

"Tooth bleaching, Trading Standards and the EU Cosmetic Directive."

On 28 January 2009 Sir Paul Beresford, BDS, MP and an executive member of the British Dental Bleaching Society managed to obtain a 30 minute adjournment debate at the end of the day. These are balloted for and enable an MP up to 15 minutes to put a point and then the minister has the remaining time to respond. Sir Paul entitled the debate "**Tooth bleaching, Trading Standards and the EU Cosmetic Directive.**"

The full debate is copied from Hansard below:

28 January 2009

7.18 pm

Sir Paul Beresford (Mole Valley) (Con): I thank the Minister for coming. The one advantage of being the last man standing is that the gates might be open when he leaves.

Let me first declare a simple interest and then add to it because of the specifics of the debate. I am a qualified and practising—admittedly very part-time practising—dentist. In addition, I am a member of the British Dental Association, the British Academy of Cosmetic Dentistry, the British Endodontic Society and the British Dental Bleaching Society. That explains why I become a target of considerable pressure on dental issues, so I hope the Minister will bear with me.

I am trying to persuade the Minister to help us sort out a situation that has been confusing dentists and trading standards officers throughout the UK for a considerable number of years. If the Minister will bear with me, I will endeavour to explain a little of the process of dental bleaching and why the present situation is producing a dilemma for dentists.

Bleaching by dentists has been around for a very long time. I first used dental bleaching about 30 years ago. My tutor was my now retired dental partner who qualified during the second world war, and his tutor was his father who qualified shortly after the first world war. It has been used for nigh on 100 years. In the early days, we used a 30 per cent. solution of hydrogen peroxide—better known as Superoxol. It was destructive to soft tissues, which needed to be protected; in those early days, that was done via a mechanism called a rubber dam. This is a small sheet of latex rubber with holes placed in it so that the teeth can go through; a tight seal then comes round the neck of the tooth so that the gingival and other oral soft tissues, including the lips, can be protected.

The aim of bleaching is to remove discolorations from the teeth without harming the teeth themselves. The discolorations can come from a number of sources: from tobacco, hard water, tea, coffee and so on. Teeth may also be iatrogenically discoloured, the most famous example being tetracycline discoloration. In the early days of antibiotics, children were given an antibiotic called tetracycline, which was one of the early broad-spectrum bacteriostatic antibiotics and was widely used. While it dealt with the targeted infection, if taken by children it discoloured the developing teeth, sometimes to a grotesque degree.

Second or adult teeth that may have received a blow can often darken quite quickly, particularly if the individual is young. The teeth most frequently hurt in this way are the upper incisors, particularly the upper central incisors. Endodontically treated teeth often darken, particularly if the operator has been unable to remove or has not removed all the pulpal tissue from the internal dentine.

Increasingly nowadays, dental restorations are of a more cosmetically acceptable material. If someone is to have a filling, it is good to do it in a cosmetically acceptable way. It is becoming increasingly accepted as standard practice that when such restorations as porcelain crowns, porcelain veneers and porcelain inlays are used for restorations, it is sensible to bleach the teeth first.

That achieves a benchmark colour to which the new restoration is colour-matched. As the patient's teeth become more discoloured over subsequent years, it is possible to use the same process to bring the teeth back to that benchmark level. Otherwise, we will end up with white teeth sticking out among the brown, which I have seen particularly in some areas of London.

Dental bleaching is not available on the national health, but I believe that in some cases it should be because it is the less destructive treatment. To provide a simple example, if a national health patient has badly tetracycline-stained teeth, the only option on the NHS to restore normal appearance is by extensive crowns or veneers. These are destructive to the teeth and much more costly, and in time they will need replacing. The cheaper approach is dental bleaching, which leaves the teeth intact and of an acceptable colour.

Techniques of dental bleaching have improved. First, the dentist must check that the patient's teeth are in good order. Then there are essentially two different bleaching techniques available. The first is the so-called home technique, where the dentist constructs close-fitting clear trays that the patient wears for a period of time at home. The bleach trays are designed to hold the gel against the teeth but away from the soft tissues.

The second method is so-called power bleaching, which is done in the surgery and generally uses much stronger hydrogen peroxide concentrations. The soft tissues are protected either with the aforementioned rubber dam or nowadays a foam that is set by an ultraviolet light. Some techniques advocate the use of light or heat source, although I personally believe that this does more for the image of the procedure to the patient than it actually benefits the bleaching process.

Hydrogen peroxide is generally delivered in varying strengths of carbamide peroxide nowadays. These strengths vary between 10 per cent. and 38 per cent. carbamide peroxide. The hydrogen peroxide concentration delivered is lower. For example, 10 per cent. carbamide peroxide delivers approximately a 6 per cent. concentration of hydrogen peroxide. As logic will tell the Minister, the higher the concentration the faster the bleaching, but the more likely it is to produce sensitive teeth.

I hope that the Minister understands from this that this material should be in the hands of a trained dental professional, as misuse can cause harm. Recent decisions of the General Dental Council state that dental bleaching by trained dental professionals is part of professional dental treatment. That has been accepted by the Secretary of State for Health for England, and I have written asking for the position of the Ministers of Health for Northern Ireland, Scotland and Wales on this issue. To date, the Minister for Health for Wales has replied and agrees with the position taken by the Secretary of State. I await the post from Scotland and Northern Ireland.

The reason for this preamble is to explain to the Minister that the dangers of the material when misused are understood, and that organisations such as the British Dental Bleaching Society run certifying training courses to ensure that the dental professional teams undertaking this treatment are properly trained. Unfortunately, there are a number of non-dental professionals, in beautician salons in particular, who are illegally bleaching teeth. Sadly, some of these individuals are using a

material called chlorine dioxide, which, although it produces an initial appearance of bleaching teeth, actually damages them.

As the Minister will be aware, the fly in the ointment is the European cosmetics directive, which restricts the sale of tooth-bleaching materials containing more than 0.1 % hydrogen peroxide. Clearly, this makes eminent sense when applied to over-the-counter medicines, but from a dental treatment point of view 0.1 per cent. hydrogen peroxide is absolutely useless.

Enforcement of the cosmetics directive is in the hands of local government trading standards officers on behalf of the Minister's Department. Most trading standards officers and departments are too busy to bother dentists. Also, most of those who do look at the issue recognise that higher concentrations of hydrogen peroxide delivered as part of dental treatment are quite different from over-the-counter sales. Indeed, some trading standards officers have visited dental surgeries that I know of and have accepted the use of such products as part of dental procedures, but not for over-the-counter sales. Unfortunately, there are a few trading standards officers who continue to threaten to prosecute dentists using more than the 0.1 per cent. concentration. I was approached in the last few weeks after dentists in Northern Ireland and, of all places, Redcar received quite aggressive letters threatening prosecution. Incidentally, if the Minister ever contacts the Redcar trading standards department, he might like to point out that his Department is no longer called the Department of Trade and Industry.

In 2005, the European Commission Scientific Committee on Consumer Products recommended that, although tooth-whitening products containing 0.1 to 6 per cent. hydrogen peroxide are not safe to be sold over the counter and should not be used freely, they are safe to be used after the approval of, and under the supervision of, a dentist. In December 2007, the SCCP reinforced this, and in November 2008 the Council of European Dentists unanimously stated that it

“Recognizes the need for regulation of availability of tooth whitening products at EU level on the basis of the December 2007 SCCP opinion; Feels that the aim of such regulation should be to protect consumers from potential harmful effects of excessive exposure to tooth whitening products and to enable distribution of the full range of tooth whitening products, under the responsibility of a dentist, as justified by scientific evidence; Expresses concern about continued delay in implementing the SCCP opinion and calls on all actors involved to ensure that a solution is found as soon as possible in the interest of patient safety; Supports the intention of the European Commission to amend the Cosmetics Directive in line with the final SCCP opinion and Encourages the European Commission to schedule a vote to amend the Cosmetics Directive at the earliest opportunity and urges Member States to contribute to a positive outcome.”

That leaves me with two simple requests for action to sort out this nonsense. First, I urge the Minister to press the Commission to change the directive speedily. The nonsense to which I refer has continued for many years, in the face of the evidence of many decades of successful and safe bleaching in the hands of dental professionals. Such techniques are commonly used in the rest of the world; it is the EU that has got itself bureaucratically out of step.

I realise—and, indeed, remember from my days as a Minister—that it will probably take some time to get the change through the EU bureaucracy, no matter how much the Minister pushes for it. It would therefore be helpful for him to suggest to trading standards departments that a more enlightened approach should be adopted to dentists using these materials in the way intended. However, I back their approach to such products when they are used as over-the-counter medicines. It would be more logical for trading standards officers to concentrate on other public sources of

bleaching gels that are being sold over the counter by the likes of beauticians who are not legally qualified to undertake any dental treatment.

At present, dentists and others in north America laugh at our smiles. We must stop that, and the way to do that is to allow the full range of dentistry, including bleaching.

7.31 pm

The Minister for Trade, Development and Consumer Affairs (Mr. Gareth Thomas): Let me begin in the usual way, by congratulating the hon. Member for Mole Valley (Sir Paul Beresford) on securing a debate on an interesting and important subject. As a result of my research for this purpose, I am substantially better informed about tooth whitening than I was a short time ago. While I nevertheless cannot begin to compete with the hon. Gentleman in terms of knowledge and expertise, I hope that I can set out some of the context of the way in which the Government have handled the issue of reform of the cosmetics directive so far. I undertake to try to keep the hon. Gentleman informed as the reform process gets under way. Of course, if he wishes to bring constituents or colleagues in the dental profession to see me to discuss the matter further, I shall be happy to receive them.

Let me now set out what the Government seek to do. I suspect that the hon. Gentleman will perceive a good deal of agreement in our respective positions, although I recognise the frustration felt by his profession at the current position. As he said, the use of hydrogen peroxide is controlled under the cosmetics directive. He will acknowledge—and, I am sure, the House will welcome the fact—that my Department takes its responsibilities under the directive, and under the United Kingdom's implementing regulations, extremely seriously. The need to ensure that only safe cosmetic products are available to consumers, and that consumers are equipped to make informed choices about which products to use and the content of those products, is an important part of the Department's role.

Hydrogen peroxide has been used in tooth whitening for many years, but, as the hon. Gentleman knows, only in the last 10 to 15 years has the desire to have much whiter teeth really taken off with consumers in the UK. I know how long some of the products described by the hon. Gentleman have been used, but I hope he will accept that the trend—stimulated in part by widespread use by consumers in the United States—has been noteworthy in the last 15 to 20 years in particular. However, there has been some confusion, as well as concern, about the regulation and enforcement of tooth whiteners under the EU cosmetics directive, so I welcome this opportunity to put the record straight and to explain what we are doing to deal with that confusion.

Let me give some of the context. I shall not go into all the lengthy detail of previous court cases in the late 1990s, but in 2001 the House of Lords ruled that tooth-whitening products should be regulated under the directive, on the basis that the whitening of teeth was a cosmetic process and discoloured teeth were not regarded as a handicap under the medical devices legislation. The directive is implemented in the UK by the Cosmetic Products (Safety) (Amendment) Regulations 2008, which—as the hon. Gentleman said—are enforced on my Department's behalf by local authority trading standards departments.

Annexe 2 of the cosmetics directive is a list of substances that cosmetics products must not contain except subject to certain restrictions and conditions. Entry number 12 in that annexe is the listing for hydrogen peroxide, which is the most widely used substance to whiten teeth. The directive states that in oral hygiene products—a definition that includes tooth whiteners—the maximum permitted percentage of hydrogen peroxide present or released is 0.1 per cent. The scientific dental and medical consensus is that this is not sufficiently strong actually to whiten teeth. It is important to

note that the directive applies to all products—those sold over the counter and those provided by dental practitioners. Since 2001, the UK has been leading the way in seeking an amendment to the cosmetics directive to allow a greater percentage of hydrogen peroxide so that the bleaching effect will actually work and teeth will be whitened. The process has proved to be far from easy to conclude, and has so far not resulted in an amending directive that has received a positive vote from the member states.

A large element of the debate on reform of the directive in relation to use of hydrogen peroxide in tooth whiteners has been around the issue of safety versus efficacy. In other words, we need a level of hydrogen peroxide in products that will actually whiten teeth, but that level must not cause harm to the health of consumers. That is one part of the reason why it has taken so long to get to the stage that we are at today.

Let me explain what has happened. First, scientific papers were submitted to the European Commission's scientific committee on consumer products showing that allowing a greater percentage of hydrogen peroxide in tooth whiteners would not be detrimental to the health of consumers. The scientific committee's view was that a greater percentage could be allowed, but it indicated that products with a higher percentage should not be used by habitual smokers and regular alcohol drinkers. That led to a discussion of what habitual meant in these circumstances. This was the start of several years of back-and-forth questions from the member states and the Commission to the scientific committee seeking clarification on that issue. There were also a number of other questions relating to use by children and pregnant women and consumer exposure to hydrogen peroxide as a whole. Without going into the protracted detail of all this scientific questioning, I can tell the hon. Gentleman that we are now at the position where we have had six opinions from the scientific committee and two draft directives from the Commission proposing changes. I should also say that we have had excellent advice from the office of the chief dental officer and his staff.

In October 2008 the Commission presented an amending directive to the experts committee on cosmetics products. It is the result of the protracted discussion I have outlined. It would allow tooth-whitening products containing a maximum of 0.1 per cent. hydrogen peroxide to be freely available to consumers, as they are today. Tooth-whitening products containing up to 6 per cent. hydrogen peroxide would be available to consumers after assessment and first application by a dental practitioner. The remainder of the kit could then be taken home and used by the consumer as directed by the dental practitioner. For kits containing 6 per cent. hydrogen peroxide, this procedure would need to be repeated every time a consumer wanted a tooth-whitening course. Products containing more than 6 per cent. hydrogen peroxide would not be available to the consumer at all. They would only be for use by dental practitioners and should not be used on children under the age of 18.

The draft directive also describes a number of labelling requirements that must appear on tooth-whitening products. Unfortunately, as a number of member states still had questions and concerns on the draft directive, the Commission did not put the text forward for a vote in October. It is hoped that the text will be re-presented at the next cosmetics expert working group in February. As the hon. Gentleman made clear, until there is a change to the directive, the maximum hydrogen peroxide level remains at 0.1 per cent. My officials and the chief dental officer's office at the Department of Health will continue to apply pressure on the Commission to bring the situation to a speedy conclusion. Any assistance that the hon. Gentleman's colleagues in the dental profession could bring, through their own contacts in other member states, would be extremely welcome.

The hon. Gentleman also alluded to the fact that trading standards departments have also been faced with the uncertainty of when and if the cosmetics directive will be amended. That has been exacerbated by manufacturers of tooth-whitening products, beauty salons and, indeed, some dental practitioners who have anticipated changes to the directive and offer products and treatments that contain more than 0.1 per cent. hydrogen peroxide. He will recognise that trading standards departments are required to consider action if they become aware of products being supplied, whether by dental practitioners or over the counter, that contain more than 0.1 per cent. hydrogen peroxide.

I recognise that the hon. Gentleman's colleagues in the dental profession face uncertainty and considerable frustration, but he will recognise the difficult position that trading standards officers are in as a result of their need to implement the directive, as required by UK law. This will not offer him complete reassurance, but to the knowledge of the Local Authorities Coordinators of Regulatory Services—LACORS—no dentists have yet been prosecuted in the UK in this regard. That does not mean that none have been visited by their local trading standards departments, and I recognise and accept the veracity of what he said about the experience in Redcar and the experience of the other dental professionals whom he said have been visited. I am aware that a number of trading standards departments have sought to take action against those selling home kits containing about 10 per cent. hydrogen peroxide. I am sure that he will continue to recognise that that is clearly a situation, regardless of reform, that we would want to see continued.

I also join the hon. Gentleman in his concern about the use of other treatments such as the use of chlorine dioxide. It is worrying that spas and, possibly, dentists are using alternatives that do not work or, worse still, are detrimental to health. I should take this opportunity to urge the dental industry and others to use only treatments that are proven to be effective and safe. In the meantime, any instances of bad practices by spas and others clearly should be brought to the attention of trading standards, so that action can be taken.

Finally, may I return to the key point of the hon. Gentleman's purpose in securing this debate? We want reform of the directive and we are seeking to achieve that, as we have been doing for some time. I hope that we will get a positive outcome shortly, but he and his colleagues in the dental profession can be assured of my officials', and now my attention, for this issue. I would be happy to keep him informed outside the Chamber and, if it is useful, to meet some of his colleagues in the dental profession to discuss this further. I hope that that will not be necessary, and that we will achieve reform shortly, but I leave that offer on the table.

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