been devoted to investigating specific co-variables such as patient age, tooth flexure, dentin sclerosis and their effects on restoration performance. Additionally, the etiology of cervical lesions is of research interest.

The clinical evaluation of computer-generated ceramic restorations (CAD/CAM) is also of particular interest, and long-term clinical studies have been conducted. Laboratory studies are centered around various aspects of adhesive bonding as well as studies regarding finishing and polishing procedures for bonded ceramic restorations.

Additional collaborative work with other faculty has centered around new vital bleaching techniques along with their safety and efficacy. Clinical trials are being conducted regarding the safety and efficacy of various commerical carbamide peroxide bleaching agents and whitening toothpastes.

PUBLICATIONS

Textbook Chapters

Sockwell CL, and Heymann, HO Chapter 11. Tooth colored restorations. In: Sturdevant CM, ed.The art and science of operative dentistry, 2nd Ed. St. Louis: CV Mosby Co; 1985.

Sockwell CL, Heymann HO, Brunson WD Chapter 12. Additional conservative and aesthetic treatments. In: Sturdevant CM, ed.The art and science of operative dentistry, 2nd Ed. St. Louis: CV Mosby Co; 1985.

Heymann, HO Chapter 11. Indirect composite resin veneers. In: Garber DA, Goldstein RE, Feinman R. Dental laminate systems, 1st Ed. Chicago: Quintessance Publishing Co.; 1988.

Goldstein RE, Haywood VB, Heymann HO, Steiner DR, West JD. Chapter 21: Vital bleaching techniques. In: Cohen S, Burns RC, eds. Pathways to the Pulp. St. Louis: CV Mosby Co; 1994.

Heymann HO, Haywood VB. Chapter entitled: Nightguard vital bleaching. In: Goldstein RE. and Garber DA. Vital bleaching techniques, 2nd Ed. Chicago: Quintessance Publishing Co.1995.

Sturdevant CM, Heymann HO, Roberson TM, Sturdevant JR, eds, The art and science of operative dentistry, 3rd Ed. St. Louis: CV Mosby Co; 1995.

Heymann HO, Roberson TM, Sockwell CL. Chapter 16. Tooth colored restorations.for Classes III, IV, and V preparations. In: Sturdevant CM, ed.The art and science of operative dentistry, 3rd Ed. St. Louis: CV Mosby Co; 1995.

Heymann HO, Sturdevant JR. Chapter 17. Tooth colored restorations.for Classes I, II, and VI preparations. In: Sturdevant CM, ed.The art and science of operative dentistry, 3rd Ed. St. Louis: CV Mosby Co; 1995.

Heymann HO, Sockwell CL, Haywood VB. Chapter 18. Additional conservative esthetic procedures. In: Sturdevant CM, ed.The art and science of operative dentistry, 3rd Ed. St. Louis: CV Mosby Co; 1995.

Roberson TM, Heymann HO, and Swift EJ, eds, The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

Roberson TM, Heymann HO, and Ritter AV. Chapter 11. Introduction to composite restorations. In: Roberson TM, ed.The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

Roberson TM, Heymann HO, Ritter AV, and Pereira, PNR. Chapter 12. Classes III, IV, and V direct composite and tooth-colored restorations. In: Roberson TM, ed.The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

Roberson TM, Heymann HO, Ritter AV, and Pereira, PNR. Chapter 13. Classes I, II, and VI direct composite and tooth-colored restorations. In: Roberson TM, ed.The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

PUBLICATIONS (Continued)

Textbook Chapters (Continued)

Heymann HO. Chapter 15. Additional conservative esthetic procedures. In: Roberson TM, ed.The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

Roberson TM, Heymann HO, and Ritter AV. Chapter 16. Introduction to amalgam restorations. In: Roberson TM, ed.The art and science of operative dentistry, 4th Ed. St. Louis: CV Mosby Co; 2001.

Journal Articles

*Shugars DA, Trent PJ, Heymann HO. Effectiveness of project ACORDE: applied research in a pre-clinical technique course. *J Dent Educ* 1979; 43(9):510-514.

Leinfelder KF, Wilder AD, and Heymann HO. Composites III. *NC Dent Gazette* 1981;3(4):6-7.

Heymann HO, Roberson TM. Operative dentistry in North Carolina: A survey. *NC Dent Gazette* 1981; 3(6):10-11.

*Heymann HO. Class III and Class V modified cavity preparations for composite resins. *J Tenn Dent Assoc* 1983; 63(4):46-49.

*Heymann HO. Resin-retained bridges: the natural tooth pontic. *Gen Dent* 1983; 31(6):479-482.

*Heymann HO, Roberson TM. Using survey information for curriculum revision. *J Dent Educ* 1984; 48(3):166-168.

*Heymann HO. Resin-retained bridges: the acrylic denture tooth pontic. *Gen Dent* 1984; 32(2):113-117.

*Heymann HO. Resin-retained bridges: the porcelain-fused-to-metal winged pontic. *Gen Dent* 1984; 32(3):203-208.

*Heymann HO, Hershey HG. The use of composite resin for restorative and orthodontic correction of anterior interdental spacing. *J Prosthet Dent* 1985; 53(6):766-774.

*Heymann HO, Wilder AD, May KN, Leinfelder KF. Two-year clinical study of composite resins in posterior teeth. *Dent Mater* 1986; 2(1):37-41.

*May KN, Heymann HO. Depth of penetration of Link series and Link Plus pins. *Gen Dent* 1986; 34(5):359-361.

*Brantley CF, Heymann HO, Shugars DA. Vann WF. The effect of latex surgical gloves on psychomotor skill acquisition among dental students. *J Dent Educ* 1986 50(10):611-613.

*Heymann HO. Indirect composite resin veneers: clinical technique and two-year observations. *Quint Inter* 1987; 18(2):111-118. Special Note: This article was selected as the U.S. entry to International Topic Focus issue of Quint Inter.

PUBLICATIONS (Continued)

Journal Articles (Continued)

*Heymann HO, Haywood VB, Andreaus SB, Bayne SC. Bonding agent strengths with processed composite resin veneers. *Dent Mater* 1987; 3(3): 121-124.

*Heymann HO. Veneers indiretti in compositi: tecnica clinica ed osservazioni a due anni. *Quint Inter* 1987; 3(4): 329-337.

*Heymann HO. The artistry of conservative esthetic dentistry. *J Amer Dent Assoc*, (special issue) 1987; 115(12E):14E-23E.

*Heymann HO. Carillas indirectas de resina compuesta: tecnica clinica y observaciones de dos anos. *Quint Inter* 1988; (2):85-94.

*Brantley CF., Heymann HO. De L'interet ou de la difficulte du port des gants. *J d'Odontologie Conservatrice* 1988; 7:47-49.

*Heymann HO, Sturdevant JR, Brunson WD, Wilder AD, Sluder TB, Bayne SC. Twelve-month clinical study of dentinal adhesives in Class V cervical lesions. *J Amer Dent Assoc*1988; 116(2):179-183.

*Haywood VB, Heymann HO, Kusy RP, Whitley JQ, Andreaus SB. Polishing porcelain veneers: An SEM and specular reflectance analysis. *Dent Mater* 1988; 4(3):116-121.

*Crumpler DC, Heymann HO, Shugars DA, Bayne SC, Leinfelder KF. Five-year clinical investigation of microfilled and conventional composite resins in anterior teeth. *Dent Mater* 1988; 4(4):217-222.

*Heymann HO, ed. Esthetic dentistry: ethics and excellence. *J Amer Dent Assoc* (special issue) 1988; 117(10).

*Haywood VB, Heymann HO, Scurria MS. Effects of water, speed, and experimental instrumentation on finishing and polishing porcelain intraorally. *Dent Mater* 1989 5(3): 185-188.

*Haywood VB, Heymann HO. Nightguard vital bleaching. *Quint Inter* 1989; 20(3): 173-176.

Heymann HO. CAD/CAM for ceramic inlays and onlays: the CEREC^{R} system. *Trans Acad Dent Mater* 1989; 2(1): 8-16.

*Heymann HO. A posterior composite teaching programme for the undergraduate. *J Dent* 1989; 17(1): 42-46.

*Haywood VB, Heymann HO. Gouttiere nocturne et blanchiment vital. *Clinic Odontologia* 1989; 10(2): 95-98.

*Haywood VB, Heymann HO. Imbianchimento di denti non devitalizzati mediante apparecchio notturno. *Quint Inter* 1990; 6(1): 37-40.

PUBLICATIONS (Continued)
Journal Articles (Continued)

*Heymann HO. Looking at CAD/CAM - the CEREC® system. *Compend Contin Educ Dent* 1990; 6(2): 64.

*Haywood VB, Leech T, Heymann HO, Crumpler DC, Bruggers K. Nightguard vital bleaching: effects on enamel surface texture and diffusion. *Quint Inter* 1990; 21(10): 801-804.

*Haywood VB, Heymann HO. Nightguard vital bleaching: How safe is it? *Quint Inter* 1991; 22(7):515-523.

*Heymann HO, Sturdevant JR, Bayne SC, Wilder AD, Sluder TB, Brunson WD. Examining tooth flexural effects on cervical restorations: a two-year clinical investigation. *J Amer Dent Assoc* 1991; 122(6):41-47.

*Haywood VB, Houck V, Heymann HO. Nightguard vital bleaching: effects of varying pH solutions on enamel surface texture and color. *Quint Inter* 1991; 22(10):775-782.

*Bayne SC, Heymann HO, Sturdevant JR, Wilder AD, Sluder TB. Contributing co-variables in clinical trials. *Am J Dent* 1991; 4: 247-250.
Heymann HO. Artistic elements in conservative esthetic dentistry. In: Aesthetic Dentistry II, *Proceedings of the FDI Symposium on Esthetics* 1991; 71:10-19.

*Haywood VB, Houck VM, Heymann HO. Uso di diversi prodotti per lo sbiancamento notturno di denti vitali con mascherine di resina. Effeto sul colore e sulla superficio dello smalto. *Quint Inter* 1992; 8(6/7):427-435.

*Haywood VB, Leech T, Heymann HO, Crumpler DC, Bruggers K. Blanqueamiento vital nocturno. Efectos sobre la textura de la superficie del esmalte y difusion. *Quint Inter* 1992; 5(2):65-68.

*Bayne SC, Taylor DF, Heymann HO. Protection hypothesis for composite wear. *Dent Mater* 1992; 8:305-309.

Heymann HO. Clinical co-variables in dentin adhesion. In: *Proceedings of international symposium on resin adhesives and glass ionomers*. 1993.

Heymann HO. Current concepts in dentin bonding. In: *Proceedings of NIH-ADA symposium on esthetic restorative materials*. American Dental Association 1993; 61-63.

*Haywood VB, Heymann HO. Blanqueamiento vital nocturno:que seguridad ofrece. *Quint Inter* 1993; 6(1):3-11.

*Heymann HO, Bayne SC. Current concepts in dentin bonding. *J Amer Dent Assoc* 1993; 124:26-36.

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Journal Articles (Continued)

*Bader J, Levitch LC, Shugars DA, Heymann HO, McClure F. Dentists' classification and treatment of non-carious cervical lesions. *J Amer Dent Assoc* 1993; 124:46-54.

*Shearer AC, Heymann HO, Wilson NHF. Two ceramic materials compared for the production of CEREC inlays. *J Dent* 1993; 21:302-304.

*Woolverton C.,Haywood VB, Heymann HO. Toxicity of two carbamide peroxide products used in nightguard vital bleaching. *Amer J Dent* 1993; 6(6):310-314.

*Shearer AC, Kusy RP, Whitley JQ, Heymann HO, Wilson NHF. Finishing of MGC Dicor CEREC restorations. *Inter J Prosthet* 1994; 7(2):167-173.

*Haywood VB, Heymann HO. Response of normal and tetracycline-stained teeth with pulp-size variation to nightguard vital bleaching: case reports. *J Esthet Dent,* 1994; 6(3):109-114.

*Heymann HO, Bayne SC. Current concepts in dentin bonding. *J Israel Dent Assoc* 1994; 11:18-28.

*Bayne SC, Heymann HO, Swift EJ. Update on composite restorations. *J Amer Dent Assoc,* 1994; 125(6):687-701..

*Levitch LC, Bader JD, Shugars DA, Heymann HO. Non-carious cervical lesions: a review. *J Dent ,* 1994; 22(4):195-207.

*Bayne SC, Taylor DF, Rekow ED, Wilder AD, Sturdevant JR, Heymann HO, Roberson TM. Confirmation of Leinfelder clinical wear standards. *Dent Mater* , 1994; 10:11-18.

*Shearer AC, Kusy RP, Whitley JQ, Heymann HO, Wilson NHF. Finitura del materiale Dicor MGC. *Odontoiatria Protesica,* 1994; 2:167-173.

*Swift EJ, Perdiago J, Heymann HO. Bonding to enamel and dentin: A brief history and state of the art. *Quint Inter,* 1995; 26(2):95-110.

*Heymann HO, Bayne SC. Current concepts in dentin bonding. *Norwegian Dent J* 1995; 105(5):232-239.

*Bayne SC, Heymann HO, Swift EJ. Puesta al dia sobre las restauraciones dentales con composite. *Arch Odonto Estomatologia* 1995; 11(10):578-594.

Heymann HO. Update on adhesive dentistry. *Dent Today* 1996; 15(1):42-45.

*Bayne SC, Heymann HO, Swift EJ. Duurzaamheid van composieten. *Nederlands Tandartsenblad* 1996; 51:566-568.

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*Heymann HO, Bayne SC, Wilder AD, Studrdevant JR, Roberson TM. Four-year clincal study of CAD/CAM generated ceramic inlays. *J Amer Dent Assoc* 1996; 127:1171-1181.

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Videotapes

Heymann HO. "Clinical Technique for Etched Porcelain Veneers." UNC, 1999.

Television Segments

May 25, 1984	-Television segment entitled "Tooth Bonding" for program entitled "Medical Beat," WRAL-TV, Raleigh, NC.
September 15, 1984	-Television segment entitled "Dentistry Today and in the Future"for program entitled "Carolina Saturday," WRAL-TV, Raleigh, NC.
August 14, 1989	-"CAD/CAM in Dentistry" CNN Interview and news brief for television.
April 12, 1991	-Television interview for Ivanhoe Communications entited "CAD/CAM in Dentistry" for nationwide distribution.
March 15, April 12, June 14, November 15,1992 and July 25, 1993 (and misc. subsequent dates)	-Television segment entitled "Esthetics in General Practice" produced by the American Dental Association and aired nationally on the weekly T.V. program *Dentistry Update* on the Lifetime Medical Network.
March 5, 1993	-Taped television segment on "CAD/CAM in Dentistry" for nationally airing on FOX TV network.
July 30, 1997	-Television segment entitled "Colgate Total Toothpaste", WRAL-TV, Raleigh, NC.
August 22, 1997	-Television segment entitled "Toothpastes: Do They Work?", WRAL-TV, Raleigh, NC.
September 22, 1997	-Television segment entitled "Oral Body Piercings", WRAL-TV, Raleigh, NC.
October 15, 1997	-Television segment on "Tooth Whitening" for nationally aired program, "Health Week" on PBS TV network.
October 29, 1997	-Television segment entitled "Adult Orthodontics", (Dr. Barabara Hershey interviewed) WRAL-TV, Raleigh, NC.
January 14, 1998	-Television segment entitled "Toothbrushing", WRAL-TV, Raleigh, NC.
February 4, 1998	-Television segment entitled "Seal the State in 98 Campaign", WRAL-TV, Raleigh, NC.

Television Segments (Continued)

February 23, 1998	-Television segment entitled "Bleaching Teeth", WRAL-TV, Raleigh, NC.
March 23, 1998	-Television segment entitled "Perio and General Health", (Dr. Ray Williams interviewed) WRAL-TV, Raleigh, NC.
June 2, 1998	-Television segment entitled "Digital X-rays", WRAL-TV, Raleigh, NC.
June 17, 1998	-Television segment entitled "Dealing with Wisdom Teeth",

	WRAL-TV, Raleigh, NC.
July 14, 1998	-Television segment entitled "Tricho Dento Osseous Syndrome", (Dr.Tim Wright interviewed) WRAL-TV, Raleigh, NC.
September 8, 1998	-Television segment entitled "Dental Trauma",WRAL-TV, Raleigh, NC.
September 22, 1998	-Television segment entitled "UNC School of Dentistry", (Dr. John Stamm interviewed),WRAL-TV, Raleigh, NC.
October 30, 1998	-Television segment entitled "Protecting Your Braces", WRAL-TV, Raleigh, NC.
January 8, 1999	-Television segment entitled "Periostat", WRAL-TV, Raleigh, NC.
February 4 & 5, 1999	-Television segments entitled "Tooth Whitening", WTVD-TV, Durham, NC.
February 15, 1999	-Television segment entitled "Dental Care for Cancer Patients", WRAL-TV, Raleigh, NC.
January 23, 2003	-Television segment entitled "What's New in Tooth Whitening", KDTV, Channel 9, Denver, CO.

Web-Based CE Courses

2001	-"Tooth Sensitivity: Causes, Prevention and Treatment," DenTrek.com.
2001	-"Perio Splinting and Provisional Resin-Bonded Bridges," DenTrek.com.
2002	-"Clinical Considerations in Light Curing," DenTrek.com.

Self-Instructional Units, Course Syllabi, and Educational Material

Heymann HO, Shugars DA. Slide-tape, self-instructional unit entitled: "Modified Cavity Preparation and Restoration of Class III Lesions for Composite Resins," UNC School of Dentistry, May, 1980.

Heymann HO, Roberson TM. Statewide questionnaire entitled: "Operative Dentistry in North Carolina: A Survey," NCMH Press, September, 1980.

Heymann HO, May KN. Dental Science I Course Syllabus, UNC School of Dentistry, Fifth, Sixth, and Seventh Editions, 1983, 1984, 1985. (150 pages-revised annually)

Self-Instructional Units, Course Syllabi, and Educational Material (Continued)

Heymann HO. Conservative Operative Dentistry Course Syllabus, UNC School of Dentistry, First through Fourth Editions, 1986-1989 (120 pages)

Heymann HO, Roberson TM. Conservative Operative Dentistry Course Syllabus, UNC School of Dentistry, Fifth -Seventh Editions, 1990-1992. (120 pages)

GRANTS AND CONTRACTS

Federal Research Grants

Title: "Biopsy and Analysis of 5 to 10 Year Old Composites"
Grant Type or Number: 1-RO1-DE08005
Grant Amount: $533,227 (Direct Costs)
Grant Period: 5-1-87 to 4-30-90
Grant Status: APPROVED (Score=174)/FUNDED $320,272
Principal Investigators: Bayne, S.C. and Taylor, D.F.
Co-Investigator: Heymann, H.O. [5%]

Title: "Evaluation of Protection Hypothesis for Composite Wear"
Grant Type or Number: 1-R01-DE08651
Grant Amount: $808,971 (Direct and Indirect Costs)
Grant Period: 12-1-88 to 11-30-91
Grant Status: APPROVED (Score=158)/FUNDED $745,304
Principal Investigator: Bayne, S.C.
Co-Investigator: Heymann, H.O. [8%]

Title: "Computer Assisted Analysis of Intraoral Surface Changes"
Grant Type or Number: 1-R01-DE0
Grant Amount: $1,039,748 (Direct and Indirect Costs)
Grant Period: 9-1-88 to 8-31-91
Grant Status: APPROVED (Score=245)/NOT FUNDED-
Principal Investigators: Rekow, E.D. and Bayne, S.C.
Co-Investigator: Heymann, H.O. [10%]

Title: "Optimizing the Surface Texture of Esthetic Materials"
Grant Type or Number: 1-RO1-DEO8691-01
Grant Amount: $433,003 (Direct and Indirect Costs)
Grant Period: 4-1-89 to 3-31-92
Grant Status: APPROVED (Score=294, Percentile=70.7)/
NOT FUNDED
Principal Investigator: Kusy, R.P.
Co-Investigator: Heymann, H.O. [10%]

Title: "Clinical Failure Analysis of Composites Versus Amalgams"
Grant Type or Number: 1-RO1-DE09019-01
Grant Amount: $1,047,688 (Direct and Indirect Costs)
Grant Period: 2-1-89 to 1-31-93
Grant Status: APPROVED (Score=296)/NOT FUNDED
Principal Investigator: Bayne, S.C.
Co-Investigator: Heymann, H.O. [10%]

GRANTS AND CONTRACTS (Continued)
Federal Research Grants (continued)

Title: "Natural History of Non-Carious Cervical Lesions"
Grant Type or Number: 1-RO1-DE/AG11096
Grant Amount: $600,000 (Direct Costs)
Grant Period: 7-1-94 to 6-30-98
Grant Status: APPROVED (Score=202) NOT FUNDED
Principal Investigator: Bader, J.D.
Co-Investigator: Heymann, H.O. [10%]

Subgrants of NIH/NIDR Dental Research Institute Grant

Title: "Clinical Evaluation of Polishable (Microfine) Composite Resin Restorations"
Grant Type or Number: NIH/NIDR 4-P50-DE02668 and RR05333
Grant Amount: Subgrant of DRI Grant
Subgrant Period: 1979-1982
Activity Period: 1979-1985
Grant Status: APPROVED/FUNDED
Subgrant Principal Investigator: Heymann, H.O.

Title: "Quantitative Measurement of Wear on Posterior Composite Restorations" (Laboratory Study)
Grant Type or Number: NIH/NIDR 4-P50-DE02668
Grant Amount: Subgrant of DRI Grant
Subgrant Period: 1983-1984
Activity Period: 1983-1985
Grant Status: APPROVED/FUNDED
Co-Investigator: Heymann, H.O.

Industrial Research Contracts

Title: "Clinical Evaluation of Posterior Composites"
Contract Numbers: RR05333 and Subgrant of 5-P50-DE02668-20
Grant Source: ESPE Dental Products Co.
Grant Amount: $15,600
Grant Period: 5-1-81 to 4-30-86
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of Posterior Composites"
Contract Numbers: RR05333 and Subgrant of 5-P50-DE02668-20
Grant Source: Johnson and Johnson
Grant Amount: $26,712
Grant Period: 3-1-82 to 2-28-85
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, A.D.
Co-investigator: Heymann, H.O.

Title: "Clinical Evaluation of Valiant Amalgam Alloy"
Contract Numbers: RR05333 and Subgrant of 5-P50-DE02668-20
Grant Source: Caulk/Dentsply
Grant Amount: $18,588
Grant Period: 2-1-82 to 10-31-85
Grant Status: APPROVED/FUNDED
Principal Investigator: May, K.N.
Co-investigator: Heymann, H.O.

Title: "Clinical Evaluation of Dentinal Adhesives"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8150
Grant Source: Caulk/Dentsply
Grant Amount: $65,640
Grant Period: 6-1-85 to 12-31-88
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H.O.

Title: "Bond Strengths of Indirect Resin Veneers"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8460
Grant Source: ESPE/Premier
Grant Amount: $1,000
Grant Period: June, 1986
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H.O.

Title:"Clinical Evaluation of a New Hybrid Composite in Class IV Preparations"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8150
Grant Source: Kerr/Sybron
Grant Amount: $30,000
Grant Period: 4-1-88 to 3-31-91
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Anterior Composite in Class III and Class V Restorations"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8460
Grant Source: ESPE Dental Products Co.
Grant Amount: $38,000
Grant Period: 10-1-88 to 9-30-91
Grant Status: APPROVED/FUNDED
Principal Investigator: Sluder, T.B.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of Computer-Generated Ceramic Inlays: The CEREC System"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8540
Grant Source: Siemens, U.S.A.
Grant Amount: $38,000
Grant Period: 3-1-89 to 8-31-93
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New Composite Resin in Posterior Teeth"
Contract Numbers: 6-66193-0-1-1-4375; Subacct. 8460
Grant Source: ESPE Dental Products Co.
Grant Amount: $64,000
Grant Period: 4-1-89 to 3-31-95
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, A.D.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New Light-Cured Glass Ionomer (Variglass)"
Contract Numbers: 4-25073-0-401-4375
Grant Source: L. D. Caulk Co.
Grant Amount: $48,000
Grant Period: 1-30-92 to 6-30-95
Grant Status: APPROVED/FUNDED
Principal Investigator: Sturdevant, J.R.
Co-Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Light-Cured Glass Ionomer (Fuji II LC)"
Contract Numbers: 4-25109-0-401-4375
Grant Source: GC America
Grant Amount: $42,000
Grant Period: 5-1-92 to 11-1-95
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, A.D.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of Dentin Adhesion in Sclerotic vs. Non-Sclerotic Lesions (Gluma 2000)"
Contract Numbers: 4-25194-0-401-4375
Grant Source: Bayer A/G
Grant Amount: $65,000
Grant Period: 11-1-92 to 4-30-96
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H. O.

Title: "Clinical Evaluation of a New Stress Breaking Dentinal Adhesive (Opti-Bond)"
Contract Numbers: 4-25141-0-401-4375
Grant Source: Kerr/Sybron
Grant Amount: $78,000
Grant Period: 11-1-92 to 4-30-96
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, A.D.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New Light-Cured Dentinal Adhesive (ProBond)"
Contract Numbers: 4-25287-0-401-4375
Grant Source: L. D. Caulk Co.
Grant Amount: $42,000
Grant Period: 9-15-93 to 12-15-96
Grant Status: APPROVED/FUNDED
Principal Investigator: Sturdevant, J.R.
Co-Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Light-Cured Glass Ionomer (Fuji II LC Caps)"
Contract Numbers: 4-25109-0-401-4375
Grant Source: GC America
Grant Amount: $11,200
Grant Period: 10-1-92 to 11-30-96
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, A.D.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New Carbamide Peroxide Tooth Whitening Agent (NuPro Gold)"
Contract Numbers: 4-25532-0-401-4375
Grant Source: Ashe/Dentsply
Grant Amount: $31,980
Grant Period: 11-1-95 to 10-31-96
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift EJ
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New Accelerated Carbamide Peroxide Tooth Whitening Agent (Platinum Overnight)"
Contract Numbers: 4-25619-0-401-4375
Grant Source: Colgate Oral Pharmaceuticals
Grant Amount: $53,966
Grant Period: 7-1-96 to 12-31-97
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, H. O.

Title: "Clinical Evaluation of a New Single Component Dentin Adhesive (Optibond Solo)"
Contract Numbers: 4-25706-0-401-4375
Grant Source: Kerr/Sybron
Grant Amount: $54,000
Grant Period: 1-1-97 to 12-31-98
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift, E.J..
Co-Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Posterior Composite (Pertac Hybrid II)"
Contract Numbers: 4-25661-0-401-4375
Grant Source: ESPE
Grant Amount: $48,000
Grant Period: 1-1-97 to 6-30-2001
Grant Status: APPROVED/FUNDED
Principal Investigator: May, K.N.
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a Treatment for Cervical Dentin Hypersensitivity (Prime and Bond 2.1)"
Contract Numbers: 4-25768-0-401-4375
Grant Source: Caulk/Dentsply
Grant Amount: $26,400
Grant Period: 8-1-97 to 12-31-99
Grant Status: APPROVED/FUNDED
Principal Investigators: Swift, E.J. & May, K.N..
Co-Investigator: Heymann, H.O.

Title: "Clinical Evaluation of a New One-Bottle Dental Bonding System (3M Single Bond)"
Contract Numbers: 4-25807-0-401-4375
Grant Source: 3M Dental Products Co.
Grant Amount: $65,000
Grant Period: 12-1-97 to 9-1-01
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann H.O..

Title: "Clinical Evaluation of a New Condensable Posterior Composite"
Contract Numbers: 4-25792-0-401-4375
Grant Source: Caulk/Dentsply
Grant Amount: $58,250
Grant Period: 10-1-97 to 12-31-01
Grant Status: APPROVED/FUNDED
Principal Investigator: Perdigão J.
Co-Investigator: Heymann, H.O.

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Adhesive (LP-2) for Composite Restorations"
Contract Numbers: 4-26048-0-401-4375
Grant Source: ESPE Dental Medizin
Grant Amount: $49,900
Grant Period: 7-1-99 to 8-31-01
Grant Status: APPROVED/FUNDED
Principal Investigator: Wilder, AD
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of a New One-Bottle Dentin Adhesive" (Excite)
Contract Numbers: 4-25998-0-401-4375
Grant Source: Ivoclar North America
Grant Amount: $39,940
Grant Period: 4-1-99 to 3-31-01
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift, EJ
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of a Novel 5.3% Hydrogen Peroxide Whitening Agent" (White Strips)
Contract Numbers: 4-26175-0-011-4375
Grant Source: Procter and Gamble
Grant Amount: $114,005
Grant Period: 3-23-00 to 6-30-00
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift EJ
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of a New Improved Whitening Agent" (White Strips)
Contract Numbers: 4-26265-0-401-4375
Grant Source: Procter and Gamble
Grant Amount: $72,000
Grant Period: 9-1-00 to 6-30-01
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift EJ
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of a New Improved Whitening Agent" (White Strips)
Contract Numbers: 4-26372-0-401-4375
Grant Source: Procter and Gamble
Grant Amount: $163,914
Grant Period: 7-1-01 to 6-30-02
Grant Status: APPROVED/FUNDED
Principal Investigator: Swift EJ
Co-Investigator: Heymann, HO

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a New Enzyme Whitening Toothpaste"
Contract Numbers: Pending
Grant Source: Colgate Oral Pharmaceuticals
Grant Amount: $46,200
Grant Period: 1-1-02 to 12-31-02
Grant Status: APPROVED/FUNDED
Principal Investigator: Heymann, HO

Title: "Clinical Evaluation of a New All-in-One Dentin Adhesive"
Contract Numbers: 4-26445-0-401-4375
Grant Source: Heraeus Kulzer Gmbh and Co. KG
Grant Amount: $56,000
Grant Period: 01-01-02 to 6-30-06
Grant Status: APPROVED/FUNDED
Co-Principal Investigators: Heymann, HO and Ritter, AV

Title: "Clinical Evaluation of a Fluoride Varnish for Cervical Dentin Sensitivity"
Contract Numbers: Pending
Grant Source: Dentsply Professional
Grant Amount: $51,454
Grant Period: 04-01-02 to 12-31-03
Grant Status: APPROVED/FUNDED
Principal Investigators: Andre Ritter
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of a Two-Component Self-Etching Adhesive and Hybrid Composite"
Contract Numbers: Pending
Grant Source: Caulk/Dentsply
Grant Amount: $75,000
Grant Period: 02-01-02 to 01-31-06
Grant Status: APPROVED/FUNDED
Principal Investigators: Ed Swift
Co-Investigator: Heymann, HO

Title: "Clinical Evaluation of the Safety and Efficacy of an Experimental Tooth Bleaching Strip Compared to a Placebo"
Contract Numbers: Pending
Grant Source: Proctor and Gamble
Grant Amount: $75,000
Grant Period: 4-21-03 to 12-31-03
Grant Status: APPROVED/FUNDED
Principal Investigators: Ed Swift
Co-Investigator: Heymann, HO

GRANTS AND CONTRACTS (Continued)
Industrial Research Contracts (continued)

Title: "Clinical Evaluation of a Self-Etching Adhesive and a Flowable Composite for Class V Restorations"
Contract Numbers: Pending

Grant Source: Tokuyama America, Inc.
Grant Amount: $43,568
Grant Period: 4-1-03 to 12-31-05
Grant Status: APPROVED/FUNDED
Co-Principal Investigators: Pereira, P and Swift, EJ
Co-Investigator: Heymann, HO

Miscellaneous Grants

Title: "Porcelain Veneers: Bond Strength, Marginal Adaptation, and Polishability"
Grant Source: Junior Faculty Achievement Award
Grant Amount : $3,000
Grant Period: 1986
Principal Investigator: Haywood, V.B.
Co-investigators: Heymann, H.O.

Education Grants

Title: "3D Animations for Teaching Synthesis of Complex Ideas"
Grant Number: 2-43302-2-101-4330
Grant Source: UNC Technology Grant
Grant Amount: $24,500
Grant Period: 1997
Principal Investigator: Bayne, S.C.
Co-investigator: Heymann, H. O.

Foundation Grants

Title: "Clinical Practice Characteristics of North Carolina Dentists in the Field of Operative Dentistry"
Grant Source: North Carolina Dental Foundation
Grant Amount: $500
Principal Investigator: Heymann, H.O.
Co-investigator: Roberson, T.M.

Study Grants

July 20-August 14, 1982	- Awarded foreign study grant by German Academic Exchange Service (Deutsche Academische Auslandsdienst-DAAD)

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CURRICULUM VITAE

IAN CRAIG MUNRO

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EDUCATION

1970 Ph.D., Toxicology and Pharmacology, Queen's University, Kingston, Ontario, Canada
1967 M.Sc., Nutrition, McGill University, Montreal, Canada
1962 B.Sc., McGill University, Montreal, Canada

ACCREDITATION

1999 Fellow of The Academy of Toxicological Sciences
1988 Fellow of Royal College of Pathologists, London, England

EMPLOYMENT HISTORY

1999-Present **University of Toronto,** Professor, Department of Nutritional Sciences, Faculty of Medicine and Associate Director, Program in Food Safety, Nutrition and Regulatory Affairs.
1999-Present **CANTOX Health Sciences International,** Mississauga, Ontario. President.
1985-1999 **CanTox Inc.,** Consultants in Health and Environmental Sciences. Mississauga, Ontario, Consultant Toxicologist & Principal.
1983-1992 **Canadian Centre for Toxicology**, Guelph, Ontario, Canada. Director.
1981-1983 **Health and Welfare, Canada**, Food Directorate, Health Protection Branch. Ottawa, Canada. Director General.
1976-1981 **Health and Welfare**, **Canada**, Bureau of Chemical Safety, Food Directorate, Health Protection Branch, Ottawa, Canada. Director.
1975-1976 **Health and Welfare, Canada**, Bureau of Chemical Safety, Health Protection Branch, Ottawa, Canada. Chief, The Division of Toxicology.
1974-1976 **Health and Welfare, Canada**, Bureau of Chemical Safety, Health Protection Branch. Ottawa, Canada. Section Head, The Division of Toxicology.

1963-1974 **Health and Welfare, Canada**, Health Protection Branch, Ottawa, Canada. Research Scientist.

COMMITTEE MEMBERSHIPS

2002	Technical Advisory Committee, World Food Program (WFP), The Food Aid Organization of the United Nations
2001	Chairman, Safety Assessment of Foods Derived from Genetically Modified Microorganisms. World Health Organization, Headquarters, Geneva, Switzerland – September 2001
2000-Present	Member, Georgetown Dialogue Science Council, Georgetown University Center for Food and Nutrition Policy (CFNP)
2000-Present	Consultant, FEMA Expert Panel
1999	Center for Food Safety and Applied Nutrition (CFSAN) Research Program Committee, Food and Drug Administration
1998-2001	Member, Minister's Advisory Board, Canadian Food Inspection Agency
1996-2002	Chairman, Institute of Medicine, Subcommittee on Upper Safe Reference Levels of Nutrients
1996 American	Member, Ad Hoc Expert Panel, Life Sciences Research Office, Federation of Societies for Experimental Biology (FASEB)
1993	Member FAO/WHO Expert Committee on Food Additives
1989	Chairman, Expert Group to Develop a Threshold of Regulation for Indirect Food Additives
1989-1991	Member, Scientific Committee, International Food Biotechnology Council
1985-2000	Member, FEMA Expert Panel
1985	Member ILSI-NF, Nutrition and Safety Committee (FNSC)
1985	Member, NAS, Committee on Carcinogenicity of Cyclamates.
1984	Member, Committee on Food Chemicals Codex.
1983-1984	Member, Panel of Chemical Carcinogenesis Testing and Evaluation (National Toxicology Program)
1983	Member, The Nutrition Foundation Project on the Use of Mouse Hepatoma Data.
1981-1983	Expert Committee on the Relevance of Mouse Liver as a Model for Assessing Carcinogenic Risk, The Nutrition Foundation, Inc.
1981-1982	Expert Advisory Committee to The Nutrition Foundation, Inc., on the Assessment of the Safety of Lead and Lead Salts in Foods.
1981	Chairman, International Committee on Hazards Associated with Dioxin in the Great Lakes.
1981	Chairman, WHO Ad Hoc Meeting on the Future of Joint Expert Committees in the Context of the International Program on Chemical Safety, Geneva.
1980-1983	Chairman, Health Protection Branch/Food Industry Liaison Committee.
1980-1983	Chairman, Interdepartmental Committee on Canning Regulations.
1980	Member, Federal Interdepartmental Salmonella Committee.
1980	Member, Senior Level Committee (U.S., U.K., Canada).
1980	Member, International Life Sciences Institute Experts in Pathology and Toxicology.
1980	Member, Technical Committee: WHO International Program on Chemical Safety.
1978-1980	Expert Committee on Food Safety - Agriculture Canada
1978-1980	Food Safety Council, Social and Economic Committee.
1978-1979	U.S. National Academy of Sciences, Subcommittee on Risk Assessment - Safe Drinking Water Committee.
1978	Chairman, Tripartite Toxicology Committee (U.S., U.K., Canada).
1977-1981	International Commission for Protection Against Environmental Mutagens and Carcinogens (ICPEMC), subcommittee 3.

1977-1979 U.S. National Cancer Institute, Cause and Prevention Scientific Review Committee.
1976-1984 WHO/FAO Joint Expert Committee on Food Additives.
1976-1980 Food Safety Council, Toxicology Committee.
1976-1979 Canadian Council on Animal Care.
1976-1979 Interdepartmental Committee on Toxicology Needs in Canada.
1976-1978 National Research Council Task Force on Mercury and Captan.
1975-1976 U.S. National Academy of Sciences Committee on Toxicology
1975-1976 WHO/FAO Committee on Criterion Documents on the Toxicology of Environmental Chemicals.

EDITORIAL RESPONSIBILITIES

1982-1996 Editorial Board Journal of the American College of Toxicology
1979-1991 Advisory Board Neurotoxicology
1978-1989 Editorial Board Journal of Environmental Pathology and Toxicology

PROFESSIONAL AFFILIATIONS

Professional Society Memberships:

Member, Society of Toxicology
Member, Toxicology Forum
Member, Society of Toxicology of Canada
Member, American College of Toxicology
Member, Institute for Risk Research
Member, International Society of Regulatory Toxicology and Pharmacology
Member, Institute of Food Technologists

Contributions to Professional Societies:

2004-Present The Academy of Toxicological Sciences, Board or Directors
1981 Professional Standards Evaluation Board in General Toxicology, Academy of Toxicological Sciences
1978-1979 Society of Toxicology, Nominating Committee
1978-1979 Society of Toxicology, Finance Committee
1976-Present Toxicology Forum, Inc., Board of Directors

AWARDS

1998 International Society of Regulatory Toxicology and Pharmacology “International Achievement Award” for his guiding role as Chairman of the Expert Panel of Members – “Interpretive Review of the Effects of Chlorinated Organic Chemicals”.
1975 Society of Toxicology "Achievement Award" for outstanding contributions to the science of toxicology by an individual 35 years of age or younger.

SCIENTIFIC PUBLICATIONS AND MONOGRAPHS

Munro, I.C., Newberne, P.M., Young, V.R., and Bär, A. 2004. Safety Assessment of γ-Cyclodextrin. Reg Toxicol Pharmacol 39:S3-S13.

Adams, T.B., Cohen, S.M., Doull, J., Feron, V.J., Goodman, J.I., Marnett, L.J., Munro, I.C., Portoghese, P.S., Smith, R.L., Waddell, W.J., and Wagner, B.M. 2004. The FEMA GRAS Assessment of Cinnamyl Derivatives Used as Flavor Ingredients. Food Chem Toxicol 42:157-185.

Munro, I.C. *et al.* 2003. Guidance for the Safety Assessment of Botanicals and Botanical Preparations for Use in Food Supplements. Expert Group Report reviewed at a Workshop held in May 2002, Marseille, France. Organized by the International Life Science Institute (ILSI) Europe Natural Toxin Task Force. Food Chem Toxicol 41:1625-1649.

Hlywka, J.J., Reid, J.E., and Munro, I.C. 2003. Review: The Use of Consumption Data to Assess Exposure to Biotechnology-Derived Foods and the Feasibility of Identifying Effects on Human Health Through Post-Marketing Monitoring. Food Chem Toxicol 41:1273-1282.

Feron, V.J., Adams, T.B., Doull, J., Goodman, J.I., Hall, R.L., Marnett, L.J., Munro, I.C., Portoghese, P.S., Smith, R.L., Waddell, W.J., and Wagner, B.M. 2004. Safety Evaluation of Natural Flavour Complexes. Toxicol Lett 144(Suppl. 1):S16.

Munro, I.C., Haighton, L.A., Lynch, B.S., Hlywka, J.J., Doull, J., and Kroes, R. 2003. Letter to the Editor – Response to "Does Exposure to Bisphenol A Represent a Human Health Risk?" Reg Toxicol Pharmacol 37:409-410.

Munro, I.C., Harwood, M., Hlywka, J.J., Stephen, A.M., Doull, J., Flamm, W.G., and Adlercreutz, H. 2002. Soy Isoflavones: A Safety Review. Nutr Rev 61(1):1-33.

Munro, I.C., Haighton, L.A., Hlywka, J.J., Lynch, B.S., Doull, J., and Kroes, R. 2002. Reply to Letter to the Editor – Carcinogenicity Bioassay of Bisphenol A. Toxicol Sci 70, pp. 283-284.

Munro, I.C. 2002. The Precautionary Principle and the Scientific Risk Assessment Process. Submitted to Regul Toxicol Pharmacol July 31, 2002.

Munro, I.C. *et al.* 2002. Exposure From Food Contact Materials: Summary Report of a Workshop Held in October 2001 in Ispra, Italy. ILSI Europe Packaging Material Task Force in Collaboration with the European Commission's Joint Research Centre (JRC). International Life Science Institute (ILSI) Press; Washington, DC.

Butchko, H.H., Stargel, W.W., Comer, C.P., Mayhew, D.A., Benninger, C., Blackburn, G.L., de Sonnevile, L.M.J. Geha, R.S., Hertelendy, Z., Koestner, A., Leon, A.S., Liepa, G.U., McMartin, K.E., Mendenhal, C.L., Munro, I.C., Novotny, E.J., Renwick, A.G., Schiffman, S.S., Schomer, D.L., Shaywitz, B.A., Spiers, P.A., Tephly, T.R., Thomas, J.A., and Trefz, F.K. 2002. Aspartame: Review of Safety. Reg Toxicol Pharmacol 35(No.2) Part 2 of 2.

Adams, T.B., Doull, J., Feron, V.J., Goodman, J.I., Marnett, L.J., Munro, I.C., Newberne, P.M., Portoghese, P.S., Smith, R.L., Waddell, W.J., and Wagner, B.M. 2002. The FEMA

GRAS Assessment of Pyrazine Derivatives Used as Flavor Ingredients. Food Chem Toxicol 40:429-451.

Munro, I.C., Hlywka, J.J., and Kennepohl, E.M. 2002. Risk Assessment of Packaging Materials. Food Addit Contam 19(Suppl. 3-12):3-12.

Munro, I.C., Haighton, L.A., Hlywka, J.J., Lynch, B.S., Doull, J., and Kroes, R. 2002. Letter to the Editor – Carcinogenicity Bioassay of Bisphenol A. Toxicol Sci 66(2) p. 356.

Stephen, A.M., Liston, A.J., Anthony, S.P., Munro, I.C., and Anderson, G.H. 2002. Regulation of Foods with Health Claims: A Proposal. Can J Pubic Health 93(5):328-331.

Haighton, L.A., Hlywka, J.J., Doull, J., Kroes, R., Lynch, B.S., and Munro, I.C. 2002. An Evaluation of the Possible Carcinogenicity of Bisphenol A to Humans. Reg Toxicol Pharmacol 35(2, Part 1) pp. 238-254.

Kennepohl, E., and Munro, I.C. 2001. Phenoxy Herbicides (2,4-D). Volume 2. Handbook of Pesticide Toxicology. Academic Press, pp. 1623-1638.

Chassy, B.M., Abramson, S.H., Bridges, A., Dyer, W.E., Faust, M.A., Harlander, S.K., Hefle, S.L., Munro, I.C., Rice, M.E. 2001. Evaluation of the U.S. Regulatory Process for Crops Developed Through Biotechnology. CAST 19:September.

Chassy, B., and Munro, I.C. 2001. Evolution d'un Principe Fondateur. La Recherche (February) 339:70-72.

Munro, I.C., and Kennepohl, E. 2001. Comparison of Estimated Daily *Per Capita* Intakes of Flavouring Substances with No-Observed-Effect Levels from Animal Studies. Food Chem Toxicol 39(4):47-70.

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PRESENTATIONS

Munro, I.C. 2004. An Overview of the Safety Evaluation of Essential Oils by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Presented at the FEMA Expert Panel Meeting, Lisbon, Portugal, October 27-29.

Munro, I.C. 2004. Safety Assessment of Nutritionally Improved Foods and Feeds Developed Through the Application of Modern Biotechnology. **Hlywka, J., and Munro, I.C.** The Feasibility of Postmarket Monitoring of Foods Derived Through Biotechnology to Identify Effects on Human Health.
Presented at the ILSI Workshop on Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology, Buenos Aires, Argentina, October 7-8.

Munro, I.C. 2004. Threshold of Toxicological Concern and Safety Evaluation of Food Ingredients. Presented at the 31st Annual Meeting of the Japanese Society of Toxicology, Osaka, Japan, July 6-8, 2004.

Munro, I.C. 2004. Biomarkers and Standards of Evidence: Requirements for a Health Claim on Foods. Presented at the Canadian Society for Clinical Nutrition (CSCN) 3rd Annual Scientific Meeting, "Nutrition and Cardiovascular Disease in Cancer", Toronto, Ontario, April 23, 2004.

Munro, I.C. 2003. **Safety Assessment of Nutritionally Improved Foods and Feeds Developed through the Application of Modern Biotechnology.** Hlywka, J., and Munro, I.C. **The Feasibility of Postmarket Monitoring of Foods Derived Through Biotechnology to Identify Effects on Human Health. Presented at the Workshop on Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved Through Biotechnology. Organized by the ILSI International Food Biotechnology Committee (IFBiC), Paris France, December 18.**

Munro, I.C. 2003. **The JECFA Procedure for the Safety Evaluation of Flavoring Substances. Presented at the 3rd ASEAN Food Safety Standards Harmonization Workshop, Jakarta, Indonesia, December 10-11.**

Munro, I.C. 2003. 1. The JECFA Procedure for the Safety Evaluation of Flavoring Substances. 2. The FEMA GRAS Program for Flavors. Presented at the Safety Assessment of Flavors – Indonesia Roundtable, Jakarta, Indonesia, December 9.

Munro, I.C. 2003. Setting Tolerable Upper Intake Levels for Nutrients. Presented at The Annual European Meeting of The Toxicology Forum, Brussels, Belgium, October 28-30

Munro, I.C. and Roberts, A.S. 2003. The Regulatory Evaluation of Functional Foods and Nutraceuticals – CANTOX Seminar co-sponsored by the Canadian Embassy, September 4, Tokyo, Japan.

Munro, I.C. 2003. Key Elements in Developing a Global Regulatory Strategy. Presented at the International Food Technologists' Pre-Annual Meeting Program "International Regulatory Approval of Food Ingredients and Dietary Supplements", July 11-12, Chicago, IL.

Munro, I.C. 2003. Managing and Interpreting Vitamin and Mineral Science. Presented at the EANS one-day workshop on "Risk Assessment and Beyond: Vitamins and Minerals", April 30, Brussels, Belgium.

Munro, I.C. 2003. Setting Tolerable Upper Intake Levels for Nutrients. Presented at the National Institute of Nutrition (NIN) – Annual Meeting, April 28, Toronto, ON.

Munro, I.C. 2003. Setting Tolerable Upper Intake Levels for Nutrients. Presented at ILSI North America – Understanding Tolerable Upper Levels Workshop, April 23-24, Washington, DC.

Munro, I.C. 2003. Managing and Interpreting Vitamin and Mineral Science. Presented at the European Academy of Nutritional Sciences (EANS) one-day workshop - Risk Assessment and Beyond: Vitamins and Minerals, April 20, Brussels, Belgium.

Munro, I.C. 2003. The Threshold of Toxicological Concern Concept. Presented at the ILSI Europe Workshop on Structure-based Thresholds of Toxicological Concern: Guidance for Application to Substances Present at Low Levels in the Diet, March 20-21, Vienna, Austria.
Munro, I.C. 2003. Current Dietary Supplement Safety Issues. Presented at the Food and Drug Law Institute's Conference: Dietary Supplements…At a Crossroads, January 16-17, Washington, D.C.

Munro, I.C., Hlywka, J., and Reid, J. 2003. Determining Unintended Health Effects of Biotechnology Derived Foods. Presented at the Workshop of the Committee on Identifying and Assessing the Unintended Effects of Genetically Engineered Foods on Human Health, The National Academies, January 7, Washington, D.C.

Munro, I.C., and Roberts, A.S. 2002. Functional Foods and Nutraceuticals -- How to Launch Nutraceuticals on the U.S. Market. A workshop conducted by Dr. Ian Munro and Dr. Ashley Roberts in association with Archimex, November 26, Paris, France.

Munro, I.C. 2002. Setting Tolerable Upper Intake Levels for Nutrients. Presented at the workshop on "Dietary Reference Intakes and Discretionary Fortification". Sponsored by the Committee on Use of Dietary Reference Intakes in Nutrition Labelling of the Food and Nutrition Board, Institute of Medicine, November 21, Washington, DC.

Munro, I.C. 2002. Setting Tolerable Upper Intake Levels for Nutrients. Presented at the American Dietetic Association, Food & Nutrition Conference & Exhibition 2002, October 21, Philadelphia, PA.

Munro, I.C. 2002. Regulatory and Safety Requirements for Obtaining GRAS Status. Presented at the American College of Nutrition's 43rd Annual Meeting, October 3, San Antonio, TX.

Munro, I.C. 2002. The JECFA Procedure for the Safety Evaluation of Flavoring Substances. Presented at the JECFA Symposium organized by the Japanese Flavor & Fragrance Material's Association (JFFMA), September 26, Tokyo, Japan.

Munro, I.C. 2002. Risks From Acrylamide in Food. Presented at the Ceres Roundtable: Acrylamide: Lessons Learned, Plans Ahead, September 9, VirginiaTech, Alexandria, VA.

Munro, I.C. 2002. The Precautionary Principle and the Scientific Risk Assessment Process. Presented at the International Society of Regulatory Toxicology and Pharmacology Meeting, June 21-22, Arlington, VA.

Munro, I.C. 2002. OECD/FAO Substantial Equivalence Framework for Whole Food Safety Assessment. Presented at the 41st Annual Meeting & ToxExpo, March 17-21, Nashville, TN.

Munro, I.C. 2001. Dietary Exposure from Migration of Packaging Materials. Presentation at the Joint JRC/ILSI Europe Workshop on Exposure from Food Contact Materials, October 15-16, Ispra, Italy.

Munro, I.C. 2001. Safety Evaluation of Foods Derived from Genetically Modified Crops. Presented at the 222nd American Chemical Society Meeting, August 29, Chicago, IL.

Munro, I.C. 2001. Appropriate Use of Preclinical Data in Drug Development. Presented at the joint meeting of the Michigan Chapter of the Society of Toxicology (MISOT) and the Michigan Society for Medical Research (MISMR), May 18, Ann Arbor, Michigan.

Munro, I.C. 2001. Risk Analysis of Food Derived from Genetically Modified Plants. Presented at the Food and Agriculture Organization of the United Nations' (FAO) "Seminar on Risk Analysis for Food Control: A Practical Approach Through Case Studies" organized jointly with ILSI and the University of Brasilia, May 9-11, Brasilia, Brazil.

Munro, I.C. 2000. Safety Evaluation of Foods Derived from Genetically Modified Crops. Presented at the Brazilian Association of Food Industries' "Safety Assessment of Biotechnology Derived Foods" seminar, December 5, 6 & 7, São Paulo, Brazil.

Munro, I.C. 2000. Risk Assessment of Packaging Materials. Presented at the 2nd International Symposium on Food Packaging. Ensuring Safety and Quality of Foods, November 8-10, Vienna, Austria.

Munro, I.C. 2000. EUROTOX/SOT Debate. An evaluation demonstrating that foods derived from GM crops are as safe as their traditional counterparts is an appropriate paradigm for assessing the safety of genetically modified foods. For the motion: Ian C. Munro (SOT). EUROTOX 2000, XXXVIII European Congress of Toxicology, September 17-20, London, England.

Munro, I.C. 2000. Safety of Foods Produced by rDNA Technology. Presented at the Institute of Medicine/Food and Nutrition Board Meeting, July 20, Woods Hole, MA.

Munro, I.C. 2000. Society of Toxicology/EUROTOX Debate Presentation. 2000 Society of Toxicology Annual Meeting, March 21, Philadelphia, PA.

Munro, I.C. 2000. Developing Integrated Scientific & Regulatory Strategies, Resolving Complex Scientific Issues, and Facilitating Timely Regulatory Approvals. TNO Nutrition and Food Research Institute, February 29, Zeist, The Netherlands.

Munro, I.C. 2000. Applying a Threshold of Regulation Concept to the Safety Evaluation of Packaging Materials. Nutripack Food & Beverage Packaging Congress, January 26-27, Paris, France.

Munro, I.C. 1999. Key Safety Issues in Bringing a Functional Food or Nutraceutical to Market. Nutraceutical Opportunities Summit, December 8-9, Toronto, Ontario.

Munro, I.C. 1999. The Concept of Thresholds in Safety Assessment. ILSI Europe Workshop on Threshold of Toxicological Concern for Chemical Substances Present in the Diet, October 5-6, Paris France.

Munro, I.C., Bechtel, D., Schinkel, H., and McColl, D. 1999. Functional Foods: International Comparisons of the Scientific and Regulatory Attributes Affecting Product Development and Market Access.

Munro, I.C., McColl, D., Bailey, R., Coutrelis, N., and Schinkel, H. 1999. Special Forum: International Regulatory Issues in Marketing Functional Foods: Barriers and Opportunities. Institute of Food Technologist's Annual Meeting, July 24-28, Chicago, IL.

Munro, I.C. 1999. 1) Safety Assessment of Process Flavors. 2) Perspective of the Food and Nutrition Board's Subcommittee on Upper Reference Levels of Nutrients. 1999 Annual Summer Meeting of The Toxicology Forum, July 12 - 16, Aspen, Colorado.

Munro, I.C. 1999. The Crucial Role of Safety and Efficacy Principles for Nutraceuticals, Functional and Medical Foods - Nutraceutical, Functional & Medical Foods Conference, May 6-7, Toronto, Ontario.

Munro, I.C. 1999. Assessing the Safety of Flavoring Substances. Flavor and Extract Manufacturers' Association of the United States - 90th Annual Convention, May 2-5, Palm Beach, Florida.

Munro, I.C. 1999. Concepts in Safety Evaluation of HPV Food Substances. Vision 20/20 Workshop - TestSmart - A Humane and Efficient Approach to SIDS Data, April 26-27, Fairfax, Virginia.

Munro, I.C. 1999. Effect of Intake Level on the Safety Evaluation of Flavoring Substances. Scientific Committee on Food - DGIII - DGXXIV Joint Workshop on Chemically Defined Flavouring Substances, March 25, Brussels, Belgium.

Munro, I.C., Berndt, W., Borzelleca, J., Flamm, G., Lynch, B., Kennepohl, E., Bär, A., and Modderman, J. 1999. Erythritol: An Interpretive Summary of the Biochemical, Metabolic, Toxicological and Clinical Data. Poster presentation at the Society of Toxicology Annual Meeting, March 14-18, New Orleans, Louisiana.

Munro, I.C. 1998. 1) A Global Perspective on Regulatory Approval for Food Ingredients, Nutraceuticals, and Dietary Supplements. 2) Gaining Product Approval in Canada. 3) Key Elements in Formulating a Global Regulatory Plan. International Food Technologist's 1998 Pre-Annual Meeting Continuing Education Program #5, June 19 & 20, Atlanta, GA.

Munro, I.C. 1998. FNB Model for Development of Tolerable Upper Intake Levels. Presented at the European Toxicology Forum Meeting, May 13, Brussels, Belgium.

Munro, I.C. 1998. International Perspectives for Ensuring Safe Food. Presented at the Institute of Medicine, April 29, Washington, D.C.

Munro, I.C. 1997. The Development of Tolerable Upper Intake Levels for Nutrients. Presented at the Insight Information Inc. Conference - New Nutrition Recommendations - Capitalizing on New Opportunities, December 11, Toronto, Ontario.

Munro, I.C. 1997. A Model for the Development of Upper Levels. Presented at the Dietary Reference Intakes Conference - New Vision, New Challenges, Ontario Institute for Studies in Education, November 24, Toronto, Ontario.

Munro, I.C. 1997. A Model for the Development of Tolerable Upper Intake Levels for Nutrients. Presented at the Calcium Workshop, Program in Food Safety, University of Toronto, October 30, Toronto, Ontario.

Munro, I.C. 1997. A Model for the Development of Tolerable Upper Intake Levels for Nutrients. Presented at Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride Workshop, Institute of Medicine, September 23, Washington, D.C.

Munro, I.C., Daniels, J.M., and Lynch, B.S. 1997. A Review of the Safety of Vitamin B6 (Pyridoxine): Implications for Determining the Safe Upper Intake from Dietary Supplements. Presented at Vitamin B6: New Data, New Perspectives, Council for Responsible Nutrition, September 8, London, England.

Munro, I.C., and Kroes, R. 1997. Application of a Threshold of Regulation Concept in the Safety Evaluation of Certain Flavoring Substances. Presented at the Forty-ninth Meeting of the Joint FAO\WHO Expert Committee on Food Additives, June 17-26, Rome, Italy.

Bechtel, D., Locke, L., and Munro, I.C. 1997. Need for Scientific Substantiation for Functionality of Food Components for Health Promotion. Presented at the ILSI N.A. Workshop - The Future of Functional Foods for Health Promotion: A Public Health Opportunity?, June 4-5, Washington, D.C.

Munro, I.C. 1997. 2,4-D - Safety and Exposure. Presented to Poisons Centre staff, academic pharmacology staff and postgraduate students at the University of Dunedin, March 13, Dunedin, New Zealand.

Munro, I.C. 1997. 2,4-D - Safety and Exposure. Presented to toxicologists and occupational health specialists from the New Zealand Ministry of Agriculture and Ministry of Environment, March 12, Wellington, New Zealand.

Munro, I.C. 1997. Development of a Procedure for the Safety Evaluation of Flavouring Substances. Presented at the International Symposium on Flavours and Sensory Related Aspects, March 6-7, Cernobbio (Como), Italy**.**

Munro, I.C. 1996. 1) Current Issues in the Evaluation of the Safety of Food and Food Ingredients. 2) Issues in the Safety Assessment of Carbohydrate/Fat Substitutes. Presented at the ASCEPT Toxicology Workshop, June 17-18, Canberra, Australia.

Munro, I.C. 1995. Interpretive Review of the Potential Adverse Effects of Chlorinated Organic Chemicals on Human Health and the Environment. Report of an Expert Panel. Presented at Dioxin 95, 15th International Symposium on Chlorinated Dioxins and Related Compounds, August 21-25, Edmonton, Alberta.

Munro, I.C. 1995. The Safety Evaluation of Flavoring Substances: The GRAS Process. Presented at the Second Workshop - Harmonization and Food Safety, April 20-21, Hong Kong.

Munro, I.C., McGirr, L.G., Nestmann, E.R., and Kille, J.W. 1994. Macronutrient Substitutes: Safety Factor Alternatives And Human Mimetic Models. Thirty-third Annual Meeting of Society of Toxicology, Dallas, Texas.

Munro, I.C., McGirr, L.G., Nestmann, E.R., and Kille, J.W. 1994. Macronutrient Substitutes: Alternatives To Traditional Safety Testing. Annual Meeting of Institute of Food Technologists, Atlanta, Georgia.

Munro, I.C. 1993. Harmonization of Conventional Toxicology Studies - A Commentary. Presented at ILSI Conference on RedBook II, December 16, Washington, DC.

Munro, I.C. 1993. The Exposure and Toxicity of 2,4-D. Presented at The Toxicology Forum, Aspen, CO. (July).

Munro, I.C. 1992. Novel Foods, Workshop on Novel Foods and Novel Food Processes. Presented at the Program in Food Safety, Nutrition and Regulatory Affairs, Department of Nutritional Sciences, Faculty of Medicine, University of Toronto. Toronto, Ontario. (November).

Munro, I.C. 1992. Toxicology and Drug Development: Managing the Issues. Presented to Ciba-Geigy Canada Ltd., Mississauga, Ontario. (October).

Munro, I.C. 1992. Adverse Effects and Indoor Air Pollution. Presented at the Thirteenth Annual Meeting of the American College of Toxicology, San Francisco, CA. (October).

Munro, I.C. 1992. Toxicology of Benzoyl Peroxide. Presented at The Toxicology Forum, Aspen, CO. (July).

Munro, I.C., Borzelleca, J.F., and Squire, R.A. 1991. The Safety of Xylitol for Use in Food. Report of an Expert Panel.

Munro, I.C. 1991. Food Safety. Presented at a Food Safety Seminar Embassy of the United States, Ottawa, Ontario, Canada.

Munro, I.C., and Orr, J. 1991. Dioxins in Paper Products. Canadian Paediatric Society Workshop on Infant Diapers.

Munro, I.C., and Orr, J. 1991. The Saccharin Lesson. Presented at the Symposium on Chemical Carcinogenesis: The Relevance of Mechanistic Understanding in Toxicological Evaluation. Berlin, Germany.

Munro, I.C. 1991. Impact of Agricultural Activities on Health Risks From Drinking Water. Presented at the Interdisciplinary Symposium on Agriculture and Water Quality Centre for Soil and Water Conservation. University of Guelph, Ontario.

Munro, I.C. 1990. Scientific Aspects of the IFBC Report. Presented to the Toxicology Forum. Washington, DC.

Munro, I.C., and Hall, R.L. 1990. Food Safety and Quality - Impact of Biotechnology. Presented at the Agricultural Biotechnology, Food, Safety and Nutritional Quality for the Consumer Second Annual Meeting. Ithaca, New York.

Munro, I.C. 1990. Food Safety and Environmental Issues in the year 2010. Presented to the Western Canadian Wheat Growers' Association, Regina, Saskatchewan, Canada.

Munro, I.C. 1990 & 1989. Issues in Food Safety, "Later in Life Learning Series", Toronto Ontario and The Environmental Forum, Belleville, Ontario.

Munro, I.C. 1989. Issues to be Considered in the Safety Evaluation of Fat Substitutes. Presented at the Workshop on Re-evaluation of Toxicity Methodology including Gross Nutrients. Limelette, Belgium.

Munro, I.C. 1989. Natural Versus Man-Made. Presented to the Ontario Institute of Agrologists, Toronto, Ontario.

Munro, I.C. Neoplasm Promotion. Prepared for Environmental Health and Safety Council of The American Health Foundation.

Munro, I.C. 1986. Governmental Approach to Regulatory Priorities and Risk Management of Flavors and Fragrances. Presented at The Tenth International Congress of Essential Oils, Fragrances and Flavors. Washington, DC.

Munro, I.C. 1985. The Role of Toxicology in Strategies for Cancer Prevention. Presented at the American Society of Preventive oncology. Eighth Annual Meeting, Toronto, Canada.

Munro, I.C. 1985. The Ingredients of Foods: How They are Tested and Why They are Selected. Presented at the ILSI Workshop on Adverse Reactions to Foods and Food Additives, Orlando, Florida.

Munro, I.C., Goldberg, L., and Farber, E. 1985. Formaldehyde Risk Assessment. Report to Ontario Ministry of Labour.

Munro, I.C. 1984. Risk Assessment and Environmental Regulation. Prepared for the ILSI Symposium on Safety Assessment. Tokyo, Japan.

Munro, I.C. 1984. Report to the Royal Commission to Inquire into the Use and Effects of Chemical Agents on Australian Personnel in Vietnam.

Munro, I.C. 1983. Artificial Sweeteners (Saccharin) - General Review of Carcinogenicity Data. Presented at the Third European Toxicology Forum. Geneva, Switzerland.

Clayson, D.B., and Munro, I.C. 1983. Safety Evaluation of Low Levels of Toxic Agents in Food with Emphasis on Carcinogenesis and Mutagenesis. Presented at the International Symposium on the Safety Evaluation of Animal Drug Residues. Berlin, Germany.

Munro, I.C., and Bradshaw, L.R.A. 1983. Government Decision-Making with Incomplete Epidemiologic Evidence. Presented at the Canadian Society for Clinical Investigations Symposium in Clinical Epidemiology. Calgary, Alberta.

Munro, I.C. 1983. Overview of Factors that Influence Food Safety Decisions. Presented at the International Life Sciences Institute Symposium, Safety Assessment: Interface Between Science, Law and Regulation. Washington, DC.

1983. The Relevance of Mouse Liver Hepatoma to Human Carcinogenic Risk. Report of a Panel to the International Expert Advisory Committee to the Nutrition Foundation.

Munro, I.C. 1983. Introductory Remarks. Presented at the Toxicology Forum Meeting. Arlington, Virginia.

Charbonneau, S.M., and Munro, I.C. 1982. Dietary Factors Affecting Pesticide and Xenobiotic Toxicity. Presented as a Poster at the Fifth International Congress on Pesticide Chemistry. Kyoto, Japan.

Tryphonas, H., and Munro, I.C. 1982. Risk-Benefit Assessment in Immunotoxicology. Presented by Mrs. Tryphonas at NATO Advanced Study Institute on Immunotoxicology. Acadia University, Wolfville, Nova Scotia.

Munro, I.C., Miller, C.T., and Krewski, D. 1982. Regulatory Control of Environmental Chemicals: A Canadian Viewpoint. Presented at the First World Congress on Toxicology and Environmental Health. Washington, DC.

Munro, I.C. 1982. The Necessity for Compatible Standards. Presented at the 1982 Annual Winter Toxicology Forum Meeting, February 15-17, Arlington, Virginia.

Munro, I.C. 1981. Regulatory Concerns - Overview. Presented at the Fourteenth Annual Symposium of the Society of Toxicology of Canada. Montreal, Quebec.

Munro, I.C., and Krewski. 1981. Risk Assessment and Regulatory Decision Making. Presented at the Toxicology Forum Meeting, August 9-13, Vancouver, British Columbia.

Munro, I.C. 1981. Risk Assessment and Regulatory Decision Making. Presented at the 64th Chemical Conference and Exhibition, Chemical Institute of Canada, May 31-June 3, Halifax, Nova Scotia.

Munro, I.C. 1981. Science and Issues of Food Additive Use. Presented at Food Additives Symposium. University of Toronto, Faculty of Medicine and Program in Human Nutrition.

Munro, I.C., and Krewski, D.R. 1980. The Role of Risk Assessment in Regulatory Decision Making. Presented at the Thirteenth Annual Symposium of the Society of Toxicology of Canada, December 2-3, Montreal, Quebec.

Munro, I.C., and Krewski, D. 1980. The Role of Risk Assessment in Regulatory Decision Making. Presented at Symposium on Health Risk Analysis, October 27-30, Gatlinburg, Tennessee.

Munro, I.C. 1980. Scientific Evaluation of Benefit Risk Assessments in Food Safety. Presented at the Gordon Research Conference on the Microbiological Safety of Foods, June 16-20, Plymouth, New Hampshire.

Munro, I.C. 1980. Regulatory Control of Carcinogens. Presented at the Toxicology Forum Meeting, February 28-March 1, Arlington, Virginia.

Munro, I.C. 1979. Reproductive Toxicity. Presented at the International Course on the Principles and Methods in Modern Toxicology, October 22-24, Belgirate, Italy.

Munro, I.C. 1979. Scientific Evaluation of Benefit/Risk Assessments in Food Safety. Presented at the 29th Annual Meeting of the Institute of Food Technologists, June 10-13, St. Louis, Missouri.

Munro, I.C. 1978. Compilation of United States and Canadian Legislation Pertaining to Environmental Safety. Prepared for the International Commission for Protection Against Environmental Mutagens and Carcinogens.

Munro, I.C. 1978. Chapter on ADI Concept. Prepared for the Safe Drinking Water Committee, National Academy of Sciences.

Munro, I.C. 1978. Detecting and Measuring Carcinogens. Presented at the Law and Public Affairs Seminar on Government Regulation of Cancer-Causing Chemicals, December, Washington, DC.

Munro, I.C. 1978. Environmental Contaminants and Food Safety. Presented at the XI International Congress of Nutrition Conference, September, Rio de Janiero, Brazil.

Munro, I.C. 1978. Reproductive Toxicity and the Problems of *In Utero* Exposure. Presented at the International Symposium on Chemical Toxicology of Food, June, Milan, Italy.

Munro, I.C. 1978. Environmental Contaminants. Presented at the Symposium on Principal Hazards in Food Safety and Their Assessment, FASEB Annual Meeting, April, Atlantic City, New Jersey.

Munro, I.C. 1977. Regulatory Applications of Short-Term Tests for Carcinogenicity. Presented at the Gordon Research Conference, August, Meriden, New Hampshire.

Munro, I.C. 1977. Overview - Dose Selection. Presented at the Toxicology Forum Meeting, July, Aspen, Colorado.

Munro, I.C. 1977. The Importance of Specifications for Substances in Their Safety Evaluation in Foods. Prepared for the Scientific Committee of the Food Safety Council.

Munro, I.C. 1977. Working Papers for 34 Food Colors. Prepared for Joint FAO/WHO Expert Committee, Geneva.

Charbonneau, S.M., Munro, I.C., and Nera, E. 1977. Chronic Toxicity of Methylmercury in the Adult Cat. Proc. X Symposium on Trace Substances in Environmental Health, Columbia, Missouri.

Munro, I.C. 1976. Considerations in Chronic Toxicity Testing: The Chemical, The Dose, The Design. Presented at the Status of Predictive Tools in Application to Safety Evaluation Conference, November, Little Rock, Arkansas.

Munro, I.C. 1975. Working Paper on Nitrates, Nitrites and Nitrosamines. Prepared for the World Health Organization.

Grice, H.C., DaSilva, Stoltz, D.R., Munro, I.C., Clegg, D.J., and Abbatt, J.D. Testing of Chemicals for Carcinogenicity, Mutagenicity, Teratogenicity.

Munro, I.C. 1974. Chemicals that Cause Food Poisoning. Proc. of Symposium on Food Poisoning and its Significance in the Food Service Industry. Department of National Health and Welfare.

Stavric, B, Lacombe, R., Munro, I.C., and Grice, H.C. 1973. Studies on Chemical Impurities in Commercial Saccharin (Interim Report). Submitted to NRC Committee on Artificial Sweeteners of the National Academy of Sciences of the United States.

Munro, I.C., Moodie, C.A., and Grice, H.C. 1973. An Evaluation of the Carcinogenicity of Commercial Saccharin. Submitted to NRC Committee on Artificial Sweeteners of the national Academy of Sciences of the United States.

Munro, I.C., Charbonneau, S.M., and McKinley, W.P. 1973. Studies on the Toxicity of Methylmercury. Commission of the European Communities, Luxembourg.

Grice, H.C., DaSilva, T.,Stoltz, D.R., Munro, I.C., Clegg, D.J., and Abatt, J.D. 1973. Testing of Chemicals, Mutagenicity and Teratogenicity. Department of National Health and Welfare.

Munro, I.C., Hasnain, S., Salem, F.A., Goodman, T., Grice, H.C., and Heggtveit, H.A. 1972. Cardiotoxicity of Brominated Vegetable Oils. Myocardiology Volume I. Recent Advances in Studies on Cardiac Structure and Function. p 588.

Jan-05

CURRICULUM VITAE

Surname	KROES	
Christian name	Robert	
Date and place of birth	31st January 1940, Amsterdam, The Netherlands	
Present position	Director of the Institute for Risk Assessment Sciences (IRAS), Utrecht University Professor in Biological Toxicology, Utrecht University (Medical, Veterinary and Biology Faculties)	
Main other positions	- Member of the Risk Assessment Task Force of the European Commission (DG XXIV - Public Health) - President ILSI Europe - Vice Chairman Netherlands Council for Accreditation - Former member of the Scientific Steering Committee of the European Commission (DG SANCO) - Vice President of Eurotox	
Languages	Dutch, English, French and German	
Education	Veterinary surgeon, Utrecht University	(1957 - 1964)
Degrees attained	B.Sc. M.Sc. in veterinary sciences D.V.M. Ph.D. in pathology Certified toxicologist Certified laboratory animal pathologist	(1960) (1963) (1964) (1970) (1988) * (1989) *
	* Registers for certification in The Netherlands were opened on the given date.	
Postdoctoral research training	Veterinary pathology Human pathology Experimental animal pathology	(1964-1965) (1966-1967) (1968-1969)

Specialisation	Laboratory animal pathology, toxicology, oncology and risk assessment (1970 - present)

Career (detailed career below)	1964-1971 Pathologist at the National Institute of Public Health and Environmental Protection (RIVM, Bilthoven, The Netherlands) 1971-1972 Research Fellowship of International Agency for Research on Cancer, spent at the National Cancer Institute, Experimental Pathology Branch, Bethesda, USA 1972-1977 Head Department of Oncology, RIVM, Bilthoven, The Netherlands 1977-1979 Deputy Director CIVO-TNO, Institute for Nutrition and Food Research, Zeist, The Netherlands 1979-1983 Director Institute CIVO Toxicology and Nutrition, TNO, Zeist, The Netherlands 1983-1989 Director RIVM, Bilthoven, The Netherlands 1989-1996 Deputy Director General RIVM, Bilthoven, The Netherlands 1995-1999 Programme Co-ordinator ESF Programme on Environment and Health (part-time) 1988-present Professor in Biological Toxicology (Risk Assessment), Utrecht University (part-time) 1999- present President ILSI EUROPE 1995-present Director of IRAS (Institute for Risk Assessment Sciences, formerly RITOX), Utrecht University (part-time) 2000- present Vice President EUROTOX (as of September 2002 President)

International activities (past and present)

- Member of numerous expert committees on toxicology, oncology and environment and health (WHO, IARC, EC and OECD)
- Editor-in-Chief of Human and Experimental Toxicology (as of 1998)
- Member of the Editorial Board of more than 10 journals (past and present)

In 1988 he was appointed as part-time professor in Biological Toxicology (with special emphasis on Risk Assessment) in the faculties of Medical Sciences, Biology and Veterinary Sciences. Since his appointment as Director RITOX in 1995 he is involved in the scientific management of this institute (approximately 50-60 persons). This Institute has been enlarged to approx. 90 persons and has been renamed into Institute for Risk Assessment Sciences (IRAS), Utrecht University. Since his retirement from the RIVM in 1995 he is involved in a number of international activities among which the programme co-ordination of the Environment and Health Programme of the European Science Foundation (ESF) and the membership of several international committees (WHO-JECFA, ILSI EUROPE and WHO-ECEH). In 1997 he was appointed as member of the Scientific Steering Committee of the European Commission (DG XXIV - Public Health). He is consultant to a number of Nationalities and (groups) of industries.

May 2002

CURRICULUM VITAE

Surname	KROES	
Christian name	Robert	
Date and place of birth	31st January 1940, Amsterdam, The Netherlands	
Present position	Director of the Institute for Risk Assessment Sciences (IRAS), Utrecht University Professor in Biological Toxicology, Utrecht University (Medical, Veterinary and Biology Faculties)	
Main other positions	- Member of the Risk Assessment Task Force of the European Commission (DG XXIV - Public Health) - President ILSI Europe - Vice Chairman Netherlands Council for Accreditation - Former member of the Scientific Steering Committee of the European Commission (DG SANCO) - Vice President of Eurotox	
Languages	Dutch, English, French and German	
Education	Veterinary surgeon, Utrecht University	(1957 - 1964)
Degrees attained	B.Sc. M.Sc. in veterinary sciences D.V.M. Ph.D. in pathology Certified toxicologist Certified laboratory animal pathologist	(1960) (1963) (1964) (1970) (1988) * (1989) *
	* Registers for certification in The Netherlands were opened on the given date.	
Postdoctoral research training	Veterinary pathology Human pathology Experimental animal pathology	(1964-1965) (1966-1967) (1968-1969)

Specialisation	Laboratory animal pathology, toxicology, oncology and risk assessment (1970 - present)

Career (detailed career below)	1964-1971 Pathologist at the National Institute of Public Health and Environmental Protection (RIVM, Bilthoven, The Netherlands) 1971-1972 Research Fellowship of International Agency for Research on Cancer, spent at the National Cancer Institute, Experimental Pathology Branch, Bethesda, USA 1972-1977 Head Department of Oncology, RIVM, Bilthoven, The Netherlands 1977-1979 Deputy Director CIVO-TNO, Institute for Nutrition and Food Research, Zeist, The Netherlands 1979-1983 Director Institute CIVO Toxicology and Nutrition, TNO, Zeist, The Netherlands 1983-1989 Director RIVM, Bilthoven, The Netherlands 1989-1996 Deputy Director General RIVM, Bilthoven, The Netherlands 1995-1999 Programme Co-ordinator ESF Programme on Environment and Health (part-time) 1988-present Professor in Biological Toxicology (Risk Assessment), Utrecht University (part-time) 1999- present President ILSI EUROPE 1995-present Director of IRAS (Institute for Risk Assessment Sciences, formerly RITOX), Utrecht University (part-time) 2000- present Vice President EUROTOX (as of September 2002 President)

International activities (past and present)

- Member of numerous expert committees on toxicology, oncology and environment and health (WHO, IARC, EC and OECD)
- Editor-in-Chief of Human and Experimental Toxicology (as of 1998)
- Member of the Editorial Board of more than 10 journals (past and present)

In 1988 he was appointed as part-time professor in Biological Toxicology (with special emphasis on Risk Assessment) in the faculties of Medical Sciences, Biology and Veterinary Sciences. Since his appointment as Director RITOX in 1995 he is involved in the scientific management of this institute (approximately 50-60 persons). This Institute has been enlarged to approx. 90 persons and has been renamed into Institute for Risk Assessment Sciences (IRAS), Utrecht University. Since his retirement from the RIVM in 1995 he is involved in a number of international activities among which the programme co-ordination of the Environment and Health Programme of the European Science Foundation (ESF) and the membership of several international committees (WHO-JECFA, ILSI EUROPE and WHO-ECEH). In 1997 he was appointed as member of the Scientific Steering Committee of the European Commission (DG XXIV - Public Health). He is consultant to a number of Nationalities and (groups) of industries.

May 2002

Curriculum Vitae
Dr. Volker Beck, Dipl.Psych.
Psychological Psychotherapist (abbr)
Psycho-Oncologist

Professional Experience

1987	Diploma in Psychology
1988- today	Coordinator for Cancer Prevention in the German Cancer Society, Frankfurt/Main
2002	PhD in Theoretical Medicine, University Frankfurt
1988- 2002	Responsible for various cancer prevention projects and prevention programs within the German Cancer Society Responsible for management and planning of national and international scientific conferences on oncological subjects
1990- 2004	Representation of the German Cancer Society on national and international level: Member of • Action Alliance Non-Smoking, ABNR (Germany) • Association „5 a Day“ (Germany) • International Study „European Prospective Investigation Into Cancer and Nutrition“ (EPIC) • Network against colorectal cancer (Germany) • Working Group Dermatological Prevention (Germany) • National Self-Help Organization for Cancer Patients (Germany) • European Cancer Leagues (ECL) • Task force on cancer prevention in the International Union against Cancer (UICC) • European Network for Smoking Prevention (ENSP) • International Study „European Prospective Investigation Into Cancer and Nutrition“ (EPIC) • Global Lung Cancer Coalition (GLCC)

2000- 2004 Coordination of the national “5 A DAY FOR KIDS” campaign in the German Cancer Society together with the federal branches of the German Cancer Society

Curriculum vitae *December 2004*

Professor Crispian Scully CBE

MD, PhD, MDS, BDS, BSc, MB BS, MRCS, LRCP, LDSRCS, FDSRCS, FDSRCPS,

FFDRCSI, FDSRCSE, FRCPath, FMed Sci

Crispian Scully is currently Dean and Director of Studies and Research at the Eastman Dental Institute for Oral Healthcare Sciences, University College London. This is a postgraduate institute, teaching graduates from home and overseas.

He is Professor of Special Needs Dentistry, University College London; Professor of Oral Medicine, Pathology and Microbiology at the University of London; and Honorary Consultant at University College Hospitals Trust, London, Honorary Consultant at Great Ormond Street Hospital for Children, London, John Radcliffe Hospital, Oxford, and at the European Institute of Oncology in Milan.

At the Eastman, he has successfully and dramatically improved ratings both in Research (RAE=5) and postgraduate Teaching (TAE=23); established the International Centre for Excellence in Dentistry (ICED; 1999) and the most active continuing education and professional development programme in the UK; initiated discussions and negotiated merger with University College London (finalized stage of merger; July 2004); initiated and helped develop discussions with Oxford leading to a new Therapy School at the Eastman; established with Prof. Raman Bedi, the World Health Organisation Collaborating Centre for Oral Health, Disability and Culture (renewed 2004); and gained the Queen's Award for Higher and Further Education in 2002/2003, the first in dentistry. Such initiatives and developments have been possible only with the help of very supportive colleagues and teams.

Professor Scully is Chairman of the International Federation of Oral Medicine; Immediate Past-President of the European Association of Oral Medicine; a member of the International Committee of the American Academy for Oral Medicine and Chair of the Division of Maxillofacial Diagnostic, Medical and Surgical Sciences at UCL Hospitals.

He is a member of the UK Academy of Medical Sciences, a member of the Medical Research Council Cross Board Committee, and a member of Court of Middlesex University.

In 2000, he was awarded the Commander of the Order of the British Empire for his service to dental patient care. In 2004, he was nominated Distinguished Scientist at the International Association for Dental Research, and President of the British Society for

Disability and Oral Health.

Background

Professor Scully qualified in Dentistry at the University of London in 1968 (Honours) and trained for a Bachelor of Science in Biochemistry (1971: first class honours). He qualified in Medicine (1974; Honours) before undertaking research as a Research Fellow funded by the Medical Research Council. His Doctor of Philosophy, in Pathology, was awarded in 1979 and he was appointed Lecturer and then Senior Lecturer in Oral Medicine and Immunology at the University of Glasgow, obtaining the Fellowship in Dental Surgery (Glasgow) in 1979.

In 1982 he was appointed to the Chair and Head of Department of Oral Medicine, Surgery and Pathology at the University of Bristol. He was appointed Head of School (Dean) from 1985-1990. He gained his Membership in Pathology (1983), Doctorate in Medicine (1987) and Mastership in Dental Surgery (1988) on the basis of research publications, the Fellowship in Oral Medicine (Ireland) by examination in 1989, the Fellowship in Dental Surgery (England) and the Fellowship of the Royal College of Pathologists in 1992, and the Fellowship in Dental Surgery (Edinburgh) in 1998.

Professor Scully was appointed to the Chair in Stomatology at the University of Geneva, Switzerland in 1993, but declined, having then been approached to become Dean at the Eastman Dental Institute (British Postgraduate Medical Federation, London).

He was appointed Dean, Director of Studies and Research, and Professor of Oral Medicine, Pathology and Microbiology at the Eastman Dental Institute for Oral Healthcare Sciences, University of London in 1994 and was re-appointed in 1999 and again in 2004.

Activities

Education

Professor Scully has the diploma of the Institute of Learning and Teaching (ILT). He initiated several new Master of Science programmes at the Eastman (e.g. Special Needs Dentistry; Surgical Dentistry; Implantology) and the new Masters of Clinical Dentistry programmes and Specialty training (Fixed & Removable Prosthodontics; Endodontics; Periodontology; Paediatric Dentistry; Surgical Dentistry). He has taught and examined undergraduates and postgraduates in the Royal Colleges and in dental schools in the UK (Guy's; Glasgow; Bristol; The London; The Eastman), North America (Vancouver BC), the Middle East (Jordan) and Europe (France; Italy; Portugal), and helped establish the teaching programmes at a new European Dental School (Viseu; Portugal). He is currently developing European Masters programmes, and European Accreditations. He has helped to develop an Oral Medicine Encyclopaedia for the European Association for Oral Medicine, and is introducing European Accreditation for Oral Medicine Training (being posted on website).

He attracted the Committee for Vocational Training in Dentistry (CVT) and the National Centre for Continuing Professional Education in Dentistry (NCCPED) to ICED, and has developed distance and electronic learning programmes. He has just established the examinations for the International Qualifying Examinations (IQE) of the GDC, at the Eastman, the first diet starting August 2004. He has presented continuing education programmes throughout the world.

Professor Scully has been Chairman of the Central Examining Board for Hygienists, and of the Joint Advisory Committee for Additional Dental Specialties (JACADS). He has been a member of the Joint Committee for Higher Training in Dentistry (JCHTD), the Higher Education Funding Council (HEFCE) Dental Research Review Panel, and the Steering Group of the European College of Dentistry.

Clinical

Professor Scully's main clinical interests are in oral medicine, oral surgery, surgical dentistry, oral pathology and special care dentistry. He has clinical experience both in hospital and primary care settings.

He was honorary consultant in Oral Medicine at the Glasgow Dental Hospital, the Bristol Royal Infirmary and Dental Hospital, and the Royal London Hospital, and honorary consultant in Special Needs Dentistry at the Nuffield Orthopaedic Centre, Oxford, the Horizon Trust, St Albans and the Royal Free Hospital, London.

He was General Manager and Clinical Director of the Eastman Dental Hospital Special Health Authority (EDH) 1995-1996, facilitating the merger of EDH with the UCLH Trust.

Professor Scully was an elected member of the General Dental Council, President and a Council member of the British Society for Oral Medicine, and a member of the working group on Oral Health of the Surgeon-General of the USA.

He has been a Consultant Advisor to two UK Chief Medical Officers (Profs Aitchison and Calman), and a member of several Department of Health Committees, including the Standing Dental Advisory Committee (SDAC), the Advisory Group on Setting NHS R&D priorities in primary dental care, the Specialist Advisory Committee on Antimicrobial Resistance (SACAR), the Advisory Committee on HIV-infected Health Care Workers, and the Expert Advisory Group on AIDS (EAGA) working party on Lookback Studies.

Professor Scully has been a member of the National Centre for Clinical Excellence (NICE) working group on Oral Cancer, the Medicines Control Agency (MCA), the Advisory Council on the Misuse of Drugs (ACMD), the Specialisation Task Force of the General Dental Council and is a specialist advisor to the British National Formulary; Dental Practitioners Formulary.

He has developed Patient Information material for the European Association for Oral Medicine (http://www.eastman.ucl.ac.uk/%7Eeaom/clinical_support.html) and, with the Norman Rowe Trust, is currently organizing training for Iraqi surgeons.

Administrative

Professor Scully has wide administrative experience in academic and health service matters, as Dean first in Bristol and in London, and on various International, National and Local Committees and Organisation as outlined below.

Local Clinical Management activities in Bristol, apart from the management input inherent in the Bristol developments, included involvement on the Management Group and, of course, as Head of School (Dean) from 1985 -1990, he spent a great deal of time and energy working on hospital management issues with the Manager direct, and at group meetings with the Manager and Chairman of Division. He was Vice-Chairman of Division. He initiated and organised various improvements in clinical care and management, ranging from phone directory to the staff rota, protocols for interviewing NHS staff, surveying staff opinions, audit, structured and computerised patient management schedules, health services research and audit, and guidelines to NHS staff concerning patient care.

In Bristol Dental Hospital (BDH), he was largely responsible for initiating and co-managing a series of clinical developments for the Area and Region; including refurbishing/re-equipping:

- New general anaesthetic suite at BDH
- Central sterilisation suite at BDH
- Oral Surgery clinic at BDH
- The Bristol Royal Infirmary dental surgery
- Radiology suite at BDH
- Funding and construction of a new and extended Emergency and Oral Medicine Unit at BDH

- Expansion of Consultant clinic rooms at BDH from 1 to 7.
- Initiation of a Microbiology service.

Clinical services initiatives included:

- Recruiting the first specialist Oral Pathology services for the region.
- Generating funding for new Lecturer and a Chair and Senior Lecturer in Oral Surgery and a new Lecturer in Oral Microbiology.
- Oral medicine services.
- A combined Oncology clinic
- Clinic at BDH for HIV/AIDS patients.
- With Tom Dowell, clinical services for Special Needs patients.
- With Dr Mark Griffiths, clinical services for Special Needs patients at the Bristol Children's Hospital.
- Recruiting the first specialist Oral Microbiologist for the region.

Local Clinical Management activities at the Eastman Dental Hospital, apart from the management input inherent in the Eastman developments, included the Hospital Management Group and he was General Manager and Clinical Director from 1995-1996, and spent a great deal of time and energy working on hospital management issues with other managers direct, and at group meetings. He was responsible for all negotiations related to the new partnership between University College London Trust (UCLH), the Eastman, and the National Hospital for Neurological Diseases, to make the new UCLH NHS Trust. This is now a Foundation Trust (2004). He also initiated and organised various improvements in clinical care and management, ranging from phone directory to the staff rota, audit, protocols for interviewing NHS staff, surveying staff opinions, structured and computerised patient management schedules, health services research, guidelines to NHS staff concerning patient care and telediagnosis.

He was largely responsible at the Eastman for initiating and co-managing a series of clinical developments for the Area and Region; including:

- New Oral Medicine Clinics at EDH
- New Oral Medicine Clinics at John Radcliffe Hospital
- Dental Unit at Horizon Trust
- Dental Practice Centre at EDI (later developed into the International Centre for Excellence in Dentistry; ICED)
- The UCLH dental surgery
- Eastman Clinical Investigation Centre
- All teaching facilities
- Teledentistry
- Currently being involved in the team developing a Head & Neck unit at the new UCLH Hospital (opens 2005).

Clinical services initiatives included:

- Establishing the first specialist Special Needs services for the region.
- The first Consultant in Special Needs in UK.
- Generating funding for new Lecturer and a Chair in Oral Medicine.
- Generating funding for new Chair in Oral Implantology.
- Oral medicine services.
- A combined oral medicine/paedodontic clinic.
- Outreach service at Horizon Trust for learning disability.
- Outreach service at Nuffield Orthopaedic Centre.
- Outreach service at John Radcliffe Hospital, Oxford.
- Currently, with others, establishing a North London Head and Neck Cancer Network.

- Initiating the development of the new School for Dental Therapy and conducting the negotiations for funding from Oxford and Anglia Region.
- Establishing, with Prof Stephen Porter, the first MSc programme in Special Needs in UK.
- Establishing (2004) sedation services.

Initiatives and developments at the Eastman Dental Institute include

EASTMAN HIGHLIGHTS 1994-04

Queens Award for Higher Education 2002

High Research Quality Rating

- Grade 5 in the 1997 UK national Research Assessment by the Higher Education Funding Council

High Teaching Quality Rating

- A rating of 23/24 in the 1999 assessment by the Quality Assurance Agency

International Recognition of Success in Research and Education

- World Health Organization Collaborating Centre
- Grant funding from Medical Research Council, National Institute for Health USA, European Union
- High Quality Publications in International High Impact Journals e.g. J. Clin.Invest, J.Exp.Med, Lancet, New Engl. J. Med
- Prizes at International Association for Dental Research
- British Medical Journal Commendation for Medical Writing

Highest Research Publication Record

- Greatest number of publications of all UK dental institutes

Increased Grant Funding

- Over 115% increased grant funding

Tremendous Increase in Resources

- Over 75% increased income

Increase in Quality Staffing

- More than 45% increase in staffing
- Greatest focus of Senior Dental Staff in UK

New Masters Courses

- Masters in Clinical Dentistry in Fixed & Removable Prosthodontics; Endodontics; Periodontology; Paediatric Dentistry

Novel Academic Departments and Their New Courses

- Continuing Education Department ; Diploma and Distance Learning Courses
- Dental and Medical Informatics Department
- Implantology Department ; Masters in Implant Dentistry
- Oral Medicine Department ; Masters in Special Needs Dentistry
- Transcultural Oral Health ; Masters and Distance Learning Courses

New Research and Education Facilities

- New Information Centre
- New Media Centre
- New and Refurbished Research Laboratories
- New Teaching Laboratories
- New Information Technology, Computer-assisted Learning and Teledentistry Units

- New International Centre for Excellence in Dentistry
- Committee for Vocational Training located at EDI
- National Centre for the Continuing Professional Education of Dentists sited at EDI

Greatest Focus of Postgraduate Dental Education in Europe

- Largest concentration of postgraduates in UK and in Europe
- 60% of postgraduates from Home, 40% overseas
- Over 50 different countries represented

Research

Professor Scully is a past winner of the Colgate Research Prize of the British Association for Dental Research and has has presented his research widely throughout the world, and in 1998 was awarded the Award Medal from Helsinki University, Finland, in 2000 the Ahmed Visiting Lecturership at Harvard University, USA and in 2004, the Webb Johnson Lectureship at the Royal College of Surgeons, England. In 2004, he was nominated Distinguished Scientist at the International Association for Dental Research.

He has been Chairman of the Chemoprevention Group of the European Organisation for Research and Treatment of Cancer and has been a member of the NHS Central Research and Development Committee (CRDC), the Medical Research Council Grants Committees, and the Joint Dental Research Committee of the Medical Research Council, the Science and Engineering Research Council and the DH.

Professor Scully established in Bristol the Centre for the Study of Oral Disease and a Clinical Investigation Centre, and has established at the Eastman an analgesic trial centre (University College London Analgesia Centre; UCLAC), and a Clinical Investigation Centre (CIC) (http://www.eastman.ucl.ac.uk/research/clinical_research.html). He was Director of Research and Development at the Eastman Dental Hospital from 1993-1996 and Chairman of the Research Ethics committee.

He has been involved in a wide range of research areas in oral medicine and pathology, predominantly in soft tissue disease and infection and immunity. However, the main research interests have been predominantly in potentially lethal diseases such as malignant and potentially malignant oral disease, and HIV, and especially the role of microorganisms in these and other oral disorders.

Professor Scully's most significant contributions in cancer have been to show a rise in oral squamous cell carcinoma (oral cancer) in Britain, and an association with viruses, that others have since confirmed in some types of oropharyngeal cancer. His team examined the epidemiology of oral cancer, initially in Scotland where they revealed for the first time, an increasing incidence, and then confirmed this worldwide. Their studies have shown *ras* oncogene mutations and tumour suppressor changes, especially some involving chromosome 3p, in oral squamous cell carcinoma. They have demonstrated the role of tobacco and alcohol in potentially malignant lesions. They demonstrated also, for the first time, evidence of RNA complementary to herpes simplex virus in oral carcinoma and then found a new human papillomavirus (HPV) in oral carcinoma, studies which have been pursued particularly to examine the possible efficacy of antiviral agents.

He has been in teams studying infectious diseases such as HIV, including various of the complicating opportunistic infections, and the role of viruses in Kaposi's sarcoma, as well as in potentially malignant oral lesions such as lichen planus, and in Sjogren's syndrome, and he has researched both viral infections such as hepatitis B, hepatitis C, hepatitis G and transfusion-

transmitted hepatitis, and other infections of oral relevance, particularly mycoses, and especially deep mycoses from the developing world.

His team were pivotal in studying the introduction to and uptake of hepatitis B immunization by, dental health care workers, the results also encouraging improved infection control in dentistry

Published work

Professor Scully has 647 papers cited on MEDLINE. He has published over 800 scholarly works including about 300 original research papers, 200 review articles, 150 chapters in books and 50 clinical papers. He has published 24 and edited 10 textbooks on applied basic sciences, oral medicine, oral surgery, oral pathology and special care dentistry. He has 4 books in press.

His book *Medical Problems in Dentistry* was awarded the Doody Prize as one of the top-selling medical or dental books worldwide, *Oral and Maxillofacial Medicine* was awarded the Society of Authors' and Royal Society of Medicine First prize for new authored books, and he has been commended in the Glaxo Prize for Medical Writing and the British Medical Association Prize for Medical Writing.

Professor Scully is currently Editor of *Oral Oncology* (http://intl.elsevierhealth.com/journals/oron) and *Oral Oncology EXTRA* (an on-line journal) (http://intl.elsevierhealth.com/journals/ooex/), Co-Editor of *Oral Diseases* (http://www.blackwellmunksgaard.com/odi), and Co-Editor of *Medicina Oral* (http://www.uv.es/medicina-oral/). He founded *Oral Oncology* and later *Oral Oncology EXTRA* and in the decade or so since he established *Oral Oncology*, both the circulation and impact factors have steadily and significantly increased, so that it is now ranked 5th amongst the dental journals (IF 1.876: 2003), despite the relatively small field covered. He also, with Prof. Newell Johnson, founded *Oral Diseases* and, with Jose Vicente-Bagan, *Medicina Oral* (a bilingual Journal).

He is currently also on the Editorial Boards of *Acta Oto-Laryngologica, Archives of Oral Biology, British Dental Journal Launchpad, CPD Dentistry, International Journal of Oncology, Journal of Epidemiology and Biostatistics, Oral Biosciences & Medicine* and several other specialty journals. He was formerly on the Editorial Boards of *Journal of Oral Pathology and Medicine, Current Opinion in Dentistry* and *European Journal of Cancer.*

PERSONAL DETAILS

NAME:	**Crispian Scully**
PRESENT ADDRESS:	Eastman Dental Institute University College London University of London 256 Gray's Inn Road London WC1X 8LD
Telephone:	Office +44 0207 915 1038 Home +441923896530
Fax:	Office +44 0207 915 1039 Home +441923896530
Email:	Scully.c@eastman.ucl.ac.uk
WEBSITE	http://www.eastman.ucl.ac.uk/~cscully/

DATE OF BIRTH:	24th May 1945
PLACE OF BIRTH:	Hove, Sussex, U.K.
FAMILY:	Married; with daughter.
HONOURS:	Commander of the Order of the British Empire (**CBE**) For *Service to dental patient care, especially those with Special Needs* (2000)
EXTRA-MURAL INTERESTS:	Swimming, skiing, windsurfing, cycling, charity work hill walking, canoeing, skating, traveling, music, organ playing, sailing.
LANGUAGES:	English, French (basic), German (basic), Greek (basic)
REGISTRATIONS:	
General Dental Council:	42161 (Specialist in Surgical Dentistry; Specialist in Oral Surgery; Specialist in Oral Medicine)
General Medical Council:	6063739
Dental Protection:	177296

Passport number:	N363424F
NHS List number;	Buckinghamshire HA 727741

UNIVERSITY QUALIFICATIONS

1968	Bachelor of Dental Surgery (**BDS**) (University of London)
1971	Bachelor of Science: Biochemistry (**BSc**) (University of London)
1974	Bachelor of Medicine: Bachelor of Surgery (**MB BS**) (University of London)
1979	Doctor of Philosophy: Pathology (**PhD**) (University of London)
1987	Doctor of Medicine (**MD**) (University of Bristol)
1988	Master of Dental Surgery (**MDS**) (University of Bristol)

DIPLOMAS OF ROYAL COLLEGES

1968	Licentiate in Dental Surgery (Royal College of Surgeons of England) (**LDS RCS**)
1974	Member (Royal College of Surgeons of England) (**MRCS**)
1974	Licentiate (Royal College of Physicians of London) (**LRCP**)
1979	Fellow in Dental Surgery (Royal College of Physicians and Surgeons of Glasgow) (**FDS RCPS**)
1983	Member (Royal College of Pathologists) (**MRCPath**)
1989	Fellow in Dental Surgery (Oral Medicine) (Royal College of Surgeons of Ireland) (**FFD RCSI**)

1992		Fellow in Dental Surgery (Royal College of Surgeons of England) (**FDS RCS**)
1992		Fellow (Royal College of Pathologists) (**FRCPath**)
1997		Fellow in Dental Surgery (Royal College of Surgeons of Edinburgh) (**FDS RCSE**)

ACADEMIC AWARDS AND HONOURS

1998		Fellow of the Academy of Medical Sciences (**FMedSci**)

Dentistry

1968	Prizes	Stephen D. Hey Prize (Open competition for the best case of completed treatment in Restorative Dentistry)
		Dolamore Prize (Periodontology)
		J.A. Smith Prize (Dental Prosthetics and Materials)
		Student's Essay Prize
		Moser Prize (Practical Dentistry)
	Scholarships	J.A. Smith Scholarship (Dental Prosthetics)
		Alfred Woodhouse Scholarship (Open competition in Practical Orthodontics, Oral Surgery and Restorative Dentistry)
	Certificates	Robert Woodhouse Certificate (Oral Surgery)
		Pathology and Bacteriology Certificate

Medicine

1974	Medals	The Dean's Medal (Medicine)
	Prizes	Preclinical Prize (Anatomy, Physiology, Biochemistry)
		Practical Anatomy Prize
		Winifred Ladd Prize (Physiology)

	Pharmacology Prize
	Waler Culverwell Prize (Anatomy)
	Lord Rank Prize (Biochemistry)
	Winifred Secretan Patch Prize (Anatomy)
	Mrs G Smith Prize (Preclinical subjects)
	E. Hanson Prize (Physiology)
	London Lock Hospital Prize (Sexually Transmitted Diseases)
	Gwendoline Lloyd Prize (Medicine)
	Helen Webb Prize (Paediatrics)
	Kenneth Hill Memorial Prize (Pathology)
	Helen Webb Prize (Medicine)
Scholarships	A. Langton Scholarship
	F. Murray Scholarship
	Mabel S. Crawford Scholarship

Publications

1990	Glaxo Prize for Medical Writing (Short listed and commendation)
1997	British Medical Association Prize for Medical Writing (Short listed and commendation)
1999	United States Rating Services (Doody) Award for *Medical Problems in Dentistry* as a best-selling book on Health Sciences
2004	Society of Authors and Royal Society of Medicine Prize for *Oral and Maxillofacial Medicine*, as a new authored book

Research

1979	The Colgate-Palmolive Prize for Dental Research (International Association for Dental Research)

1984	T.C. White Prize for Dental Research (Royal College of Physicians and Surgeons of Glasgow).
2004	International Association for Dental Research Distinguished Scientist Award nominee

Teaching

2001	Institute of Learning and Teaching (ILT) diploma: 14773

Medals and Invited Eponymous Lectures

1984	TC White Lecture (Royal College of Physicians and Surgeons of Glasgow)
1994	David Parker Memorial Lecture (Royal Army Medical Corps)
1996	Professor Joze Rant Memorial Lecture (University of Ljubljana), Slovenia
1998	William Fair Memorial Lecture (University of California),USA
1998	Award Medal (University of Helsinki), Finland
1998	University Lecture (University of Ljubljana), Slovenia
2000	Ahmed Lecture (University of Harvard), USA
2001	Caldwell Memorial Lecture (University of Glasgow), UK
2002	Wystan Peach Lecture (BDA Wales), UK
2002	Christos Laskaris Memorial Lecture (University of Belgrade), Serbia
2003	John Rayne Memorial Lecture (University of Oxford), UK
2004	Webb Johnson Lecture (Royal College of Surgeons of England), UK

2004	Honorary Fellowship (Societas Latina Capitis Et Colli)

Research Awards to Supervisees

1989	The Hoyt Prize for Dental Research (British Society for Dental Research) to Mr Simon Rice (BSc student) for work on carcinogenesis
1990	British Society for Oral Pathology Prize to Dr Martyn Cox (PhD student) for work on papillomaviruses.
1990	Federation Dentaire Internationale Prize to Mr Paul Harper (MSc student) for work on lasers

DISTINCTIONS

1968	**BDS** Honours in: Dental Surgery and Pathology; Orthodontics
1971	**BSc** (Biochemistry) First Class Honours
1974	**MB, BS** Honours in: Pathology; Surgery; Pharmacology and Therapeutics.

EDUCATION

SECONDARY EDUCATION

1956-1962	Collyer's School Horsham, Sussex.

UNIVERSITY EDUCATION

1963-1967	Royal Dental Hospital School of Dental Surgery University of London.
1968-1974	Royal Free Hospital

	School of Medicine University of London.
1976-1979	United Medical and Dental Schools (Guy's Hospital Medical and Dental Schools) University of London.
1979	University of Edinburgh [appointed but declined in favour of Glasgow]
1979-1982	Glasgow Dental Hospital and School University of Glasgow.
1982-1993	Bristol Dental Hospital and School University of Bristol.
1993	University of Geneva [appointed but declined in favour of London]
1993-1995	Eastman Dental Institute and London Hospital Medical College Dental School University of London
1995-	Eastman Dental Institute and University College London University of London

POSTGRADUATE EDUCATION

Clinical Lecturer 1974	Clinical Lecturer (part-time) Department of Oral Surgery Royal Dental Hospital School of Dental Surgery University of London.
Research Fellow 1976-1979	Medical Research Council Research (MRC) Training Fellow Guy's Hospital Medical and Dental Schools University of London.
Lecturer 1977-1979	Lecturer (Honorary) Department of Oral Immunology and Microbiology Guy's Hospital Medical and Dental Schools University of London.
Lecturer 1979-1981	Lecturer in Immunology and Oral Medicine Department of Oral Medicine and Pathology Glasgow Dental Hospital and School University of Glasgow.

Senior Lecturer 1981-1982	Senior Lecturer Department of Oral Medicine and Pathology Glasgow Dental Hospital and School University of Glasgow.
Professor 1982-1992	Professor and Head of Department Department of Oral Medicine, Surgery and Pathology (including Periodontology and Radiology) Bristol Dental Hospital and School University of Bristol.
Professor 1992-1993	Professor and Head of Department Department of Oral Medicine, Pathology and Microbiology (including Radiology) Bristol Dental Hospital and School University of Bristol
Head of School (Dean) 1986-1990	Bristol Dental Hospital and School University of Bristol
Director 1989-1993	Centre for Study of Oral Disease University of Bristol
Head 1993-1995	Joint Department of Oral Medicine, Eastman Dental Institute and London Hospital Medical College Dental School
Dean and Director of Studies & Research 1993-1998	Eastman Dental Institute University of London
Dean and Director of Studies & Research 1998-	Eastman Dental Institute University College London
Professor 1993-	Professor of Oral Medicine, Pathology and Microbiology University of London
1994-	Honorary Senior Associate European Institute of Oncology, Milan (Italy)
1994-	Honorary Consultant (Academic) Middlesex and University College Hospitals, Department of Genitourinary Medicine
1995- 1997	Senior Lecturer (Honorary), University College London

1997-	Professor of Special Needs Dentistry, University College London.
1999-	Honorary Professor, University of West of England
2000-	Honorary Professor; School of Health, Biological and Environmental Sciences, Middlesex University

Visiting Professor

1983-	University of Bath University of West of England University of Athens (Greece) University of Marmara (Turkey)
1989	University of British Columbia (Canada) University of Campinas (Brazil)
1990	University of Ioaninna (Greece) University of Amman (Jordan) University of Western Ontario (Canada) Cidade University, Lisbon (Portugal)
1991	University of Campinas (Brazil) University of Ioannina (Greece) University of Khartoum (Sudan)
1992	University of Bordeaux (France) European Institute of Oncology (Milan)
1993	University of Amsterdam (Netherlands) University of Ankara (Turkey) University of Araraquara (Brazil) University of Berne (Switzerland) University of Campinas (Brazil) University of Chieti (Italy) University of Chile University of Kuala Lumpur (Malaysia) University of London University of Oporto (Portugal) University of Sao Paulo (Brazil)
1994	University of Amsterdam (Netherlands) University of Chieti (Italy) University of Istanbul (Turkey)
1995	University of Araraquara (Brazil) University of Amsterdam (Netherlands) University of Chieti (Italy)

	University of Coimbra (Portugal)
	University of Granada (Spain)
	University of Istanbul (Turkey)
	University of Nagoya (Japan)
	University of Singapore
	University of Tel Aviv (Israel)
1996	Haddassah University (Israel)
	Queens University (Belfast)
	University of Ljubljana (Slovenia)
	University of Athens (Greece)
	University of Brisbane (Australia)
	University of Coimbra (Portugal)
	University of Hong Kong
	University of Leeds (declined)
	University of Melbourne (Australia)
	University of Milan (Italy)
	University of Padua (Italy)
	University of Santiago de Compostela (Spain)
	University of Sydney (Australia)
1997	Tata Memorial Institute (India)
	University of Buenos Aires (Argentina)
	University of Campinas (Brazil)
	University of Coimbra (Portugal)
	University of Glasgow (declined)
	University of Jeddah (Saudi Arabia)
	University of Ljubljana (Slovenia)
	University of Padua (Italy)
	Aristotle University of Thessaloniki (Greece)
	University of Turin (Italy)
	University of Valencia (Spain)
1998	University of Amsterdam (Holland)
	University of Genoa (Italy)
	University of Helsinki (Finland)
	University of Nagoya (Japan)
	University of Matsumoto (Japan)
	University of Oporto (Portugal)
	University of California (USA)
	Aristotle University of Thessaloniki (Greece)
	University of Valencia (Spain)
	Matsumoto University (Japan) (declined)
1999	University of Chieti (Italy)
	University of Turin (Italy)
	Royal College of Physicians and Surgeons of Glasgow
	University of Leeds
	Royal College of Surgeons of Edinburgh
	University of Sao Paulo (Brazil)

	University of Lisbon (Portugal)
	University of Athens (Greece)
	University of Florence (Italy)
	University of Prague (Czech Republic) (declined)
	University of Istanbul (Turkey)
	University of Paris (France)
	University of Salzburg (Austria)
	University of Brescia (Italy)
	Royal College of Surgeons of England
2000	University of Lisbon (Portugal)
	University of Istanbul (Turkey)
	University of Guatemala
	University of West Indies
	University of Harvard (USA)
	University of Recife (Brazil) (declined)
	National Taiwan University (declined)
	University of Athens (Greece) (declined)
	University of Madrid (Spain)
	University of Kuwait (declined)
2001	National Taiwan University (declined)
	Matsumoto University (Japan)
	University of Amsterdam (Holland)
	University of West Indies
	American Dental Association (declined)
	University of Khartoum (Sudan) (declined)
	University of Montreal
	University of Estonia
	University of Santiago de Compostella
	University of Salzburg (Austria)
	University of Viseu (Portugal)
	University of Lyon (France)
	University of Glasgow
	University of Oporto (Portugal)
	University of Birmingham
	Trinity College Dublin
	University of Liverpool
	University of Campinas (Brazil)
2002	University of Viseu (Portugal)
	University of Milan (Italy)
	University of Birmingham
	University of Seville (Spain)
	University of Sao Paulo (Brazil)
	University of Athens (Greece)
	University of Lisbon (Portugal)
	University of Bari (Italy)
	University of Valencia (Spain)
	University of Barcelona (Spain)

	University of Dokkyo (Japan) (declined)
	University of Belgrade (Serbia)
	University of Vienna (Austria)
	Royal College of Surgeons (Ireland)
	European Institute of Oncology (Milan)
2003	University of Athens (Greece)
	European Institute of Oncology (Milan)
	Catholic University of Rome (Italy)
	University of Jordan (Jordan) (declined)
	University of Salzburg (Austria)
	University of Paris (France)
	University of Oxford (UK)
	University of Toulouse (France)
	University of Prague (Czech Republic)
	University of Ancona (Italy)
	University of Santiago (Chile) (declined)
	University of Recife (Brazil) (declined)
	University of Karachi (Pakistan) (declined)
	University of Melbourne (declined)
	University of Iasi, Romania (declined)
	Aristotle University of Thessaloniki (Greece)
	University of Rome (Italy) (declined)
	University of Berlin Humboldt (Germany)
	University of Rochester (USA) (declined)
2004	University of Bangkok (Thailand) (declined)
	Royal College of Surgeons of England
	Lebanese University (Lebanon)
	University of Rome (Italy)
	University of Strasbourg (France)
	University of Tripoli (Libya) (declined)
	Eastman Dental Hospital Rome (Italy)
	University of Rochester (USA) (declined)
	University of Malaysia (Brunei)
	University of Glasgow
	University of Jordan
	University of Naples (Italy)
	University of Oporto (Portugal)
	University of Campinas (Brazil) (declined)
	University of Berlin Humboldt (Germany)
	New York University (USA) (declined)
	University of Siena (Italy) (declined)
	University of Izmir (Turkey) (declined)
	University of Turku (Finland)
2005	
	University of Kuala Lumpur (Malaysia)
	University of Istanbul (Turkey)
	Central Research Institute for Stomatology (Russia)

University of Athens (Greece)

EXTERNAL EXAMINERSHIPS

1982	University of London (PhD)
1982-	Royal College of Physicians and Surgeons of Glasgow (Final FDSRCPS)
1984-1987	University of Ireland (BDS)
1987-1991	University of Glasgow (BDS)
1988-	University of London (BDS, PhD)
1988	University of Wales (MSc)
1990-1994	University of Jordan, Amman (BDS)
1990-	Royal College of Surgeons of England (Final FDSRCS)
1990-	Royal College of Surgeons of Ireland (Final FFDRCSI)
1991-1994	University of Benghazi, Libya (BDS)
1992	University of Bordeaux, France (Dip)
1993	University of Amsterdam, Netherlands (PhD)
1993-	University of London (MSc)
1994	University of Liverpool (PhD)
1994	University of Brisbane, Australia (PhD)
1995-1998	University of Hong Kong (BDS)
1997	University of London (PhD)
1997	University of Santiago de Compostella, Spain (PhD)
1997	University of Oporto, Portugal (PhD)
1997	University of Witswatersrand, South Africa (PhD)
1997	University of Lagos, Nigeria (PhD)

1998 University of London (PhD)

1998- Royal College of Surgeon of Edinburgh (MFDS; FDS)

1998- 2003 University of Glasgow (BDS)

1999 University of Oporto, Portugal (PhD)

EDITORIAL COMMITMENTS (Editorial Board unless otherwise stated)

1985-1988 *Journal of Oral Pathology* (***Associate Editor***)

1988-1993 *Journal of Oral Pathology and Oral Medicine* (***Associate Editor***)

1989 *Current Opinion in Dentistry* (***Associate Editor***)

1991-1996 *European Journal of Cancer* (***Associate Editor***)

1993- 2001 *British Journal of Oral and Maxillofacial Surgery* (***Section Editor***: Research)

1991- *Oral Oncology* (***Founder and Editor***)

1993- *Launchpad*: British Dental Journal for Students

1993- *Brazilian Oral Research* (Pesuisa Odontologica Brasilieira)

1993- *Acta Oncologia Brazileira*

1994- *Oral Diseases* (***Co-Founder and Co-Editor***)

1994- *Journal of Hard Tissue Biology*

1995- *Journal of Epidemiology and Biostatistics*

Stoma: Journal of Portuguese Academy of Oral Medicine

1996- *International Journal of Oral Biology*

International Journal of Oncology

Medicina Oral; Journal of Spanish and Ibero-American Societies of Oral Medicine (***Co- Editor***) (now entitled *Medicina Oral, Patologia Oral y Cirugia Bucal.)*

2000- *CPD Dentistry*

Chulalongkorn University Dental Journal

Middle East Journal of Oral Surgery

2002- *Archives of Oral Biology*

2003- *China Journal of Oral and Maxillofacial Surgery*

Oral Biosciences & Medicine

2004- *Oral Oncology EXTRA* **(Editor)**

2004- *Acta-Oto-Laryngologica*

CLINICAL EXPERIENCE

HOSPITAL APPOINTMENTS

1968 House Surgeon (Periodontology and Preventive Dentistry)
Royal Dental Hospital, London.

1968-1979 Assistant Dental Surgeon* (Associate Specialist)
(Dental Care of the Handicapped), Forest Hospital, Horsham, Sussex.

1974-1979 Assistant Dental Surgeon* (Associate Specialist)
(Dental Care of the Handicapped), Harperbury Hospital, Radlett, Herts.

1975 House Physician, Royal Free Hospital, London.

1975 House Surgeon, Royal Free Hospital, London.

1976 Senior House Officer (Oral and Maxillofacial Surgery)
Guy's Hospital, London.

1976-1979 Registrar (Honorary) (Oral Immunology and Microbiology)
Guy's Hospital, London.

1976-1979 Clinical Assistant (Honorary)*, Department of Immunology
Institute of Child Health, Hospital for Sick Children, Great Ormond Street, London.

1978-1979 Assistant Dental Surgeon* (Associate Specialist) (Conservative Dentistry)

Guy's Hospital, London.

1979-1981 Registrar (Honorary) (Oral Medicine and Pathology)
Glasgow Dental Hospital, Glasgow.

1979 Clinical Assistant (Honorary)*, Department of Haematology
Royal Hospital for Sick Children, Glasgow.

1980-1981 Clinical Assistant (Honorary)*, Department of Oral and Maxillofacial Surgery
Victoria Infirmary, Glasgow.

1981-1982 Consultant (Honorary) (Oral Medicine and Immunology)
Greater Glasgow Health Board, Glasgow.

1982-1991 Consultant (Honorary) (Oral Surgery), Bristol and Weston District Health Authority
Bristol, and South West Regional Health Authority.

1991-1993 Consultant (Honorary) (Oral Surgery), United Bristol Healthcare Trust.

1993-1996 Consultant (Honorary), Eastman Dental Hospital, London.

1994-1995 Consultant (Honorary), The Royal London Hospitals Trust, London

1994-2000 Consultant (Honorary), Horizon Trust, St Albans

1995-1996 Clinical Director, Eastman Dental Hospital, London

1998- 2002 Consultant (Honorary), John Radcliffe Hospital, Oxford

2004- Consultant (Honorary), John Radcliffe Hospital, Oxford

1999- 2002 Consultant (Honorary), Nuffield Orthopaedic Centre, Oxford

2001- 2002 Consultant (Honorary), Royal Free Hospital, London

1995- Consultant (Honorary), University College London Hospitals

1995- Consultant (Honorary), European Institute for Oncology, Milan

1998- Consultant (Honorary), Great Ormond Street Hospital for Children, London

GENERAL PRACTICE:*

1968- General Dental Practice (various)

1975-1983 Dental Care of the Handicapped

St Raphael's Centre, Potter's Bar, Herts.

1979 General Medical Practice

* part-time appointments

ADMINISTRATIVE EXPERIENCE (In addition to Committee Assignments)

Management

Assistant Warden 1980-1982	Wolfson Hall University of Glasgow
Head of Department 1982-1995	Department of Oral Medicine, Oral Surgery, Oral Pathology and Microbiology and Periodontology (including Radiology) Bristol Dental Hospital and School University of Bristol
Head of School (Dean) 1985-1990	Bristol Dental Hospital and School University of Bristol
Director 1989-1993	Centre for Study of Oral Disease University of Bristol
Head of Department 1993-1995	Joint Department of Oral Medicine, Eastman Dental Institute and London Hospital Medical College Dental School
General Manager 1995-1996	Eastman Dental Hospital University College London NHS Trust London
Clinical Director 1995-1996	Eastman Dental Hospital University College London NHS Trust London
Vice-Chairman 1999- 2002	Eastman Oral Health Care
Dean and Director of Studies & Research 1993-1998	Eastman Dental Institute University of London
Co-Director 1996-	World Health Organisation Collaborating Centre for Oral Health, Disability And Culture University of London

Dean and Director of Studies & Research 1998-2003	Eastman Dental Institute University College London
Director 2003-2008	Eastman Dental Institute University College London

Committee Assignments

INTERNATIONAL COMMITTEE ASSIGNMENTS (member unless otherwise stated)

1988	1st World Workshop on Oral Medicine: ***Rapporteur***
1990	European Community: Working Group on Oral Manifestations of HIV Infection: Oral lesions
	European Community: Working Group on Dental Education in Oral Cancer
1990-	European Community: Collaborative Group on Sjogren's syndrome
1991-	Federation Dentaire Internationale: Working Group 12 (Nutrition)
1992	European Community: Working Group on Oral Manifestations of HIV Infection:
	Classification
1993	European Community: Working Group on HIV infection: Educational and Ethical aspects
	European Academy of Periodontology Working Group on Periodontal Manifestations of Systemic Disease: ***Chairman***
	2nd World Workshop on Oral Medicine: ***Rapporteur***
1994-	European Academy of Oral Medicine: ***Founding member***
	European School of Oncology Advisory Group on Oral Carcinogenesis
	European Community: Working Group on “Europe Against Cancer”
	European Organisation for Research and Treatment of Cancer : ***Chairman***:
	Chemoprevention group
1995-	American Academy of Oral Medicine; International Affairs Committee

Federation Dentaire Internationale: Project 1-93 HIV/AIDS Pandemic and Dentistry

European Association of Oral Medicine; Steering Group

Fifth International Congress on Oral Cancer; Organising Committee

1996 World Workshop on Periodontology

European College of Dentistry Steering Group

Third International Workshop on the Oral Manifestations of HIV Infection International Scientific Committee

1996- European Association of Oral Medicine; ***Secretary General***

1997- Third World Workshop on Oral Medicine; ***Vice Chairman*** & ***Rapporteur***

International Federation for Oral Medicine; ***Founding Member and Chairman***

European Association of Dermatology

European Association of Oral Medicine Meeting, Amsterdam (organising committee)

1998- 2nd International Head and Neck Congress, Brazil 2002 (organising committee)

8th International Congress on Oral Cancer, Brazil (organising committee)

Data Centre for International Survival in Cancers of the Head and Neck.

Fourth International Workshop on the Oral Manifestations of HIV Infection;

(international scientific committee)

1999- 2000 Surgeon General's Report on Oral Health; National Institutes of

Health, USA (working group)

2000- European Association of Oral Medicine; ***Vice-President***

Fourth World Workshop on Oral Medicine

2001 American Association of Oral Medicine/European Association of Oral Medicine Meeting; section ***Chair***

2002	World Congress in Dermatology; section ***Chair***
	World Congress on Haemophilia; section ***Chair***
	International Society for Disability and Oral Health; section ***Chair***
	European Association of Oral Medicine; section ***Chair***
2002-2003	European Code against Cancer 2002-2003; executive committee
2002-2004	European Association of Oral Medicine; ***President***
2004-	European Association of Oral Medicine; ***Immediate Past-President***

NATIONAL COMMITTEE ASSIGNMENTS (Member unless otherwise stated**)**

1981-1982	West of Scotland Immunology Group : ***Secretary***
1981-1982	Scottish Immunology Group
1982-1984	Royal College of Physicians and Surgeons of Glasgow : Dental Council
1983-1984	Medical Research Council: Grants Committee A
1984-1989	Medical Research Council, Science and Engineering Research Council and Health Departments; Joint Dental Council
	General Dental Council : Education Subcommittee:
1985-1986	Royal Society of Medicine, Odontological Section: Council
1985-1989	Home Office; Advisory Council on the Misuse of Drugs
1984-1994	General Dental Council
1985-1994	British Dental Association; Scientific Advisor to the Dental Health and
	Science Committee
1985-1987	Department of Health; Working Party on AIDS
1986-1990	Dental Education Advisory Committee
	University Hospitals Association

1986-1996	Department of Health : ***Consultant Advisor in Dental Research***
	Home Office; Assessor on Animal Research
	Hepatitis B Peer Group
1987-1988	General Dental Council; Central Examining Board for Dental Hygienists
1987-1988	British Society for Oral Medicine : ***Council Member***
1987	British Society for Oral Medicine **:** ***President Elect***
1988	British Society for Oral Medicine : ***President***
1988-1994	General Dental Council
	Central Examining Board for Dental Hygienists: ***Chairman***
	General Dental Council, Health Committee
	British Sjogren's Syndrome Association : ***Council Member***
	British Society for Oral Medicine : ***Council Member***
	Royal College of Physicians and Surgeons of Glasgow : ***Regional Adviser***
1988- 1998	Academic Medicine Group (founders of Academy of Medical Sciences)
1990-1993	Medicines Control Agency: Committee on Dental and Surgical Materials
1990- 1999	Joint Committee for Higher Training in Dentistry
1991	British Dental Association: Working Group on HIV
1991-1994	General Dental Council: Special Purposes Committee
	General Dental Council: Oral Health Education Committee
1991-1995	Department of Health: Central Research and Development Committee
1991-	Department of Health: UK Advisory Panel for HIV-infected Health Care Workers
1991-1999	Joint Advisory Committee for Additional Dental Specialties

	UK Working Group on Screening for Oral Cancer and Precancer
1992	Intercollegiate Specialty Assessment Board in Oral Medicine
1993-1999	Department of Health: Standing Dental Advisory Committee
1993-	University Hospitals Association
	Council of Deans of Dental Schools
1994-1996	British Association of Oral and Maxillofacial Surgeons; Audit Subcommittee of Working party on Management of White Patches of the oral mucosa*:* ***Chairman***
	Department of Health: Advisory Group on setting NHS R&D priorities in primary dental care
	Department of Health: UK Collaborative Group on Oral Cancer
	Department of Health: Advisory Panel on Postgraduate Dental Training
1994-2004	British Council : Health Advisory Committee : ***Advisor in Dentistry***
1995-1998	Department of Health: Chief Medical Officer's Advisory Group on Ethics in Research
	Department of Health: National Advisory Group on Screening for Oral Cancer
	Royal College of Surgeons: Joint Advisory Committee for Additional Dental Specialties : ***Chairman***
	Royal College of Surgeons: Manpower Advisory Panel
	Joint Committee for Higher Training in Dentistry
1996-1998	General Dental Council; Task Force on Specialisation
1996-	Raynaud's and Scleroderma Association; Medical Advisory Panel.
1997-	Royal College of Surgeons of Edinburgh; ***Advisor***
	British Society for Oral Medicine; ***Council Member***
1998-	Academy of Medical Sciences
	Royal College of Surgeons of Edinburgh; ***Examiner in Special Needs Dentistry***

	Royal College of Surgeons of Edinburgh; ***Examiner in Oral Medicine***
	Royal College of Surgeons of Edinburgh; Committee on Additional Dental Specialties
1999-2001	Higher Education Funding Council; Research Assessment Exercise; Clinical Dentistry Panel
1999-	Medical Research Council; Cross-Board sub-committee
2001-	Department of Health: Expert Advisory Group on AIDS (EAGA); Working Group on HIV patient notification exercises
2001-	National Institute for Clinical Excellence (NICE); Working Group on oral cancer (DH)
2001-2002	Department of Health: Specialist Advisory Committee on Antimicrobial Resistance (SACAR)
2001-2003	General Dental Council; Elected member: Professional Conduct Panel Registration Sub-Committee
2001-	British Association for Head and Neck Oncology: Working Group on Guidelines for Oral Cancer
2004	National Institute for Clinical Excellence (NICE); Dental Recall Intervals guideline (DH)
2004-	British National Formulary; Dental Practitioners Formulary; Specialist advisor
2004-	International Qualifying Examination (GDC); Examiner
2004-	Mouth Cancer Foundation; Trustee
2004-	Royal College of Surgeons of Edinburgh; Regional Adviser North Thames
2004-	National Institute for Clinical Excellence (NICE); CJD advisory subcommittee (DH)

LOCAL AND REGIONAL COMMITTEE ASSIGNMENTS (member unless otherwise stated)

1978-1979	University of London, Guy's Hospital : Ethical Committee
1980-1982	University of Glasgow, Wolfson Hall: ***Assistant Warden***
1982-1984	Bristol and Weston Health Authority

1982-1993 University of Bristol

Board of Medical Faculty
Senate
Committee of Professors in the Medical Faculty
Board of Dental Studies
Dental Division Steering Group (subsequently Management Group)
Staff Appointments Committee
Regional Committee on Postgraduate Education
Students Progress Committee
Dental Division
Health and Safety Committee
University Court
Student Admissions Committee
Cross Infection Committee
Regional Dental Committee
Equipment Sub-committee
Human Disease Sub-committee
Curriculum Sub-committee

1982-1992 King Edward Surgeons Committee (subsequently Division of Surgery)

1983-1991 South West Regional Committee for Hospital Dental Services

1984-1989 Bristol Dental Hospital Dental Division: ***Vice-Chairman***

1985-1990 Regional Committee for Specialist Training (SouthWest Region)

1986-1990 Regional University Liaison Committee (Bristol)

1986-1993 University of Bristol : Faculty of Medicine Sub-committee on Higher Degrees

1992-1994 South West Regional Hospital Medical : Advisory Committee Dental Specialties Sub-committee

1992-1994 United Bristol Healthcare Trust : Research and Development Committee

1992-1994 South West Regional Health Authority : Research and Development Scientific Committee

1993-1995 University of London, London Hospital Medical College Dental School
Dental Education Group Committee
Standing Committee in Dentistry
Academic Board
Medical Council

1993-1996 University of London, British Postgraduate Medical Federation
Executive Committee

Finance Committee

1993-1996 Eastman Dental Hospital : ***Director of Research and Development***

1996 Merger Steering Group: UCLH Trust

1993- University of London; Dental Subject Panel

Eastman Dental Research Foundation (Later Eastman Foundation for Oral Research & Training; EFFORT)

1993-2000

Camden and Islington Health Authority; Research and Ethics Committee

Joint Research and Ethics Committee: ***Chairman***

1993-1996 Eastman Dental Hospital
Board of Governors

1995-1996 University College Hospitals Trust; ***Clinical Director***
General Manager, Eastman
Dental Hospital

1993-1999 Eastman Dental Institute
Committee of Management
Board of Governors
Chairman
Academic Board
Steering Group
Joint Consultative Committee
Ethics Committee
Research Committee
Graduate and Continuing Education Committee
Administration Committee
Resource and Policy Committee
Dental Practice Centre Committee
Safety Committee

1995- North Thames Regional Health Authority; Specialty Higher Training Committee in Dentistry

1996-2000 Clinical Research Network Board

North East Thames Region; Advisory Committee on Distinction Awards

University of London; Metropolitan Deans Committee

University College London; UCL and RFH Medical School Strategy Group

	UCL Biomedicine Strategy Group
1999-	Middlesex University; Court
2001- 2003	UCLH Trust, ***Chairman***, Specialist Services Directorate: Discretionary Award Committee
2001-	North London Cancer Network; Head and Neck Tumour Board
	London Infectious Disease Network; Board
	UCL Sabbatical Committee
2003-	International Centre for Evidence-based Oral Health; Board

REFEREE

Acta Odontologica Scandinavica
Acta Pathologica Microbiologica et Immunologica Scandinavica
AIDS
Alimentary Pharmacology and Therapeutics
American Journal of Dentistry
American Journal of Obstetrics and Gynecology
Annals of the Rheumatic Diseases
Archives of Oral Biology
Autoimmunity
Bone
Bone Marrow Transplantation
British Dental Journal
British Journal of Cancer
British Journal of Dermatology
British Journal of Oral and Maxillofacial Surgery
British Medical Journal
Cancer Chemotherapy and Pharmacology
Cancer Epidemiology, Biomarkers and Prevention
Cancer Letters
Cancer Research
Clinical and Experimental Dermatology
Clinical and Experimental Immunology
Clinical and Experimental Rheumatology
Community Dentistry and Oral Epidemiology
CPD Dentistry
Current Science
Cytokine
Dental Practice
Dental Update
Drugs and Aging
European Journal of Cancer

European Journal of Cancer Prevention
European Journal of Neurology
European Journal of Oral Sciences
Gerodontology
Gut
Health Trends
Hemophilia
International Dental Journal
International Journal of Cancer
International Journal of Oncology
Journal of Antimicrobial Chemotherapy
Journal Biology Buccale
Journal of Clinical Microbiology
Journal of Clinical Pathology
Journal of Dental Research
Journal of Dentistry
Journal of Dermatological Treatment
Journal of Epidemiology and Biostatistics
Journal of the European Academy of Dermatology and Venereology
Journal of Intellectual Disabilities Research
Journal of Oral Pathology and Oral Medicine
Journal of Periodontal Research
Journal of Public Health Dentistry
Lancet
Medical Principles and Practice
Medicina Oral
Microbes and Infection
Microbial Ecology in Health and Disease
Molecular Medicine Today
Nature Reviews
Occupational and Environmental Medicine
Oral Biosciences and Medicine
Oral Diseases
Oral Oncology
Oral Surgery, Oral Medicine and Oral Pathology
Pathology, Research and Practice
Postgraduate Dentist
Scandinavian Journal of Dental Research
Special Care Dentistry
Supportive Care in Cancer
The Cancer Journal
Trends in Molecular Medicine
UICC; Union Internationale Contre Cancer

AD HOC REVIEWER/SITE VISITOR FOR

Association for International Cancer Research
BUPA Research Foundation
Canadian Institutes of Health Research

Cancer Research Campaign
Cancer Research UK
Charitable Infirmary Charitable Trust (Dublin)
Department of Health
Dutch Cancer Society
Engineering and Physical Sciences Research Council
European Commission Information Society Directorate-General
Guy's and St. Thomas' Charitable Trust
Health Research Board (Ireland)
Health and Personal Social Services in Northern Ireland
Hong Kong Medical Research Council
Imperial Cancer Research Fund
Irish Medical Research Council
Italian Ministry for University and Research
King's Fund
Kuwait Government
Leverhulme Trust
Medical Research Council (Hong Kong)
Medical Research Council (UK)
Middlesex University
National Institutes of Health, USA
North West Regional Health Authority
Northern Ireland Health & Social Services Central Services Agency
Nuffield Foundation
Phillip Morris Research Fund
Royal Free Hospital NHS Trust
Saudi Government
Scottish Home and Health Department
Scottish Office Clinical Research Audit
South East Thames Health Authority
South West Regional Health Authority
Spastic Society
Swiss National Research Foundation
University and Polytechnic Grants Committee (Hong Kong)
University of Bristol
University of California appointments
University of Dublin; Trinity College
University of Glasgow
University of Helsinki appointments
University of Hong Kong appointments
University of Lagos promotions
University of Liverpool appointments
University of London appointments
University of Manchester appointments
University of Melbourne appointments
University of Newcastle appointments
University of Sao Paulo Assessment Committee
University of Strasbourg (France)
University of Turku: appointments
University of West of England

University of Witswatersrand
Wellcome Trust
Welsh Scheme for the Development of Health and Social Research

ORGANISATION OF NATIONAL/INTERNATIONAL CONFERENCES

1988 World Congress on Dentistry, Bristol (co-organiser)*

1989 British Society of Oral Medicine, Bristol (organiser)

1993 British Council Course (9349): HIV and other Special Needs (organiser)*

1993 European meeting on Non-invasive Oral Health Care, London (co-organiser)*

1994 European School of Oncology: Head and Neck Cancer, Lugano, Switzerland (co-organiser)

1995 European meeting on Lichen Planus, Villars, Switzerland (organiser)*

1996 Third World Workshop on Oral Manifestations of HIV, London (co-organiser)*

1996 Oral Pathogens contributing to Systemic Infections, London (co-organiser)

1996 European School of Oncology: Head and Neck Cancer, Milan, Italy (co-organiser)

1996 European Association of Oral Medicine Meeting, Belfast (co-organiser)

1997 5th International Congress on Oral Cancer, London (co-organiser)*

1997 Special Needs in Dentistry European Meeting, Verbier, Switzerland (organiser)

1997 European Association of Oral Medicine Meeting, London (organiser)

1998 European Association of Oral Medicine Meeting, Amsterdam (co-organiser)

1999 8th International Congress on Oral Cancer, Brazil (co-organiser)

1999 European Association of Oral Medicine Meeting, London (co-organiser)

2000 European Oral Medicine Meeting (co-organiser)*

2002 2nd International Head and Neck Congress, Brazil (co-organiser)

2002 European Association of Oral Medicine Meeting, Lisbon (co-organiser)

2003 International Consensus meeting on Lichen Planus, Chamonix, France (organiser)*

2004 3rd International Congress on Oral Malodour, London (co-organiser)*

2005 10th International Congress on Oral Cancer, Greece (co-organiser)

* Peer-reviewed publications resulted

PUBLIC SERVICE

British School of Osteopathy Appeals Charity; Vice-Patron

RESEARCH FUNDING

RESEARCH FELLOWSHIPS AND STUDENTSHIPS

1. MEDICAL RESEARCH COUNCIL (£9,000)
   Research Studentship (3 years) to investigate proteins in Sjogren's syndrome (Christine Carr).

2. MEDICAL RESEARCH COUNCIL (£9,000)
   Research Studentship (3 years) to investigate oncogenes in oral cancer (Louise Torrance).

3. MEDICAL RESEARCH COUNCIL (£37,725)
   Research Training Fellowship (3 years) to investigate the immunology of rapidly progressive periodontitis (Stephen Porter).

4. MEDICAL RESEARCH COUNCIL (£37,500)
   Research Training Fellowship (3 years) to investigate tissue culture of oral carcinoma. (Jane Luker).

5. MEDICAL RESEARCH COUNCIL (£25,500)
   Research Training Fellowship (3 years) to investigate salivary protein abnormalities in Sjogren's syndrome (Stephen Flint).

6. MEDICAL RESEARCH COUNCIL (£3,000)
   Advanced Course Studentship (1 year).
   (Growth characteristics of oral epithelial cells in culture) (Lisa Davies).

7. WELLCOME TRUST (£105,000)
   Wellcome Lectureship (5 years) for research into Immunology of Oral Disease. (15826/126; 124608-00-17) (Isobel Crane).

8. COLGATE RESEARCH AWARD (£1,500)
   To raise monoclonal antibodies against protease of Bacteroides gingivalis. (Mustafa O Ismaiel).

9. OVERSEAS RESEARCH STUDENT AWARD (£20,000)

Research Studentship (3 years) to investigate Bacteroides gingivalis protease. (ORS/85051)
(Mustafa O Ismaiel).

10. MEDICAL RESEARCH COUNCIL (£9,000)
Research Studentship (3 years) for studies on growth factors in epithelial differentiation and tumourigenicity (RS/87/72) (Mary Donnelly).

11. COLGATE RESEARCH AWARD (£1,000)
To study viral aetiology of salivary gland disease (Stephen Flint).

12. MEDICAL RESEARCH COUNCIL (£3,000)
Advanced course studentship (1 year) (Oral lichen planus in vitro) (John Bowden).

13. GREEK GOVERNMENT SCHOLARSHIP (£3,000)
The study of the lectin Europeus type 1 to study epithelial cells surfaces in normal and oral mucosa and oral white lesions (Dimitris Malamos).

14. COMMONWEALTH SCHOLARSHIP (£12,000)
Major histocompatibility antigens in oral carcinogenesis (Athula Pitigala-Arachchi).

15. TURKISH GOVERNMENT SCHOLARSHIP (£45,000)
Epithelial-lymphocyte interactions in oral malignancy (Serdar Mutlu).

16. MEDICAL RESEARCH COUNCIL
Research studentship (3 years) for studies on papillomavirus (Martyn Cox).

17. COLGATE RESEARCH AWARD (£823)
To study in vitro carcinogenesis (Stephen Game).

18. WELLCOME TRUST (£50,393)
Wellcome Lectureship (2 years) for research to immunology of oral disease (1586126) (Isobel Crane).

19. BRAZILIAN GOVERNMENT SCHOLARSHIP (£10,000)
To study EGF and TGF receptors (Maria Regina Spostos).

20. COLGATE RESEARCH AWARD (£1,000)
To study Sjogren's syndrome (Serdar Mutlu).

21. OVERSEAS DEVELOPMENT ADMINISTRATION
Study visit on management of HIV-infected patients (Carol Sopida).

22. UNILEVER/MENTADENT RESEARCH AWARD (£574)
To study DNA sequences from dental plaque (Melanie Wilson).

VISITING PROFESSORSHIPS

1. BENJAMIN MEAKER VISITING PROFESSORSHIP (£2,000)

Awarded to have Professor Alan Drinnan (University of Buffalo) visit, 1989.

2. BENJAMIN MEAKER VISITING PROFESSORSHIP (£2,300)
Awarded to have Professor Joel Epstein (University of British Columbia) visit, 1990.

3. BENJAMIN MEAKER VISITING PROFESSORSHIP (£3,000)
Awarded to have Dr David Wiesenfeld (University of Melbourne) visit, 1991.

4. BENJAMIN MEAKER VISITING PROFESSORSHIP (£3,600)
Awarded to have Professor Oslei Almeida (University of Sao Paulo) visit, 1992.

5. BRITISH COUNCIL
Awarded for Professor M Deo (Bombay; Tata Memorial Institute) visit, 1993.

6. WORLD HEALTH ORGANISATION
Awarded for Professor Peter Lockhart (University of Carolina) visit, 1994.

7. IRONMONGERS COMPANY (£1,000)
Awarded to Professor Adriano Piattelli (University of Chieti) lecture, 1995

8. IRONMONGERS COMPANY (£1,000)
Awarded to Professor Isaac van der Waal (University of Amsterdam) lecture, 1998

9. IRONMONGERS COMPANY (£1,000)
Awarded to Professor Per-Ingvar Branemark (University of Gothenburg) lecture, 2000

10. IRONMONGERS COMPANY (£1,000)
Awarded to Professor Oslei Paes de Almeida (University of Campinas) lecture, 2000

RESEARCH AND OTHER GRANTS

Investigators	Year	Source	Title	Amount
C Scully	1976-1979	Medical Research Council	To investigate the immunology of caries	Personal
C Scully J Beeley	1981-1984	Nuffield Foundation Oliver Bird Trust Fund	To investigate salivary proteins in connective tissue diseases	Project grant
C Scully	1981-1984	Scottish Home and Health Department	To investigate the cellular response in oral lichen planus, lichenoid reactions and lupus erythematosus	Biomedical Research Grant
C Scully	1982-1985	South West Regional Health Authority	To investigate the cellular response in oral lichen planus, drug-induced	£15,337

			lichenoid lesions and oral lupus erythematosus	
C Scully	1982-1985	South West Regional Health Authority	To investigate the role of viruses in the aetiology of human squamous cell carcinoma	£13,554
C Scully J Whicher	1983-1986	Medical Research Council	To examine salivary proteins and immunology of Sjogren's syndrome	£24,718
C Scully L Gathercole	1983-1986	Medical Research Council	Periodontal ligament structure	£42,610
C Scully L Gathercole	1986	Medical Research Council	Extension to above	£7,658
C Scully S S Prime N Maitland	1987-1990	Cancer Research Campaign	An investigation of cell surface and genetic changes in oral carcinogenesis in vitro	£78,363
C Scully N Maitland S S Prime	1987-1990	Cancer Research Campaign	Viral aetiology of oral dysplasia and carcinoma	£44,743
C Scully M Stack	1987-1989	Bristol and Weston District Health Authority	Examination of trace elements in developing teeth	£10,287
C Scully C Stephens M Griffiths	1987-1990	Bristol and Weston District Health Authority	Medical diagnosis related to data derived from patient management	£927
C Scully J Whicher K Bhoola	1986-1989	Medical Research Council	To examine salivary kallikreins in Sjogren's syndrome and connective tissue disease	£74,148
C Scully L Gathercole	1987-1990	Medical Research Council	To examine the integrity and damage in periodontal basement membrane structure and the role and aggregation properties of Type IV collagen	£62,163
C Scully I Crane N Maitland	1987-1990	Medical Research Council	To manipulate MHC antigen expression in oral keratinocytes by transfection of MHC	£11,085

			genes	
C Scully	1989	Erasmus Bureau	Study visit to schools in Germany, Spain, France, Greece and the Netherlands	ECU 4,150

Investigators	Year	Source	Title	Amount
C Scully S Manton M Midda	1988-1989	Bristol and Weston District Health Authority	Tetracycline therapy for patients with refractory periodontal disease	£2,325
C Scully J Eveson J Bradfield N Maitland A Morgan	1989	Cancer Research Campaign	To examine viral aetiology of salivary gland disease	£2,000
C Scully N Maitland S Prime	1989	Cancer Research Campaign	Viral aetiology of oral dysplasia and carcinoma	£30,000
C Scully S Prime N Maitland	1989	Cancer Research Campaign	An investigation of cell surface and genetic changes in oral carcinogenesis: the role of growth factors	£92,560
C Scully J Eveson S Prime	1989	Cancer Research Campaign	To characterize salivary gland tumour cells in vitro and in vivo	£1,750
C Scully J Greenman K Morgan	1988-1989	Medical Research Council	To examine broken mouth in sheep as a model for periodontal disease in man	£21,000
C Scully	1989	Fairhurst Fund University of Bristol	To examine immunoglobulin subclasses in recurrent aphthous stomatitis	£500
C Scully S Prime	1988	Denman Charitable Trust	Oral carcinogenesis	£12,500
C Scully	1989	Bristol University Research Committee	Oral carcinogenesis	£3,146
C Scully	1989	British Council	Travel grant	£700
C Scully	1989	Royal College of Physicians and Surgeons	Travel grant	£600
C Scully	1989	University of British	Kaposi's sarcoma	£2,000

		Columbia		
C Scully S Prime	1989-1991	Denman Charitable Trut	Oral carcinogenesis	£33,000
C Scully	1991	Bristol and Weston District Health Authority	To investigate the periodontal flora and immune responses in Sjogren's syndrome and other connective tissue disorders	£4,300
C Scully P Maddison S Mutlu	1991	Arthritis and Rheumatism Council	An investigation of periodontal flora and immune responses in Sjogren's syndrome with systemic lupus erythematosus	£15,322
C Scully	1991-1992	Blendax	An investigation of candida carriage and the effect of a peroxygen medication	£70,000
C Scully	1990	3M Health Care Ltd	Drug trial	£4,000
C Scully	1991	Royal College of Physicians and Surgeons	Travel grant	£300
C Scully	1991	SmithKline and Beecham	An investigation of infection control in dentistry	£2,000
C Scully	1983-1990	Industrial support from smaller companies	Clinical trials	£14,800
C Scully	1991	Special Trustees of United Bristol Hospitals	Travel grant	£700
C Scully S Mutlu	1991	Fairhurst/Chirney/Harrison amalgamated fund (University of Bristol)	A longitudinal investigation of the periodontal flora in English HIV seropositive persons	£2,000
C Scully S Prime	1992-1995	Denman Charitable Trust	Oral carcinogenesis	£50,000
C Scully J Greenman	1992	Procter and Gamble	Halitosis	$1,000,000
C Scully SR Porter	1993	Overseas Development Administration	HIV training	£10,000
C Scully	1993	Procter and Gamble	Funding of lectureship and other staff	£275,000

C Scully	1993	Procter and Gamble	An investigation of an oral antimicrobial	£45,000
C Scully S Porter D Warnock	1993	United Bristol Healthcare Trust	Fluconazole susceptibility of candida	£7,400
C Scully A Harrison	1993	Erasmus Bureau	Student mobility programme	ECU 4,600
C Scully W Wade	1993	South West Regional Health Authority	Molecular analysis of microflora in dentoalveolar abscess	£46,833
C Scully	1993	British Council	Travel grant	-
C Scully S Porter	1993	Department of Health	CAL project: oral manifestations of HIV	£16,000
C Scully	1994	European Institute of Oncology	Molecular analysis of oral cancer	£100,000
C Scully	1994	Eastman Research Foundation	Research into special needs patients	£45,000
C Scully	1994	European Commission	Participation in review of “Europe against Cancer”	£1,500
C Scully S Porter	1994	Procter and Gamble	Anti-calculus dentifrice	£150,000
C Scully N Johnson P Lamey	1994	National Health Service Executive	Premalignant lesions	£3,192
S Porter C Scully	1994	3M	Benzydamine in lichen planus	£4000
C Scully	1995	Australian Vice-Chancellors Committee	Visiting Fellowship	£10,000
C Scully	1995	CNPq (Brazilian Medical Research Committee)	Visiting Research Fellowship	£2,000
C Scully R Bedi	1994	European Commission	Establishment of Transcultural Oral Health Centre	£75,000
C Scully R Bedi	1994	Department of Health	Establishment of Transcultural Oral Health Centre	£100,00
S Porter C Scully	1995	Proctor and Gamble	Study of anticalculus agent	£30,000
C Scully	1995	British Council	Travel grant	£354
C Scully	1996-2001	Nobel Biocare	Funding for Chair in Implantology	£500,000
S Porter C Scully	1997	National Institutes of Health USA	Importance of HHV-8 in oral disease	£108,601
C Scully S Porter	1997,1998 1999	Horizon Trust	Special Needs Dentistry	£150,000

S Porter C Scully D Pollard	1998	Department of Health	Use of CAL in CPED	£20,000
C Scully	1999	Higher Education Funding Council	Project Capital Research Allocation	£200,000
R Bedi, R Walker C Scully	2000	Matsumoto Dental Research Fund	Expectations and experiences of dental care of Japanese patients	£132,887
C Scully and others	2000	EU Directorate on Education & Culture	DentEdEvolves	230,400 euros
C Scully AR Samsudin	2001	British Council	Centre for Craniofacial Sciences	£2000
P Speight, C Scully, G Williams, To Zung	2002	Special Trustees of UCLH - Clinical Research and Development Committee	Analysis of DNA content (ploidy) and DNA replication licensing proteins in oral epithelial dysplasia.	£29,239
C Scully	2002-2004	Nobel Biocare	Funding for Implantology	£50,000
C Scully	2003-2006	BBSRC	Tissue bioreactor science	£242.113

MEMBERSHIP OF PROFESSIONAL SOCIETIES

Academy of Medical Science
British Dental Association
British Society of Paediatric Dentistry
British Society for Dental and Maxillofacial Radiology
British Society for Dermatology
British Society for Disability and Oral Health
British Society for Dental Research
British Society for Immunology - membership number 78049
British Society for Oral Medicine
British Society for Oral Pathology - membership number 00848417
Dental Editors Forum
Dental Protection - membership number 177296
European Academy of Oral Medicine
Glasgow Odontological Society
International Association for Dental Research - membership number 0045720
International Association for Disability and Oral Health
International Association of Oral and Maxillofacial Pathology and Medicine
International Federation for Oral Medicine
Medico-Legal Society

Pathological Society of Great Britain and Ireland
Royal Society of Medicine

APPENDIX 2

SUMMARY OF CLINICAL TRIALS CONDUCTED ON TOOTH WHITENING PRODUCTS

Tooth Whitening Product Clinical Studies (1996 – 2004)

Table 1. Studies of 1 – 14 Day Product Exposure

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcome
OTCHC-904 P&G in-house	33	• 10% Carbamide Peroxide (CP) [~3.3% Hydrogen Peroxide (HP)] Opalescence	• 6-8 hrs/day for 7 days • 2 hrs/day for 14 days	• Treatment groups had similar adverse event (AE) profiles • 67% of subjects had oral soft tissue (OST) AEs and 45% had tooth sensitivity (TS). • Some OST AEs may have been related to poorly fitting customized delivery device.
1997080 P&G in-house	63	• 10% CP (~3.3% HP) Opalescence	• 2 hrs/day for 14 days • With or without prophylaxis	• Groups had similar AE profiles • With prophylaxis: 16% of subjects had OST AEs, 23% had TS, and 0% had non-OST/TS • Without prophylaxis: 19% of subjects had OST AEs, 22% had TS, and 3% had non-OST/TS • All AEs were mild in severity
1997103 P&G in-house	45	• 10% CP (~3.3% HP) gel on strip (Opalescence)	• Maxillary and mandibular strips • All products used 5 days/week for 14 days • 3 h/day (1 strip) • Excess gingival overlap • 2 h/day (1 strip) • 2 h/day (2 strips, 1 h/strip)	• AE incidence & AE profiles were comparable between groups; • For both the 3 h/day (1 strip) & Excess gingival overlap (1 strip): 20% of subjects had OST AEs, 20% of subjects had TS • 2 h/day (1 strip): 22% of subjects had OST AEs, 15% of subjects had TS • 2h/day (2 strips, 1 h/strip): 50% of subjects had OST AEs, no TS were reported
1998036 P&G in-house	109	• 10% CP (~3.3% HP; Rapid White) 10 min. Kit • 10% CP (~3.3% HP; Natural White) 4 min. Kit	• All products used 1X/day for 14 days • Maxillary only	• AEs were primarily mild; OST AEs were more frequent than TS. • Incidence of AEs per group

		• 5.3% HP, pH 4.5 CWS gel in Natural White tray • 10% CP (~3.3% HP), pH 7 gel on a strip, 120 min. • 3.3% HP, pH 5.5 gel strips 30 min. • 5.3% HP, pH 5.5 gel strips 60 min. • 5.3% HP, pH 5.5 gel strips 30 min. • 5.3% HP, pH 4.5 gel strips 30 min.		was as follows: • Rapid White, 10 min: 42% had OST AEs, 8% had TS. • Natural White, 4 min: 0% had OST AEs, 8% had TS; the single OHT was moderately severe. • 5.3% HP gel, pH 4.5, 4 min: 25% had OST AEs, none had TS. • 5.3% HP gel strip, pH 4.5, 4 min: 8% had OST AEs, 15% had TS; one OHT AE was severe leading to subject withdrawal from study. • 10% CP on strip, pH 7, 120 min: 58% had OST AEs, none had TS. • 3.3% HP gel strip, pH 5.5, 30 min: 23% had OST AEs, 8% had TS. • 5.3% HP gel strip, pH 5.5, 60 min: 67% had OST AEs, 8% had TS. • 5.3% HP gel strip, pH 5.5, 30 min: 36% had OSTAEs, none had TS. • 5.3% HP gel strip, pH 4.5, 30 min: 33% had OST AEs, none had TS.
1999051 P&G in-house	57	• 5.3% HP gel strips • Placebo	• 30 min, 2X/day for 2 weeks • Maxillary & mandibular treatment	• 5.3% HP gel strip: 14% of subjects had OST AEs, 11% had OHT AEs. • Placebo strip: 14% of subjects had OST AEs, 3% had OHT AEs. • No subjects experienced any non-OST/TS. • All OHT AEs were mild in severity. • OST AEs were mild or moderate in severity.
1999103	41	• 5.3% HP gel strips	• Gel strips: 30 min, 2X/day for	• 5.3% HP: 22% of subjects had

Gerlach et al. Comp. Cont. Ed. Dent., 21 (Suppl 29), S22-28, 2000, P&G In-house		• 10% CP (~3.3% HP) Opalescence • 15% CP (~5% HP) Opal + NaF • 20% CP (~6.7% HP) Opal (includes NaF)	2 weeks, maxillary & mandibular treatment • Opalescence trays: 2 hours/day, 1x/day, for 2 weeks	OST AEs, 0% had TS • 10%Opal:10% of subjects had OST AEs, 10% had TS • 15%Opal: 9% of subjects had OST AEs, 27% had TS • 20%Opal:40% of subjects had OST AEs, 60% had TS
1999112 Hill Top	51	• 5.3% HP gel strips (brush as usual with marketed dentifrice) • Crest Extra Whitening (use placebo gel strip)	• Gel strips: 30 min, 2X/day for 2 weeks, maxillary only • Dentifrice: brush at least 2X/day	• 5.3% HP gel strip: 23% of subjects had OST AEs, 15% had TS. • Whitener dentifrice: 16% of subjects had OST AEs, 4% had TS.
2000001 Univ. Pacific	49	• 5.3% HP gel strips • Placebo	• Maxillary only • 30 min/application, 2X/day, for 2 weeks	• Mild to moderate tooth pain, gingival pain, and/or lip ulcers may be potential AEs
2000005 Univ. North Carolina	36	• 5.3% HP gel strips • 10% CP (~3.3% HP) Opalescence • 20% CP (~6.7% HP) Opalescence, with NaF	• Gel strips: 30 min, 2X/day for 2 weeks, maxillary only • Opalescence trays: overnight (~8 hours) 1x/day for 2 weeks • Because maximal whiteness was achieved, exposure was terminated on day 10 for 1 subject using 5.3% HP; on day 7 and 10 for 2 subjects using 10% CP; on day 7 for 5 subjects using 20% CP	• AEs for all visits: • 5.3% HP gel strip: 62% of subjects had OST AEs, 15% had TS • Opal-10: 91% of subjects had OST AEs, 18% had TS. • Opal-F-20: 92% of subjects had OST AEs, 42% had TS. • The severity of OHTAEs was mild in all groups. • For OST AEs, in the 5.3% HP gel strip group, 95% were mild and 5% were moderate (1 gingivitis AE); in the Opal-10 group, 91% were mild and 9% were moderate (1 gingivitis and 1 pain AE); in the Opal-F-20 group, 56% were mild, 37% were moderate (7 gingivitis and 2 pain AEs), and 7% were severe (2 gingivitis AEs). • No serious AEs occurred.
2000010 TKL Research, NJ	40	• 5.3% HP gel strips • 10% CP (~3.3% HP) Opalescence • 20% CP (~6.7% HP) Opalescence, with NaF	• Gel strips: 30 min, 2X/day for 2 weeks, maxillary only • Opalescence trays: overnight (~8 hours) for 2 weeks	• 5.3% HP gel strip: 25% of subjects had OST AEs, 17% had TS • Opal-10: 28% of subjects had

				OST AEs, 14% had TS. • Opal-F-20: 71% of subjects had OST AEs, 28% had TS. • All AEs were moderate and most resolved within 2 weeks.
2000022 Univ. FL	29	• 5.3% HP gel strips (brush with Crest Cavity Protection) • Crest Extra Whitening (with placebo strip)	• Gel strips: 30 min, 2X/day for 2 weeks, maxillary only • Dentifrice: brush at least 2X/day	• 5.3% HP strip: 27% of subjects had OST AEs, 20% had TS. • Crest Extra: 14% of subjects had OST AEs, 0% had TS.
2000096 P&G In-house	36	• 5.3% HP gel strips with pre-brushing • 6.5% HP gel strips with pre-brushing • 6.5% HP gel strips without pre-brushing	• Maxillary and mandibular treatment • Use gel strips 30 min/use, 2X/day, for 2 weeks	• 5.3% HP with pre-brushing: 17% of subjects had OST AEs, 17% had TS, and 0% had non-OST/TS. • 6.5% HP without pre-brushing: 67% of subjects had OST AEs, 25% had TS, and 0% had non-OST/TS. • 6.5% HP with pre-brushing: 67% of subjects had OST AEs, 17% had TS, and 0% had non-OST/TS.
2000125 Gerlach et al., Am. J. Dent., 15, 7A-12A, 2002 P&G In-house	50	• 6.0% HP gel strips without pre-brushing • 10% CP (~3.3% HP; Rapid White) US marketed product	• Gel strips: 30 min, 2X/day for 14 days (maxillary only) • Rapid White: 10-20 min, 1 or 2x/day, for 7 days (maxillary and mandibular treatment)	• All OST AEs were mild; in CWS group, 1 OHT was moderate, the rest were mild in severity • CWS: 12% of subjects had OST AEs and 24% had TS • Rapid White: 52% of subjects had OST AEs and none had TS. • Data for non-OHT/OST AEs were not collected. • No severe or serious AEs occurred.
2000159 P&G In-house	12	• 6% HP gel strips, mandibular only, use rubber dental dam • 6% HP gel strips, mandibular only, no rubber dental dam	• Supervised use of the product, 1X/day for 10 working days	• No TS were reported for either group • One OST AE was reported in the group without the dental dam.
2000163 P&G In-house	20	• 5.3% HP gel strips • 6.0% HP gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• 5.3% HP: 10% of subjects had OST AEs, 20% had TS • 6.0% HP: 20% of subjects had

				OST AEs and 10% had TS. • Overall, 83% of AEs mild in severity, no serious or severe AEs
2001013 Univ. FL	60	• CWS Retail Kit (6% HP gel strips) • Rembrandt Plus Superior Bleaching System (10% CP/~3.3% HP gel) in tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Rembrandt Plus: 20 – 30 mins/application, 2X/day, for 14 days	• CWS: 35% of subjects had OST AEs, 17% had TS. • Rembrandt Plus: 57% of subjects had OST AEs, 11% had TS. • Overall, 85% of AEs mild in severity, no serious or severe AEs.
2001018 Gerlach et al., Am. J. Dent. 14, 267-272, 2001 P&G In-house	20	• CWS Retail Kit (6% HP gel strips) • Rembrandt Plus Superior Bleaching System (10% CP/~3.3% HP gel) in tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Rembrandt Plus: 20 – 30 mins/application, 2X/day, for 14 days	• CWS: 10% of subjects had OST AEs, 40% had TS • Rembrandt Plus: 70% of subjects had OST AEs, 10% had TS • Overall, 80% of AEs mild in severity, no serious or severe AEs
2001023 P&G In-house	36	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 6% HP gel strips (0.15 gm gel load) • 6% HP gel strips (0.10 gm gel load) • 6% HP gel strips (0.05 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 58% of subjects had OST AEs, 17% had TS • 6% HP/0.15 gm: 50% of subjects had OST AEs, 8% had TS • 6% HP/0.10 gm: 67% of subjects had OST AEs, 17% had TS • 6% HP/0.05 gm: 17% of subjects had OST AEs, 17% had TS • Overall, 92% of AEs mild in severity, one (4%) severe OHT AE (hyperesthesia) in the 6% HP/0.10 gm group
2001031 Univ. North Carolina	75	• CWS Retail Kit (6% HP gel strips) • Opalescence 10 (10% CP/~3.3% HP gel) in custom tray • Opalescence F 20 (20% CP/~6.7% HP gel, 0.11% fluoride) in custom tray	• Maxillary Only • CWS: 30 mins/ application, 2X/day, for 14 days • Opalescence Trays: overnight (~ 8 hours) for 14 nights	• CWS: 17% of subjects had OST AEs, 13% had TS • Opal-10: 21% of subjects had OST AEs, 38% had TS • Opal-F-20: 72% of subjects had OST AEs, 56% had TS • Overall, 53% of AEs were mild in severity, 35% were

				moderate and 11% were severe, no serious AEs • Severe AEs included 4 OST (gingivitis) and 3 OHT (hyperesthesia), all in the Opal-F-20 group.
2001058 P&G In-house	40	• CWS Retail Kit (6% HP gel strips)	• Maxillary Only • Two strips per day, back to back, for 14 days. • Application regimens as follows: 10 minutes/10 minutes 10 minutes/20 minutes 20 minutes/20 minutes 30 minutes/30 minutes	• 10/10: 60% of subjects OST AEs, 10% had TS • 10/20: 80% of subjects had OST AEs, 10% had TS • 20/20: 70% of subjects had OST AEs, 20% had TS • 30/30: 80% of subjects had OST AEs, 10% had TS • Overall, 91% of AEs were mild in severity • One non-OST/OHT AE serious and severe (gastritis) in the 10/10 group, not related to test product
2001059 P&G In-house	40	• CWS Retail Kit (6% HP gel strips)	• Maxillary Only • Two strips per day, for 14 days • Application regimens as follows: 10 minutes AM – PM 20 minutes AM – PM 30 minutes AM – PM 30 minutes/30 minutes back to back	• 10 mins: 50% of subjects had OST AEs, 30% had TS • 20 mins: 80% of subjects had OST AEs, 10% had TS • 30 mins: 80% had OST AEs, no TS • 30/30: 80% had OST AEs, 30% had TS • Overall, 96% of AEs mild in severity, one (2%) severe OHT AE (hyperesthesia) in the 30/30 group
2001066 Univ. FL	60	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 6% HP gel strips (0.10 gm gel load) • 6% HP gel strips (0.05 gm gel load) • 10% HP gel strips (0.05 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 28% of subjects had OST AEs, 28% had TS • 6% HP/0.10 gm: 11% of subjects had OST AEs, 28% had TS • 6% HP/0.05 gm: 17% of subjects had OST AEs, 33% had TS • 10% HP/0.05 gm: 25% of subjects had OST AEs, 17% had TS

				• Overall, 87% of AEs mild in severity, no serious or severe AEs
2001080 P&G In-house	24	• Rembrandt Plus (10% CP/~3.3% HP gel) (two groups, stock or custom tray)	• Maxillary Only • 20 – 30 mins/application, 2X per day, for 14 days	• Stock Tray: 82% of subjects had OST AEs, 9% had TS • Custom Tray: 33% of subjects had OST AEs, 17% had TS • All AEs were mild in severity
2001081 P&G In-house	24	• CWS Retail Kit (6% HP gel strips) • CWS Base Upgrade (6% HP gel strips, 0.075 mg Saccharin)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS Retail: 45% of subjects had OST AEs, 9% had TS • CWS Base Upgrade: 17% of subjects had OST AEs, 25% had TS • All AEs mild in severity
2001085 P&G In-house	19	• CWS Retail Kit (6% HP gel strips) (two groups, High and Low Efficacy Responders)	• Maxillary Only • 10 mins/day for 2 days	• High Responders: 33% of subjects had OST AEs, 11% had TS • Low Responders: 20% had OST AEs, 10% had TS
2001091 P&G In-house	34	• CWS Retail Kit (6% HP gel strips) • Colgate Platinum Gentle Plus Professional Whitening System (5% CP/ ~1.7% HP gel) in custom tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Colgate Platinum: 6-8 hours/day, for 14 days	• CWS: 56% of subjects had OST AEs, 13% had TS • Colgate Platinum: 56% of subjects had OST AEs, 22% had TS • Overall, 96% of AEs mild in severity, no serious or severe AEs
2001106 Hill Top, OH	51	• CWS Retail Kit (6% HP gel strips) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 8% of subjects had OST AEs, 12% had TS • Placebo: no subjects had OST or TS • Overall, 63% of AEs mild in severity, 25% moderate, and 13% severe, no serious AEs • One severe OHT AE was hyperesthesia in CWS group
2001109 Safety/Efficacy vs. Professional Marketed Product	50	• CWS Retail Kit (6% HP gel strips) • Colgate Platinum Daytime Professional Tooth Whitening System (10% CP/ ~3.3% HP gel) in custom tray	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 12% of subjects had OST AEs, 24% had TS • Colgate: 8% of subjects had OST AEs, 12% had TS • Overall, 81% of AEs mild in severity, no serious or severe AEs

2001111 Italy	44	• CWS Retail Kit (6% HP gel strips) • Opalescence 10 (10% CP/~3.3% HP gel) in custom tray	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 33% of subjects had OST AEs, 19% had TS • Opal-10: 23% of subjects had OST AEs, 5% had TS • All AEs mild in severity • See text
2001118 Safety/Efficacy vs. Placebo	61	• CWS Retail Kit (6% HP gel strips) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 4% of subjects had OST AEs, 4% had TS • Placebo: no subjects had OST or TS • 75% of AEs mild in severity • One (25%) non-OST/OHT serious and severe (injury accident) in the Placebo group, not related to test product
2001121 P&G In-house	32	• CWS Retail Kit (6% HP gel strips) with rubber dental dam (RD) and water • CWS Retail Kit (6% HP gel strips) with rubber dental dam • CWS Professional Kit (6.5% HP gel strips) immersed in 6% HP with rubber dental dam • CWS Retail Kit (6% HP gel strips) only	• Supervised Use of Product • Mandibular Only • 30 minss/day for a total of 8 days (1 day with no treatment between the first 4 days and the last 4 days)	• CWS+RD: 25% of subjects had OST AEs, 25% had TS • CWS Prof+Immersed+RD: 25% of subjects had OST AEs, 25% had TS • CWS+RD +Water/CWS Only groups: no OST or TS • Overall, 89% of AEs mild in severity, no serious or severe AEs
2001123 P&G In-house	14	• CWS Retail Kit (6% HP gel strips) • 16% HP gel strips (0.05 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 86% of subjects had OST AEs, 29% had TS • 16% HP: 43% of subjects had OST AEs, 57% had TS • All AEs mild in severity
2001124 P&G In-house	30	• CWS Retail Kit (6% HP gel strips) • Colgate Platinum Daytime Professional Whitening System (10% CP/~3.3% HP gel) in custom tray	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 47% of subjects had OST AEs, 20% had TS • Colgate: 20% of subjects had OST AEs, 20% had TS • Overall, 81% of AEs mild in severity, no serious or severe AEs
2001131 Hill Top, OH	58	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 10% HP gel strips (0.05 gm gel load) • 13% HP gel strips (0.05 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 14% of subjects had OST AEs, 7% had TS • 10% HP/0.05gm: 13% of subjects had OST AEs, 13% had TS • 13% HP/0.05 gm: 29% of

		• 16% HP gel strips (0.05 gm gel load)		subjects had OST AEs, 21% had TS • 16% HP/0.05 gm: 27% of subjects had OST AEs, 27% had TS • Overall, 78% of AEs mild in severity, no serious or severe AEs
2001140 P&G In-house	30	• 5.3% HP paint-on gel • 3.96% HP paint-on gel • 6% HP strip	• 5.3% HP paint-on gel used overnight for 14 days • 3.96% HP paint-on gel used 2x/day for 14 days • 6% HP strip used 2x/day for 30 minutes each application	• All AEs were mild in severity except for 1 OST AE in 6% HP strip treatment which was moderate • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • Subject Reported: - 5.3% HP paint-on gel had 1 (10%) OST AEs and 1 (10%) TS AE - 3.96% HP paint-on gel had 3 (30%) OST AEs and no TS AEs • 6% HP strip had 3 (30%) OST AEs and 6 (60%) TS AEs • Examiner Observed: - 5.3% HP paint-on gel had 1 (10%) OST AE - 3.96% HP paint-on gel had 1 (10%) OST AE - 6% HP strip had 4 (40%) OST AEs
2001141 A Polish Medical Academy, Warsaw	100	• 6% HP strip • 5.3% HP paint-on gel • Placebo paint-on gel	• 6% HP strip used 2x/day for 30 minutes each application for 2 weeks • 5.3% HP paint-on gel used overnight for 2 weeks • Placebo paint-on gel used overnight for 2 weeks	• Treatment groups had similar types of AEs • AEs were generally mild in severity • No Serious AEs occurred • HP groups AE incidence rate of 15-36% • 6 (32%) subjects with possible/probable treatment

				related AEs in 5.3% HP paint-on gel group, of which: - 3 (32%) subjects reported OST AEs • 4 (10%) subjects with oral AEs in Placebo group, of which: - 3 (7.5%) reported TS AEs - 2 (5%) reported OST AEs • 12 (57%) subjects reported possible/probable treatment related oral AEs, in 6% HP strip group, of which: - 12 (57%) subjects reported TS AEs - 4 (19%) subjects reported OST AEs • Investigator observed, possible/probable treatment related oral AEs: - 1 (5%) OST AE in 5.3% HP paint-on gel group -1 (5%) OST AE in Placebo group - 3 (14%) OST AEs in 6% HP strip group • Resolution of AEs occurred during treatment or upon cessation of treatment
2001141 B Polish Medical Academy, Warsaw	76	• 5.3% HP paint-on gel • Placebo paint-on gel • Dentifrice (no HP content)	• Paint-on Gels used overnight for 2 week • Dentifrice used as normal for brushing for 2 weeks	• All AEs were mild in severity except for 1 moderate AE in 5.3% HP paint-on gel treatment • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5 (13.8%) for AEs 5.3% HP paint-on gel, of which - 1 (2.8 %) OST AE - 4 (11.1 %) TS AEs • 2 (9%) AEs for Placebo paint-on gel, of which - 1 (4.5%) OST AE

				- 1 (4.5%) TS AE • 1 (5.6%) TS AE for Dentifrice
2001141 C Polish Medical Academy, Warsaw	101	• 5.3% HP paint-on gel • 5.3% HP paint-on gel + whitening dentifrice • Placebo paint-on gel	• Use overnight for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation • of treatment • 5.3% HP paint-on gel had 3 (5%) AEs of which, - 1 (1.7 %) OST AE - 2 (3.4 %) TS AEs • 5.3% HP paint-on gel + whitening dentifrice treatment had 0 OST AEs and 2 (9%) TS • Placebo had no AEs
2001141 D Polish Medical Academy, Warsaw	74	• 5.3% HP paint-on gel • 9.3% HP paint-on gel • Placebo paint-on gel	• Use overnight for 2 weeks	• All AEs were mild in severity except for 1 OST of moderate severity in 9.3% HP paint-on gel treatment group • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 11 (14.9%) AEs, of which - 1 (1.4%) OST AE - 1 (1.4%) non-oral related AE - 9 (12.2%) TS AEs • 9.3% HP paint-on gel had 3 (20%) AEs, of which, - 2 (11.8 %) OST AEs - 1 (6.7%) TS AE • Placebo had 1 (5.9%) TS
2001141 G Polish Medical	87	• 5.3% HP paint-on gel • 4.2% HP paint-on gel	• Used overnight for 2 weeks	• All AEs were mild in severity

Academy, Warsaw		• Placebo paint-on gel		• No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 8 (14.5%) AEs, of which, - 1 (1.8%) OST AE - 7 (12.7%) TS AEs • 4.2% HP paint-on gel had 1 (6.7%) AE, of which, - 1 (6.7%) OST AE - 0 TS • Placebo paint-on gel had 3 (17.6%) AEs, of which, - 1 (5.9%) OST AE - 2 (11.8%) TS
2001141 H Polish Medical Academy, Warsaw	101	• 8.4% HP paint-on gel • 6.5% HP paint-on gel • 5.9% HP paint-on gel • 5.3% HP paint-on gel • Placebo paint-on gel	• 5.3% HP paint-on gel used overnight for substantivity test • 8.4%, 5.9% and 5.3% HP products used overnight for 2 weeks • 6.5% HP paint-on gel used 2x/day for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 8.4% HP paint-on gel had 3 (16.7%) AEs of which, - 1 (5.6%) OST AE - 2 (11%) TS AES • 6.5% HP paint-on gel had 3 (16.7%) AEs of which, - 3 (16.7%) OST AEs - 0 TS AE • 5.9% HP paint-on gel had 4 (21%) AEs of which - 4 (21%) OST AEs - 0 TS AE • 5.3% HP paint-on gel had 6 (17.6%) AEs of which, - 4 (11.8%) OST AEs - 2 (5.9%) TS AEs • Placebo paint-on gel had 1 (8.3%) AEs of which, - 0 OST AE - 1 (8.3%) TS AE

2001141 I Polish Medical Academy, Warsaw		• 5.9% HP paint-on gel • 5.3% HP paint-on gel • Placebo paint-on gel	• Used overnight for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.9% HP paint-on gel had 1 (5%) TS AE only and 0 OST AE • 5.3% HP paint-on gel had 3 (16.7%) TS AEs only and 0 OST AE • Placebo paint-on gel had 2 (18%) OST AEs only and 0 TS AE
2001157 Hill Top, FL	90	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 6% HP gel strips (0.100 gm gel load) • 6% HP gel strips (0.075 gm gel load) • 12% HP gel strips (0.100 gm gel load) • 12% HP gel strips (0.075 gm gel load) • 12% HP gel strips (0.050 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 20% of subjects had OST AEs, 27% had TS • 6% HP/0.10 gm: 7% of subjects had OST AEs, 13% had TS • 6% HP/0.075 gm: 13% of subjects had OST AEs, 13% had TS • 12% HP/0.10 gm: 20% of subjects had OST AEs, 20% had TS • 12% HP/ 0.075 gm: 40% had OST AEs, no TS • 12% HP/ 0.05 gm: 20% of subjects had OST AEs, 20% had TS • Overall, 89% of AEs mild in severity, no serious or severe AEs
2001158 P&G In-house	74	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 12% HP gel strip (0.075 gm gel load) (two groups, 15 and 30 minutes)	• Maxillary Only • Two Strips per day for 14 days • Regimens as follows: CWS: 30 minutes AM – PM 12% HP: 30 minutes AM – PM 12% HP: 15 minutes AM – PM	• CWS: 54% of subjects had OST AEs, 17% had TS • 12% HP/30 mins: 44% of subjects had OST AEs, 35% had TS • 12% HP/15 mins: 46% of subjects had OST AEs, 25%

				had TS • Overall, 86% of AEs mild in severity, no serious or severe AEs
2002021 P&G In-house	36	• 9.3% HP paint-on gel • 5.3% HP paint-on gel • Negative Control (water) • Vehicle Control	• Used overnight; applied 1x/day by dental hygienist for 2 weeks (weekdays only)	• All AEs were mild in severity except 1 moderate AE in subject using 9.3% HP paint-on gel and water treatments. Subject withdrew from study. • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 4 (22%) OST AEs and 0 TS AEs • 9.3% HP paint-on gel had 3 (17%) OST AEs and 0 TS AE • Placebo paint-on gel had 1 (6%) OST AE and 0 TS AE
2002032 P&G In-house	19	• CWS Retail Kit (6% HP gel strips) • 10% HP gel strips (0.087 gm gel load)	• Both Maxillary and Mandibular Teeth • 30 mins/application, 2X/day, for 12 days	• CWS: 11% of subjects had OST AEs, 44% had TS • 10% HP: 30% of subjects had OST AEs, 20% had TS • Overall, 58% of AEs mild in severity, 33% moderate, and 8% severe, no serious AEs • One severe OHT AE was hyperesthesia in the 10% HP group
2002048 Hill Top, FL	64	• CWS Retail Kit (6% HP gel strips) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• 3% of subjects in both groups had OST AEs, 3% in both groups had TS • All AEs mild in severity, no serious or severe AEs
2002053 Polish Medical Academy, Warsaw	52	• 5.3% HP paint-on gel • Placebo paint-on gel	• Used overnight for 2 weeks	• All AEs were mild in severity except 1 moderate OST AE 5.3% HP paint-on • No serious AEs occurred • Resolution of AEs

				occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 6 (24%) AEs of which, - 2 (8%) OST AEs - 3 (12%) TS AEs - 1 (4%) non-oral AE reported as itchiness in the skin of the neck • Placebo paint-on gel had 6 (22%) AEs of which - 3 (11%) OST AEs - 2 (7.4%) TS AEs - 1 (3.7%) non-oral AE reported as headache during application
2002099 P&G In-house	30	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 40% of subjects had OST AEs, 13% had TS • 6.5% HP: 21% of subjects had OST AEs, 21% had TS • 93% of AEs mild in severity, no serious or severe AEs
2002104 Hill Top, OH	40	• CWS Retail Kit (6% HP gel strips) • Rembrandt Dazzling White (12% CP/ ~4% HP gel) in tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Rembrandt: 30 mins or more/ application, 2X/day, for 14 days	• CWS: 21% of subjects had OST AEs, no TS • Rembrandt: 72% of subjects had OST AEs, 6% had TS • 86% of AEs mild in severity, no serious or severe AEs
2002105 Hill Top, FL	22	• CWS Retail Kit (6% HP gel strips) • Mentadent Tooth Whitening System containing an oral rinse and whitening gel (~0.75% HP)	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Mentadent: 10 mins/application, 1X per day, for 14 days	• CWS: 22% of subjects had OST AEs, 11% had TS • Mentadent: 17% of subjects had OST AEs, 8% had TS • All AEs mild in severity
2002106 Hill Top, OH	49	• CWS Retail Kit (6% HP gel strips) • Plus + White Complete Whitening System (~6% HP gel)	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 14 days • Plus + White: 5 mins/application, 2x/day, for 14 days	• CWS: 9% of subjects had OST AEs, 9% had TS • Plus + White: 24% of subjects had OST AEs, 8% had TS • All AEs mild in severity
2002114 Univ. FL	32	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• CWS: 38% of subjects had OST AEs, 19% had TS • 6.5% HP: 31% of subjects had

				OST AEs, no TS • 80% of AEs mild in severity, no serious or severe AEs
2002116 Catholic University of Leuven, Belgium		• 5.3% HP paint-on gel • Placebo paint-on gel • Whitening Dentifrice	• Paint-on gels used overnight for 2 weeks • Dentifrice used as normal for brushing	• All AEs were mild in severity except for 2 moderate AEs in 5.3% HP paint-on gel treatment • No serious AEs occurred • Resolution of all AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 7 (28%) AEs of which - 2 (7.7%) OST AEs - 5 (19%) TS AEs • Placebo paint-on gel had 6 (12%) AEs of which - 3 (6%) OST AEs - 3 (6%) TS AEs • Whitening Dentifrice had 3 (11%) AEs of which - 1 (3.7%) OST AE - 2 (7.4%) TS AEs
2002146 Univ. TX Health Sci. Ctr., San Antonio	69	• 5.3% HP paint-on gel • 6.5% HP paint-on gel	• 5.3% HP paint-on gel used overnight for 2 weeks • 6.5% HP paint-on gel used 2x/day for 2 weeks	• All AEs were mild in severity except for 2 moderate AEs in 5.3% HP paint-on gel treatment • No serious AEs occurred • Resolution of all AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 9 (26%) AEs of which - 3 (8.8%) OST AEs - 5 (14.7%) TS • 6.5% HP paint-on gel had 3 AEs of which - 0 OST AE - 3 (8.6%) TS AEs

2003010 Nova SE Univ., FL	39	• 9.5% HP gel strips (0.13 gm gel load) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 14 days	• 9.5% HP: 16% of subjects had OST AEs, 16% had TS • Placebo: 5% of subjects had OST AEs, 5% had TS • All AEs mild in severity • See text
2003013 P&G In-house	28	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 3 days • 6.5% HP: 30 mins/application, 2X/day, for 14 days	• CWS: 39% of subjects had OST AEs, 23% had TS • 6.5% HP: 7% of subjects had OST AEs, no TS • 78% of AEs mild in severity, no serious or severe AEs
2003029 P&G In-house	34	• 5.3% HP paint-on gel	• Used overnight for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 11 (32%) AEs of which - 10 (29%) OST AEs • - 1 (2.9%) TS AE
2003040 Hill Top, OH	57	• 5.3% HP paint-on gel • 6.5% HP paint-on gel	• 5.3% HP paint-on gel used overnight for 2 weeks • 6.5% HP paint-on gel used 2x/day for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 4 (13%) AEs of which - 3 (10%) OST AEs - 1 (3.3%) TS AEs • 6.5% HP paint-on gel had 1 (3.7%) TS AE only and 0 OST AE
2003044 P&G In-house	38	• CWS Retail Kit (6% HP gel strips) • 9% HP Paint On gel	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 3 days • 9% HP: 8 hours/night, for 14 nights	• CWS: 40% of subjects had OST AEs, 20% had TS • 9% HP: 11% of subjects had OST AEs, 11% had TS • 91% of AEs mild in severity, two (9%) severe TS

				(hyperesthesia) – one in each group
2003045 P&G In-house	37	• CWS Retail Kit (6% HP gel strips) • 9% HP Paint On gel	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 3 days • 9% HP: 8 hours/night, for 14 nights	• CWS: 39% of subjects had OST AEs, 17% had TS • 9% HP: 26% of subjects had OST AEs, 11% had TS • 92% of AEs mild in severity, no serious or severe AEs
2003058 P&G In-house	19	• CWS Retail Kit (6% HP gel strips) • Rembrandt Intense Stain Removal Kit (5% HP) in tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 7 days • Rembrandt: 15 mins/application, 2X/day, for 7 days	• CWS: no subjects had OST AEs, 11% had TS • Rembrandt: 10% of subjects had OST AEs, no TS • All AEs mild in severity
2003062 **Nova SE Univ., FL**	41	• CWS Retail Kit (6% HP gel strips) • Claren Dental Whitening Solution (~ 4.8% HP oral strips)	• Maxillary (first 2 weeks) and Mandibular (second 2 weeks) • 30 mins/application, 2X/day, for 14 days	• CWS: 10% of subjects had OST AEs, 19% had TS • Claren: no subjects had OST AEs, 5% had TS • All AEs mild in severity
2003063 **Univ. FL**	40	• 10% HP gel strips (0.13 gm gel load) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 7 days	• 10% HP: 37% of subjects had OST AEs, 37% had TS • Placebo: 5% of subjects had OST AEs, 5% had TS • 95% of AEs mild in severity, no serious or severe AEs • See text
2003072 Hill Top, FL	81	• 5.3% HP paint-on gel • 6.5% HP paint-on gel • 9.0% HP paint-on gel	• 5.3% HP product used overnight for 2 weeks • 6.5% HP product used 2x/day for 2 weeks • 9.0% HP product used overnight for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 4 (15%) AEs of which - 1 (17%) OST AE - 3 (12%) TS AEs • 6.5% HP paint-on gel had 3 (12%) AEs of which - 1 (4%) OST AE - 2 (8%) TS AEs • 9.0% HP paint-on gel had 8 (30%) AEs of which - 8 (30%) OST AEs

				- 0 TS AE
2003092 Hill Top, OH	36	• 10% HP gel strips (0.13 gm gel load) • 9% HP Paint On gel	• Maxillary Only • 10% HP: 30 mins/application, 2X/day, for 7 days • 9% HP: 8 hours/night for 14 nights	• 10% HP: 21% of subjects had OST AEs, no TS • 9% HP: 24% of subjects had OST AEs, no TS • All AEs mild in severity
2003093 Univ. FL	40	• 10% HP gel strips (0.13 gm gel load) • 9% HP Paint On gel	• Maxillary Only • 10% HP: 30 mins/application, 2X/day, for 7 days • 9% HP: 8 hours/night for 14 nights	• 10% HP: 15% of subjects had OST AEs, 30% had TS • 9% HP: 35% of subjects had OST AEs, no TS • 77% of AEs mild in severity, no serious or severe AEs
2003097 P&G In-house	76	• 5.3% HP paint-on gel	• Used overnight for 2 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 16 (21%) AEs of which - 13 (17%) OST AEs • - 3 (4%) TS AEs

Study #	# Subjects Enrolled	Formulas Tested[A]	Exposure	Outcome
Collins et al., J. Dent 32 (Supl. 1), 47-50, 2004	20 subjects divided in to 2 groups	6% HP gel 18% CP marketed gel	Group 1 – two weeks twice daily brushing followed by application of 6% HP gel product to facial aspects of six upper and 6 lower incisors/canines, twice in succession with 30 minutes between applications. Group 2 – as above but 18% CP marketed gel replaced 6% HP gel	No evidence of irritation that was either building or developing during the course of the study. No subject withdrew from the study because of these effects
Collins et al., J. Dent 32 (Supl. 1), 13-17, 2004	117 subjects divided into 2 groups	6% HP gel	Group 1 –two weeks brushing with toothpaste twice daily followed by application of 6% HP whitening gel to facial aspects of six upper incisors/canines Group 2 - two weeks brushing with toothpaste twice daily	Only mild and transient irritation was observed in a small proportion of the panel, and one person reported TS. No subject withdrew from the study because of these effects.
1	38	10% CP 6% HP	Once daily for 1 hour – for 14 days Twice daily for 30 minutes – for 14 days Twice daily for 30 minutes – for 14 days	• No Serious AE's reported • All AE's were mild to moderate in severity • No subjects discontinued in study due to AE's • Total number of 13 AE's reported for peroxide formulations tested 8=oral, 5= non-oral
2	145	10% CP 6% HP Negative Control	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported • All AE's were mild to moderate in severity • No subjects discontinued in study due to AE's • Total number of 31 AE's reported for peroxide formulations tested 25=oral, 6= non-oral • All non oral AE's were unrelated to product, 18 oral AE's were not/ unlikely to be related to product and 7 were possibly / probably related to product usage • Total number of AE's for the negative control group=8
3	102	10% CP 6% HP	Twice daily for 30 minutes – for 14 days	• 3 Serious AE's reported – all were non-oral: leg

		10% CP Negative control		infection, rash on thorax, upper legs and face and back nerve disorder • All other AE's were mild to moderate in severity • 2 subjects discontinued in study due to AE's: leg infection, rash on trunk, upper legs and face • Total number of 24 AE's reported for peroxide formulations tested 21=oral, 3= non-oral • All non oral AE's were unrelated to product, 8 oral AE's were not/ unlikely to be related to product and 13 were possibly / probably related to product usage • Total number of AE's for the negative control group=5
4	63	10% CP 16% CP Negative control	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported to the peroxide products • All AE's were mild in severity • No subjects using the peroxide products discontinued in study due to AE's • Total number of 34 AE's reported for peroxide formulations tested 32=oral, 2= non-oral • All non oral AE's were unrelated to product, 11 oral AE's were not/ unlikely to be related to product and 21 were possibly / probably related to product usage • Total number of AE's for the negative control group

				=16
5	100	10% CP Negative control	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported to the peroxide products • All AE's were mild to moderate in severity • No subjects using the peroxide products discontinued in study due to AE's • Total number of 36 AE's reported for peroxide formulations tested 22=oral, 14= non-oral • Total number of AE's for the negative control group=9 • 1 non-oral AE's were related to product (nausea), 9 oral AE's was not related / unlikely to be related to product and 13 were possibly / probably related to product usage
6	89	10% CP Negative control	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported to the peroxide products • All AE's were mild to moderate in severity • 1 subject using the peroxide product discontinued in study due to moderate gingival irritation • Total number of 14AE's reported for peroxide formulations tested 11=oral, 3= non-oral • Total number of AE's for the negative control group=1 • All non oral AE's were

				unrelated to product, 1oral AE's was not related / unlikely to be related to product and 10 were possibly / probably related to product usage
7	76	10% CP Negative control	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported to the peroxide products • All AE's were mild to moderate in severity • No subjects using the peroxide products discontinued in study due to AE's • Total number of 11 AE's reported for peroxide formulations tested 11=oral, 0= non-oral • Total number of AE's for the negative control group=2 • All non oral AE's were unrelated to product, 2 oral AE's were not related / unlikely to be related to product and 9 were possibly / probably related to product usage
8	154	10% CP	Twice daily for 30 minutes – for 14 days	• No Serious AE's reported to the peroxide products • All AE's were mild to moderate in severity • No subjects using the peroxide products discontinued in study due to AE's • Total number of 37 AE's reported for peroxide formulations tested 31=oral, 6= non-oral • Total number of AE's for the negative control group=6
9	30	10% CP	Single application	• No Serious or non-serious AE's reported to the peroxide

				products
10	30	10% CP	Single application	• No Serious or non-serious AE's reported to the peroxide products
11	62	10% CP	Twice daily for 30 minutes for 2 days	• No Serious AE's reported to the peroxide products • All AE's were mild to moderate in severity • No subjects using the peroxide products discontinued in study due to AE's • Total number of 2 AE's reported for peroxide formulations tested 2=oral, 0= non-oral
12	103	10% CP 6% HP	Twice daily for 30 minutes for 2 days	• No Serious AE's reported to the peroxide products • Total number of 1 AE's reported for peroxide formulations tested GSK 5 1=oral, 0= non-oral
13	12	10% CP	Once daily for up to 30 mins – for 5 days	• No Serious AE's reported to the peroxide products • Total number of 1 AE's reported for peroxide formulations tested 0=oral, 1= non-oral
3 Safety/Efficacy of Marketed Product	38	6.5% paint-on gel	2 x /day	• No reports of oral soft tissue irritation or TS
4 Safety/Efficacy of Marketed Product	40 40 40	9% paint-on gel	3 x daily 2 x daily (back to back) 2x daily (AM and PM)	• No reports of oral soft tissue irritation or TS
5 Safety/Efficacy of Marketed Product	40 40	6.5% paint-on gel 9% paint-on gel	2 x/day	• No reports of oral soft tissue irritation or TS
6 Safety/Efficacy of Marketed	50	9% paint-on gel	2 x daily	• No reports of oral soft tissue irritation or TS

Product				
7 Safety/Efficacy of Marketed Product	40 40 40	6.5% paint-on gel	2 x daily 3 x daily 4 x daily	1 tooth sesitivity • (4 x daily group)
8 Safety/Efficacy of Marketed Product	60	6.5% paint-on gel	2 x daily	• No reports of oral soft tissue irritation or TS
9 Safety/Efficacy of Marketed Product	40 40	6.5% paint-on gel 9% paint-on gel	1 x daily	• No reports of oral soft tissue irritation or TS
10 Safety/Efficacy of Marketed Product	40 40	6.5% paint-on gel	2 x daily	• No reports of oral soft tissue irritation or TS
11 Safety/Efficacy of Marketed Product	45 45	6.5% paint-on gel 9% paint-on gel	2 x daily	• No reports of oral soft tissue irritation or TS
12 Safety/Efficacy of Marketed Product	40 40	9% paint-on gel 8.75%	1 x daily	• No reports of oral soft tissue irritation or TS
13 Safety/Efficacy of Marketed Product	50	8.75%	1 x daily	• No reports of oral soft tissue irritation or TS
14 Safety/Efficacy of Marketed Product	30	8.75%	1 x daily	• No reports of oral soft tissue irritation or TS
15 Safety/Efficacy of Marketed Product	40	8.75%	1 x daily	• No reports of oral soft tissue irritation or TS
16 Safety/Efficacy of Marketed Product	40	8.75%	1 x daily	• No reports of oral soft tissue irritation or TS

Table 2. Studies of 15 – 30 Days Product Exposure

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
1996093 P&G In-house	95	• 10% CP (~3.3% HP) gel (Opalescence)	• Maxillary & mandibular trays • 120 min/day for 14 days • 60 min/day for 28 days • 30 min/day for 42 days • 15 min/day for 42 days	• Groups had similar AE profiles • TS, OST, and accidental injury accounted for most AEs. • ~34% incidence of tooth discomfort AEs • ~28% incidence of OST AEs • ~15% incidence of accidental injury AEs • Potential trend toward increased tooth discomfort with application duration
1998047 P&G In-house	120	• 7% HP gel strips, high viscosity • 5.3% HP gel strips, low viscosity • 5.3% HP gel strips, low viscosity • 5.3% HP gel strips, high viscosity • 5.3% HP gel strips, high viscosity • 5.3% HP gel strips, high viscosity • 5.3% HP gel strips, high viscosity • 5.3% HP gel strips, high viscosity	• 30 min, 1X/d, 14 d, mandibular only • 30 min, 2X/d, 14 d, mandibular only • 30 min, 1X/d, 14 d, mandibular only • 60 min, 1X/d, 14 d, mandibular only • 30 min, 1X/d, 14 d, maxillary only • 30 min, 1X/d, 42 d, mandibular only • 30 min, 2X/d, 14 d, mandibular only • 60 min, 1X/d, 42 d, mandibular only	• Across all treatments, 60/105 (57%) subjects experienced AEs • TS was the most frequently reported AE overall (44% of all AEs). • No subjects experienced any non-OST/TS.
1999006 P&G In-house	68	• 19% Sodium Percarbonate (NaPC) (~5.3% HP) silicone film (vial) • 9.5% NaPC (~2.7% HP) silicone film (vial) • 15% CP (~5%HP) silicone film (vial) • Placebo silicone film (vial)	• Maxillary and mandibular treatment • 2X/day, 5 days/week for 21 days	• Treatment groups had similar types of AEs • 19% NaPC (vial): 0% of subjects had OST AEs, 7% had TS, 0% had non-OHT/OST AEs • 9.5% NaPC (vial): 0% of subjects had OST AEs, 7% had TS, 0% had non-OHT/OST AEs • 15% CP (vial): 0% of subjects had OST AEs, 13% had TS,

				7% had non-OHT/OST AEs • Placebo (vial): 0% of subjects had OST AEs, 0% had TS, 0% had non-OHT/OST AEs
1999029 Fourth Military Medical Univ., Xi'An, China	121	• 19% NaPC (~5.3% HP) silicone film (pen) • 19% NaPC (~5.3% HP) silicone film (vial) • 15% CP (~5% HP) silicone film (vial) • Placebo silicone film (vial)	• Maxillary and mandibular treatment • 90 min/application • 2X/day, 7 days/week, for 28 days	• Treatment groups had similar types of AEs • 19% NaPC (pen): 3% of subjects had OST AEs, 10% had TS • 19% NaPC (vial): 7% of subjects had OST AEs, 3% had TS • 15% CP (vial): 23% of subjects had OST AEs, 13% had TS • Placebo (vial): 3% of subjects had OST AEs, 0% had TS • No subjects experienced any non-OST/TS.
1999097 P&G in-house	22	• 5.3% HP gel strips • 6.5% HP gel strips	• Maxillary and mandibular treatment • 30 min/application, 2X/day, for 30 days	• 5.3% HP: 75% of subjects had OST AEs, 25% had TS • 6.5% HP: 70% of subjects had OST AEs, 50% had TS
2000116 Hill Top, OH	40	• 5.3% HP gel strips with pre-brushing • 6.0% HP gel strips w/o pre-brushing	• Maxillary only • 30 min/application, 2X/day, for 21 days	• 5.3% HP strip: 10% of subjects had OST AEs, 5% had TS • 6.0% HP strip: 20% of subjects had OST AEs, 15% had TS • No subjects experienced any non-OST/TS.
2000136 Univ. FL	69	• 6.5% HP CWS Professional kit • 10% CP (~3.3% HP) Professional kit	• CWS: Use product 30 min. 2X/day for 3 weeks • CP: Use product 2 hrs/day for 14 days	• CWS: 26% of subjects had OST AEs, 26% had TS • 10% CP: 29% of subjects had OST AEs, 15% had TS
2000089 P&G In-house	45	• 5.3% HP paint-on gel • Placebo (water)	• Use product 2x/day, supervised on Day 1 • Use product overnight only for Days 2 – 28	• 5.3% HP paint-on gel had 4 (13%) TS AEs and 10 (33%) OST AEs • Placebo had no TS AEs and 3 (20%) OST AEs • All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment

2001030 P&G In-house	66	• 5.3% HP paint-on gel • Placebo (water)	• Use product 2x/day, supervised on Day 1 • Use product overnight only for Days 2 – 28 • Note: 16 – 24 subjects continued using their assigned product for 4 additional weeks.	• 5.3% HP paint-on gel had 34 AEs of which, - 17 (27%) OST AEs and 19 (30%) TS AEs • Placebo had no OST AEs and 2 (12.5%) TS AEs • All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment
2001089 P&G In-house	110	• 5.3% HP paint-on gel • Placebo paint-on gel	• Use product 2x/day, supervised on Day 1 • Use product overnight only for Days 2 – 28	• 5.3% HP paint-on gel had 16 (17%) TS AEs and 38 (27%) OST AEs • All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment
2001090 Colonia Colina del Sur, Mexico	40	• 6.5% HP gel strips (two groups, one with dental fluorosis-type staining) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 21 days	• 6.5% HP: 20% of subjects had OST AEs, 27% had TS • 6.5% HP + fluorosis: 50% of subjects had OST AEs, 10% had TS • Placebo: 13% of subjects had OST AEs, no TS • Overall, 94% of AEs mild in severity, one (6%) severe OST AE (gingivitis) in the 6.5% HP + fluorosis group • See text
2001110 Univ. TX Health Sci. Ctr.	50	• CWS Retail Kit (6% HP gel strips) • Patterson Brand Tooth Whitening Gel (10% CP/~3.3% HP gel) in custom tray	• Maxillary Only • CWS: 30 mins/application, 2X/day, for 28 days • Patterson: 1 hour/day, for 28 days	• CWS: 8% of subjects had OST AEs, 32% had TS • Patterson: 8% of subjects had OST AEs, 28% had TS • All AEs mild in severity
2001127 Univ. FL	60	• CWS Retail Kit (6% HP gel strips) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for	• CWS: 35% of subjects had OST AEs, 24% had TS

			28 days	• Placebo: 4% of subjects had OST AEs, 4% had TS • Overall, 95% of AEs mild in severity, no serious or severe AEs
2001141 F	92	• 5.3% HP paint-on gel • 6.5% HP paint-on gel • Placebo paint-on gel	• 5.3% HP and Placebo paint-on gel products used overnight for 3 weeks except 18 subjects in 5.3% HP paint-on gel treatment group used only 2 weeks (consistent with intended use) • 6.5% HP paint on gel used 2x/day for 3 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 5 (8.9%) AEs of which - 0 OST AE - 5 (8.9%) TS AEs • 6.5% HP paint-on gel had 5 (26.3%) AEs of which, - 3 (15.8%) OST AEs - 2 (10.5%) TS AEs • Placebo paint-on gel had 2 (11.8%) TS AEs
2002029 Universitaria, Ciudad, Mexico	74	• CWS Retail Kit (6% HP gel strips) • Placebo gel strips	• Maxillary Only • 30 mins/application, 2X/day, for 28 days	• CWS: 45% of subjects had OST AEs, 55% had TS • Placebo: 22% of subjects had OST AEs, 11% had TS • Overall, 85% of AEs mild in severity, four (7%) severe AEs – 2 OST AEs (gingivitis) and 2 TS (hyperesthesia) in the 6% HP group
2002121 Hill Top, FL	55	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel • Crest Dual Action Whitening Dentifrice	• Maxillary Only (for non-dentifrice) • CWS: 30 mins/application, 2X/day, for 14 days • 6.5% HP: 30 mins/application, 2X/day, for 21 days • Crest Dentifrice: 2X/day, for 6 weeks	• CWS: 7% of subjects had OST AEs, no TS • 6.5% HP: no subjects had OST AEs, 5% had TS • Crest Dentifrice: 6% of subjects had OST AEs, no TS • All AEs mild in severity
2002147	45	• 5.3% HP paint-on gel • 6.5% HP paint-on gel	• All treatments: use product 1x/day, supervised Day 1 • 5.3% paint-on gel use overnight only for 4 weeks	• All AEs were mild in severity • No serious AEs occurred • Resolution of AEs

			• 6.5% HP paint-on gel used 2x/day for 3 weeks	occurred during treatment or upon cessation of treatment • 5.3% HP paint-on gel had 12 (54%) AEs of which - 8 (36.4%) OST AEs - 4 (18.2%) TS AEs • 6.5% HP paint-on gel had 1 (4.5%) AE only
2003055 Hill Top, FL	73	• CWS Retail Kit (6% HP gel strips, 0.20 gm gel load) • 10% HP gel strips (0.13 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 21 days	• CWS: 17% of subjects had OST AEs, 10% had TS • 10% HP: 23% of subjects had OST AEs, 33% had TS • All AEs mild in severity • See text
1 Safety/Efficacy of Marketed Product	40	6.5% paint-on gel	2 x /day for 2 or 3 weeks-0	• No reports of oral soft tissue irritation or TS
2 Safety/Efficacy of Marketed Product	48	6.5% paint-on gel	2 x/day for 2 or 3 weeks	• No reports of oral soft tissue irritation or TS

Table 3. Studies of 31 – 42 Days Product Exposure

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
1998073 Bleaching Regimen Comparison	108	• 5.3% HP gel strips, pH 5.5, low viscosity	3-Phases Treatment Phase: • 4 weeks, 30 min, 1X/day • 8 weeks, 30 min, 1X/day Maintenance Phase: • 30 min, 1X/week • 30 min, 4 consecutive days /month • Untreated Re-treatment Phase: • 4 weeks, 30 min, 1X/day • 8 weeks, 30 min, 1X/day	• TS was most frequent AE. • TS AE incidence was not related to treatment duration • 4-Week treatment: 0.33 AEs/subject; 14% of subjects had TS • 8-Week treatment: 0.35 AEs/subject; 15% of subjects had TS
2000101 Univ. North Carolina	40	• 6.0% HP gel strips • Placebo	• Maxillary only • 30 min/application, 2X/day, 7 days/week, for 6 weeks	• 6% HP strip: 20% of subjects had OST AEs, 40% had TS • Placebo strip: 10% of subjects had OST AEs, 10% had TS • No subjects experienced any non-OHT/OST AEs.
Karpinia KA, et al., Am. J. Dent. 16 (Spec. No.), 12B-16B, 2003	50	• 5.3% HP paint-on gel • Placebo paint-on gel	• Use product 1x/day, supervised Day 1 • Use product overnight only, Days 1 - 42	• All AEs were mild in severity • No serious AEs occurred • All AEs resolved during treatment or upon completion of treatment • 7 (14%) subjects reported possible/probable treatment related oral symptom AEs in 5.3% HP paint-on gel group, of which 5 (20%) were TS AEs and 2 (8%) reported OST AEs • One of the subjects with TS (5%) discontinued treatment after week 4 due to TS • 4 (16%) subjects reported oral symptom AEs in Placebo group, of which all were OST AEs • Investigator observed oral

				symptom AEs: - 1 (4%) OST AE for 5.3% HP paint-on gel group - 1 (4%) OST AE for Placebo
2002096	152	• 5.3% HP paint-on gel	• Used overnight for 6 weeks	• All AEs were mild in severity, except 1OST AE which was moderate in severity • No serious AEs occurred • Resolution of all AEs occurred during treatment or upon cessation of treatment • All OST AEs which were deemed possibly or Probably treatment related were reported by subjects, with 1 exception, a mild aphthous stomatitis, which the examiner observed. • Overall, 8 (5.3%) subjects reported OST AEs determined by the investigator to be possibly or probably treatment related • Overall, 4 (2.6%) subjects reported TS AEs determined by the investigator to be possibly or probably treatment related

Table 4. Studies of 90 - 180 Days Product Exposure

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
2000043 Kugel et al. Comp. Cont. Ed. Dent., 23 (1A), 29-34, 2002 Tufts Univ.	40	• 6.3% HP gel strips (N=30) • 10% CP (~3.3% HP) Opalescence (N=10)	• Gel strips: 30 min, 2X/day for 6 months • 10% Opal. tray: overnight use • Subjects with tetracycline stained teeth	• 6.3% HP strip: 43% of subjects had OST AEs, 47% had TS. • 10% Opal.: 30% of subjects had OST AEs, 40% had TS. • All AEs were reported; none were observed by the examiner • No subject dropped from the study
2002063 Safety/Efficacy on Tetracycline Dental Stain Loma Linda Univ.	35	• CWS Retail Kit (6% HP gel strips) • 9.5% HP gel strips (0.13 gm gel load)	• Maxillary Only • 30 mins/application, 2X/day, for 3 months	• CWS: 6% of subjects had OST AEs, 44% had TS • 9.5% HP: 6% of subjects had OST AEs, 59% had TS • Overall, 73% AEs mild in severity, 23% moderate, and 4% severe, no serious AEs • One severe tooth sensitivity in the 9.5% group

Published reports:

- A review article by Haywood (J. Esthet. Dent., 9(1), 13 – 19, 1997) discusses a 6 month study with patients (N=10) using 10% carbamide peroxide gel in a custom-fitted mouthguard tray. Four subjects discontinued product use in the first 2 weeks due to adverse events (tooth sensitivity, gingival irritation and/or throat irritation/taste). Five of the remaining 6 subjects reported experiencing tooth sensitivity sometime during the study. Symptoms resolved 24 hours post treatment.
- Leonard et al. (J. Esthet. Dent. 11, 265-277, 1999) reported on a study with 6 month exposure to a 10% carbamide peroxide gel in a custom-fitted mouthguard tray, with follow-up visits at 6, 12 and 54 months post treatment. There were 21 subjects at the start of treatment. Twelve subjects completed all study visits. Eighty percent of subjects reported adverse events during the 6 month treatment period. There were no reports of tooth whitener related adverse events at the 6 month post-treatment visit. One subject reported having tooth sensitivity or gingival irritation at the 12 month post-treatment visit. Three subjects reported having tooth sensitivity or gingival irritation at 54 months post-treatment. However, two of these three subjects had reported pre-treatment tooth sensitivity. None of the subjects reported having to have a crown restoration or root canal therapy that they felt was whitening-related. SEM photomicrographs indicated no obvious differences between the facial surfaces of the treated maxillary teeth and the untreated surfaces of the mandibular teeth immediately after treatment or 54 months post-treatment.
- Leonard et al. (J. Esthet. Rest. Dent. 15 (3), 142 – 152) reported on the 90 month post treatment follow-up with the patients from the study published in 1999. At this visit, 15 of the original study participants were examined. None of the subjects reported having to have a crown restoration or root canal therapy that they felt was whitening-related. One subject reported having tooth sensitivity at the 90 month post-treatment visit; however, this subject also reported pre-treatment tooth sensitivity. No pathological alterations were seen on the radiographs for these subjects. SEM photomicrographs indicated no obvious differences between the facial surfaces of the treated maxillary teeth and the untreated surfaces of the mandibular teeth at 90 months post-treatment. These same patients were observed at about 7.5 years post treatment and the only adverse event reported was the one subject with pre-treatment tooth sensitivity who reported continuing tooth sensitivity (Leonard et al., J. Dent. Res. 81 (Spec. Iss A), 254, 2002).

Table 5. Studies with Follow-up Visits Post-treatment

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
1999089 Kugel and Kastali, Comp. Cont. Ed. Dent., 21 (Suppl 29), S16-21, 2000 Tufts Univ.	70	• 5.3% HP gel strips • Placebo	• Maxillary only • 30 min/application, 2X/day, for 2 weeks • Follow-up visits ~ 3 & 6 months post-treatment	• TS was the only AE reported. • 5.3% HP strip: 6% of subjects had OHT AE • Placebo strip: No AEs were reported. • Gingival Index & Plaque Index were the same for both groups at the 3 & 6 month visits
1999091 Hill Top, FL	70	• 5.3% HP gel strips • Placebo	• Maxillary only • 30 min/application, 2X/day, for 4 weeks • Follow-up visits ~ 3 & 6 months post-treatment	• 5.3% HP strip: 3% of subjects had OST AEs, 0% had TS • Placebo strip: No subjects experienced any OST or TS. • No subjects experienced any non-OST/TS. • Gingival Index & Plaque Index were the same for both groups at the 3 & 6 month visits
1999113 Hill Top, OH	95	• 5.3% HP gel strips • Placebo	• Maxillary only • 30 min/application, 2X/day, for 2 or 4 weeks • Follow-up visits ~ 3 & 6 months post-treatment	• Placebo strip: 3% of subjects had OST AEs, 0% had TS, 0% had other (non-OHT/OST) AEs • 5.3% HP strip (2 weeks): 39% of subjects had OST AEs, 3% had TS, 3% had other (non-OHT/OST) AEs • 5.3% HP strip (4 weeks): 15% of subjects had OST AEs, 15% had TS, 0% had other (non-OHT/OST) AEs • Gingival Index & Plaque Index were the same for both groups at the 3 & 6 month visits
2001031 Univ. of NC	75	• 6% HP gel strip • 10% Opalescence • 20% Opalescence F	• 30 min/application, 2X/day for 2 weeks • 8-10 hrs/day exposure for trays • Maxillary only • Follow-up visits ~ 3 & 6 months post-treatment	• Gingival Index & Plaque Index were the same for both g
2001118 Hill Top, OH	60	• 6% HP gel strips • Placebo strips	• 30 min/application, 2X/day for 2 weeks	• Gingival Index & Plaque Index were the same for both g

			• Maxillary only • Follow-up visits ~ 3 & 6 months post-treatment	
2001127 Univ. of FL	60	• 6% HP gel strips • Placebo strips	• 30 min/application, 2X/day for 4 weeks • Maxillary only • Follow-up visits ~ 3 & 6 months post-treatment	• Gingival Index & Plaque Index were the same for both g

Published reports:

- Leonard et al. (J. Esthet. Dent. 11, 265-277, 1999) reported on a study with 6 month exposure to a 10% carbamide peroxide gel in a custom-fitted mouthguard tray, with follow-up visits at 6, 12 and 54 months post treatment. There were 21 subjects at the start of treatment. Twelve subjects completed all study visits. Eighty percent of subjects reported adverse events during the 6 month treatment period. There were no reports of tooth whitener related adverse events at the 6 month post-treatment visit. One subject reported having tooth sensitivity or gingival irritation at the 12 month post-treatment visit. Three subjects reported having tooth sensitivity or gingival irritation at 54 months post-treatment. However, two of these three subjects had reported pre-treatment tooth sensitivity. None of the subjects reported having to have a crown restoration or root canal therapy that they felt was whitening-related. SEM photomicrographs indicated no obvious differences between the facial surfaces of the treated maxillary teeth and the untreated surfaces of the mandibular teeth immediately after treatment or 54 months post-treatment.
- Leonard et al. (J. Esthet. Rest. Dent. 15 (3), 142 – 152) reported on the 90 month post treatment follow-up with the patients from the study published in 1999. At this visit, 15 of the original study participants were examined. None of the subjects reported having to have a crown restoration or root canal therapy that they felt was whitening-related. One subject reported having tooth sensitivity at the 90 month post-treatment visit; however, this subject also reported pre-treatment tooth sensitivity. No pathological alterations were seen on the radiographs for these subjects. SEM photomicrographs indicated no obvious differences between the facial surfaces of the treated maxillary teeth and the untreated surfaces of the mandibular teeth at 90 months post-treatment. These same patients were observed at about 7.5 years post treatment and the only adverse event reported was the one subject with pre-treatment tooth sensitivity who reported continuing tooth sensitivity (Leonard et al., J. Dent. Res. 81 (Spec. Iss A), 254, 2002).
- Ritter et al. (J. Dent. Res. 80, 246, 2001; J. Esthet. Rest. Dent. 14 (5), 275-285, 2002) reported a longitudinal study with patients who had previously bleached with 10% carbamide peroxide gel in a custom-fitted nightguard tray for 6 weeks. Subjects were evaluated for gingival index and external cervical resorption (ECR) by radiographic examination 10 years post-treatment. For the examined teeth, 93% had a normal GI score, 5% had a GI = 1 (mild inflammation) and 1% had a GI = 2 (moderate inflammation). No evidence of ECR was found during an evaluation of the x-rays and no apical lesions were observed. GI and ECR findings were considered normal suggesting minimal post whitening effects at 10 years post treatment.

Table 6. Peroxide Degradation Kinetics Studies

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
2000045 Safety: Peroxide Kinetics P&G In-house	12	• 5.3% HP gel strips • 10% CP (~3.3% HP) Opalescence • 20% CP (~6.7%) Opalescence	• Gel strips: 5, 10, 30 & 60 minutes • Opal. trays: 10, 30, 60 & 120 min.	• Daily HP exposure (HP in devices) was significantly lower for 5.3% HP compared to the 10% or 20% Opal. products. • The median saliva HP levels were < 0.003% in all groups, suggesting minimal systemic exposure to HP.
2000143 Kinetics P&G In-house	12	• 6.1% HP gel strips without pre-brushing	• Measure HP in strip, saliva and teeth after 5, 10, 30 & 60 min. wear time	• HP levels in the device and in the gel on the teeth declined over wear time. • Median salivary HP levels were $\leq$ 0.018% HP at every time point. • Based on median salivary HP AUC, use of 4 strips, for 60 minutes each, results in < 4 mg HP/day.
2002060 Kinetics P&G In-house	16	• 9.5% HP gel strips (0.13 gm gel load)	• Maxillary Only • 5 applications, 1X/day, for 4 days	• HP levels in the device, in the gel on the teeth and on the gingival declined over wear time. • Median salivary HP levels were $\leq$ 0.014% HP at every time point. • Only one OST and one OHT AE reported
2002126 Kinetics P&G In-house	16	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel	• Maxillary Only • CWS: up to 30 mins/application, 1X/day, for 2 days (AM) • 6.5% HP: up to 30 mins/application, 1X/day, for 5 days (PM)	• HP levels in the device (CWS) and in the gel on the teeth declined over wear time. • HP levels on the teeth initially increased with the pain-ton product and then rapidly declined • Median salivary HP levels were $\leq$ 0.008% HP for CWS at every time point and $\leq$ 0.22% for the paint-on product.

				• Five AEs reported – 4 OST AEs and 1 OHT AE
2002144 Kinetics P&G In-house	15	• 6.5% HP Paint On gel	• Maxillary Only for 2 days • Day 1 = 2 mins • Day 2 = 5 mins	• No AEs reported
2003009 Kinetics P&G In-house	15	• 14% HP gel strips (0.10 gm gel load)	• Maxillary Only • 5 applications, 1X/day, for 4 days	• HP levels in the device and in the gel on the teeth declined over wear time. • Median salivary HP levels were ≤ 0.073% HP at every time point. • No AEs reported
2003012 Kinetics P&G In-house	15	• CWS Retail Kit (6% HP gel strips) • 6.5% HP Paint On gel (two groups – one with lips retracted for 30 seconds and one with no lip retraction)	• Maxillary Only • Up to 5 applications, 2X/day, for 5 days	• HP levels in the device (CWS) and in the gel on the teeth declined over wear time. • HP levels on the teeth initially increased with the paint-on product and then rapidly declined • Salivary HP levels were not determined • No AEs reported
2003043 P&G In-house	17	• 5.3% HP Paint On gel • 6.5% HP Paint-On gel	• Maxilliary only • Up to 4 applications	• HP on the teeth was 5.2% and 4.5% at the 30 sec. & 5 min time points for the 5.3% HP product • HP on the teeth was 4.6% and 0.2% at the 30 sec. & 5 min time points for the 6.5% HP product • Salivary HP levels were low for both products (≤ 0.04%)
2003046 Gerlach et al., Comp. Cont. Ed. Dent., 25, No. 8 (Suppl 2), 14-20, 2004 P&G In-house	17	• 6.5% HP gel strips • 14% HP gel strips (0.10 gm gel load)	• Maxillary Only • 5 applications, 1X/day, for 4 days	• HP levels in the device and in the gel on the teeth declined over wear time for both products • Median salivary HP levels were ≤ 0.011% HP at every time point for both products • No AEs reported
2003098 P&G In-house	17	• 5.3% Paint-On gel	• Maxillary Only • 4 applications, 1X/day, for 4 days	• HP levels on the teeth declined over time. • HP levels in saliva ≤ 0.0048%

				at any time point

Published reports:

- Marshall et al. (AM. J. Dent. 14, 39-45, 2001) determined the clearance of peroxide from the oral cavity after I minute brushing with a 3% hydrogen peroxide dentifrice (Marshall et al., 2001). Seventy percent of the hydrogen peroxide decomposed during the minute of brushing for infants (3-4 years), juveniles (7-12 years), adults with normal salivary flow and adults with diminished salivary flow (Sjorgren's syndrome).
- The degradation of 10% carbamide peroxide (~ 3.6% hydrogen peroxide), worn in a custom-fitted tray, was determined over 10 hours (N=15). The degradation rate in the tray and in the gel on the teeth was rapid for the first hour, and then slowed, with a 50% loss of active ingredient seen at 2 hours, and 90% loss following 9 hours of exposure (Matis et al., JADA, 130, 227-235, 1999).
- Slezak, et al. (Comp. Cont. Ed. Dent. 23, No. 11 (Suppl. 1), 4-11, 2002) determined the concentration of peroxide in saliva after application of a 6.5% HP paint-on gel. Saliva samples were taken at baseline and at 1, 5, 15 and 30 minutes post product application from 10 subjects in a clinical trial. Peroxide concentrations were 0.03%, 0.0042% and 0.0001% at 1, 5 and 15 minutes respectively. After 15 minutes, no peroxide was detectable in the saliva.
- Mahony et al. (Am. J. Dent. 16, 9B-11B, 2003) determined the peroxide concentration on teeth and in saliva at various time points after application of a 5.3% hydrogen peroxide paint-on product. The median peroxide concentration on teeth was 4.56% and 0.14% at 5 minutes and 4 hours respectively, post application. The median peroxide concentrations in saliva were no more than 0.001% at any time point.

Table 7. Studies in Special Populations

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
2000014 Donly and Gerlach, Gen Dent., 50, 242-245, 2002 Univ. TX Health Sci. Ctr.	30/57 2 cohort study 12-18 y/o	• 5.3% HP gel strips • 10% CP (~3.3% HP) Opalescence	• Maxillary, 30 min, 2X/day for 4 weeks, then • Mandibular, 30 min, 2X/day for 4 weeks	• 5.3% HP: 2% of subjects had OST AEs, 8% had TS • 10% CP: 0% of subjects had OST AEs, 2% had TS
2000102 Donly et al., Comp. Cont. Ed. Dent., 23 (1A), 22-28, 2002, Univ. TX Health Sci. Ctr.	106 12-18 y/o	• 6.5% HP gel strips without pre-brushing • 10% Opalescence	• Maxillary, 30 min, 2X/day for 4 weeks, then • Mandibular, 30 min, 2X/day for 4 weeks	• 5.3% HP: 24% of subjects had OST AEs, 35% had TS. • 10%Opal: 9% of subjects had OST AEs, 34% had TS.
2002090 Nova SE Univ., FL	61 12 -18 y/o	• 5.3% HP paint-on gel • 6% HP strip • Placebo (water)	• Used overnight for 4 weeks by juveniles • Maxillary, 30 min, 2X/day for 4 weeks, then	• All AEs were mild in severity • No serious AEs occurred • All AEs resolved during treatment or upon completion of treatment • 1 (4%) subjects reported TS AE in 5.3% HP paint-on gel group • 1 (7%) subjects reported TS AE in 6% HP strip group • 2 (8%) subjects reported TS AE in Placebo group • No subject reported treatment related OST AEs for any treatment group • No examiner observed OST or TS AEs for any treatment group
2003016 Univ. TX Health Sci. Ctr.	57 12-18 y/o	• 9.5% HP gel strips (0.13 gm gel load) • Opalescence 10 (10% CP/~3.3% HP gel) in custom tray	• Maxillary (first 2 weeks) and Mandibular (second 2 weeks) • 9.5% HP: 30 mins/application, 2X/day, for 14 days • Opal-10: overnight (~8 hours)	• 9.5%: 13% of subjects had OST AEs, 18% had TS • Opal-10: no subjects had OST AEs, 42% had TS • 75% of AEs mild in severity,

			for 14 nights	one (4%) severe OHT AE (hyperesthesia) in the 9.5% HP group • See text

Table 8. Other Safety Studies

Study #	# Subjects Enrolled	Formulas Tested	Exposure	Safety Outcomes
2000017 Treatment Frequency Comparison P&G In-house	45	• 5.3% HP gel strips	• Maxillary only • 30 min, 4X/day for 1 week (QID) • 30 min, 2X/day for 2 weeks (BID) • 30 min, 1X/day for 4 weeks (QD)	• QID: 23 AEs in 14/15 (93%) subjects, including 3 severe events (2 gingivitis, 1 pain) in 3 subjects • BID: 14 AEs in 7/15 (47%) subjects, including 2 severe events (1 pain and 1 hyperesthesia) in 2 subjects • QD: 7 AEs in 5/15 (33%) subjects, including no severe events
2000018 P&G In-house	9, all with prior clinical history of TS from bleaching	• 5.3% HP gel strips • 10% CP (~3.3% HP) Opalescence • Placebo strip	• Four regimens were used: HP strip, placebo strip, 2-hr Opalescence, and 8-hour Opalescence. • Each regimen lasted 2 days and was followed by a 24-48 hour washout period. • Each subject received each 2-day regimen twice over a 4 week period.	• TS was reported more frequently for the 5.3% HP strip (8 events = 50% of all uses) than for the other regimens (10% CP 8-hr: 4 events = 25% of all uses; 10% CP 2-hr: 3 events = 21% of all uses; placebo strip: 3 events = 18% of all uses). • Gum irritation was less prevalent than tooth irritation for all 4 regimens, and did not differ notably among them.
2000028 P&G In-house	41	• Pre-brush with Crest Cavity Protection, apply 5.3% HP gel strips • No pre-brushing, apply 5.3% HP gel strips	• Gel strips: 30 min, 2X/day for 14 days over a 3-week period (weekends excluded), maxillary only	• pre-brush: OST sensitivity in 13/20 (65%) subjects with 2 graded moderate or severe; OHT in 6/20 (30%) subjects with 5 graded moderate or severe; 23 AEs in 12/20 (60%) subjects, primarily mild gingivitis and hyperesthesia (moderate in 3 cases) • no pre-brush: OST sensitivity in 8/21 (38%) subjects with 2 graded moderate or severe; OHT in 5/21 (24%) subjects with 2 graded moderate or

				severe; 20 AEs in 9/21 (43%) subjects, primarily mild gingivitis and hyperesthesia (moderate in 2 cases)
2002062 Treatment Frequency Comparison P&G In-house	44	• 9.5% HP gel strips (0.13 gm gel load)	• Maxillary Only • 30 mins/application • Treatment Frequencies as follows: 1X per day for 14 days (QD) 2X per day for 7 days (BID) 3X per day for 5 days (TID)	• QD: 13% of subjects had OST AEs, 13% had TS • BID: 50% of subjects had OST AEs, 14% had TS • TID: 47% of subjects had OST AEs, 7% had TS • Overall, 73% of AEs mild in severity, 21% moderate, 6% severe, no serious AEs • Two severe TS were hyperesthesia – one each in the QD and BID groups • See text