American Medical Association endorses consumer products

Fred B Charatan, *Florida*

For the first time in its 150 year history the American Medical Association (AMA) is endorsing consumer products, in a move that has attracted much criticism.

Sunbeam, based in Florida, is better known for its kitchen products such as blenders, cake mixers, and toasters, but it also manufactures blood pressure monitors, heating pads, thermometers, humidifiers, and vaporisers. Under the five year deal such products in Sunbeam's "health at home" product line will now bear the AMA's logo to alert consumers that they are designed for healthier living.

In addition, the AMA and Sunbeam will create a doctors' advisory panel to help to develop future products, and the two organisations will join retailers in sponsoring education events for the public, such as blood pressure

screenings. In return Sunbeam will pay royalties, potentially worth millions of dollars, that will fluctuate with the commercial success of the products. The AMA said the money would be spent on public health campaigns, medical education initiatives, and scientific research.

The *New York Times* in a highly critical editorial about the venture said: "When criticised for over testing and over treating patients under fee for service insurance coverage, doctors habitually protest that their sole focus is the patient's well-being, not their personal bank accounts. These sanctimonious pronouncements would sound more convincing if the AMA had not itself been so brazenly self serving."

Dr Sidney Wolfe, executive director of the Washington

based Public Citizens' Health Research Group, criticised the association for acting more like a business, trying to do whatever it can to raise money. He said that there had been no scientific evaluation of Sunbeam's products, and he compared the AMA unfavourably with Consumer Reports, an organisation that studies and rates products without payment.

Dr Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania School of Medicine, said that he was shocked, disappointed, and puzzled as to why the AMA would move into product endorsement or certification. He pointed out that the association, unlike Consumer Reports or Underwriters Laboratories, does not have the capability for testing products. This puts the associa-

tion in a vulnerable position in the event of product failure.

He said: "Endorsing products also erodes the AMA's independence as a source of impartial health information. Money can't make up for the loss of credibility."

Other medical groups in the United States have entered into commercial ventures with companies, although these tend not to be for profit. For example, the American Dental Association charges manufacturers for its seal of approval on hundreds of products, most famously Crest toothpaste. However, the association says that its fees only cover the cost of the testing procedure. The American Heart Association also provides a seal of approval on food products, but again the fees only cover the cost of certification. □

Drugs must be tested for use in children

Terri Rutter, *Boston*

Pharmaceutical companies in the United States will have to test new drugs specifically for their effects in children to ensure that they are safe and that appropriate dosages are used, following an executive order signed by President Bill Clinton last week.

Although 80% of drugs are prescribed for children as well as adults, less than half of them have actually been tested on children and as a result are not labelled for paediatric use. Doctors then have to estimate doses for children; in some cases they may be reluctant to prescribe a drug. For example, children with

AIDS may be missing out on the potential benefits of protease inhibitors because they are not labelled for paediatric use.

"The rule I announced today will put an end to this guess work," said President Clinton when he signed the order.

"Adults have had the benefits of testing and labelling for over half a century," said Dr Joseph Zanga, vice president of the American Academy of Pediatrics, which supported the new law. "For children, we label the food they eat and the television shows they watch. However, when it comes to prescribing children's medicine, information about how much and how often to give it to them is sorely lacking."

The president's action was partly in response to cases of severe reactions, including death, that children have experienced after being given an inappropriate drug or the wrong dosages.

The new law will affect all new drugs that offer therapeutic benefits over existing treatments or that will be widely prescribed to children. Existing drugs will

need to be tested for their effect on children only if the Food and Drug Administration decides there is an overwhelming need to do so. □

There is little information on paediatric use of drugs

ZEPH/THE STOCK MARKET

In brief

Brazilians offered free sterilisation: Brazil's president, Fernando Henrique Cardoso, has signed a law granting free sterilisation to men and women over 25 who have more than two children. Poor women routinely choose to have caesarean sections so that they can bribe doctors to sterilise them at the same time.

Plans for Liverpool blood centre to be reviewed: The health secretary, Frank Dobson, said that there would be an independent review of the proposals to transfer bulk processing and testing of blood from Liverpool to Manchester after many groups, including the BMA, campaigned against the plan. Professor John Cash, president of the Royal College of Physicians of Edinburgh and former director of the Blood Transfusion Service in Scotland, will lead the review, which will report in the next month.

Millions of hamburgers recalled in the United States: The US Department of Agriculture has warned consumers that more than 1.2 million pounds of frozen hamburgers may be contaminated with *Escherichia coli*. So far 16 people have become ill from eating the contaminated meat.

Benefits Agency form to change: The Benefits Agency is to redesign the IB113 form—which relates to a patient's claim for incapacity benefit—to make it simpler and quicker for doctors to handle. The BMA's General Medical Services Committee welcomed the revision of the form as a short term solution but said that certification should be removed from GPs' terms of service.

Guidelines on organophosphate sheep dip to be drawn up: The royal colleges of physicians and psychiatrists are investigating the management of patients chronically exposed to organophosphate sheep dips and want to hear from any doctors with direct experience of treating such patients. The Department of Health has asked the two colleges to draw up guidelines. Information should be sent to Professor David London by 22 September (tel: 0171 935 1174).

Molecular basis underlying Huntington's chorea found

Deborah Josefson, *San Francisco*

The molecular mechanism underlying several inherited neurodegenerative disorders has been uncovered, a discovery that should lead to new approaches to treatment.

Huntington's chorea and spinocerebellar ataxia type III, two autosomally dominant diseases that lead to late onset dementia and crippling movements, are caused by an abnormal expansion of the DNA

trinucleotide sequence cytosine-adenine-guanine (*Cell* 1997;90: 537-8 and *Neuron* 1997;19:333-44). This sequence codes for the amino acid glutamine, and the abnormal expansion causes excess glutamine residues to be inserted into proteins, leading to the formation of insoluble proteinaceous aggregates.

Such proteins are normally restricted to the cell's cytoplasm.

In Huntington's chorea and spinocerebellar ataxia, however, the aggregates invade the neurone's nucleus, inducing cell death. Dr Randall Pitmann, from the University of Pennsylvania School of Medicine and a coauthor of the *Neuron* paper, said: "These abnormal proteins take over a significant portion of space in the nucleus and at some point will begin to shut down the nuclear processes central to the cell's survival. It's a pathological hallmark that suggests that a single disease mechanism may underlie this group of diseases."

Sequences of trinucleotide repeats appear normally in many genes. Expansion of these repeats is implicated in several neurological disorders, including spinal and bulbar muscular atrophy, Machado-Joseph disease, Alzheimer's disease, and Creutzfeldt-Jakob disease. Interestingly, in all the known diseases caused by the repeated cytosine-adenine-guanine sequence the disease occurs only when the number of polyglutamine repeats exceeds 30. People with fewer than 30 repeats almost never get the diseases, those with over 40 are virtually assured of being affected. Moreover, the more repeats, the greater the severity of the disease.

Scientists hope that the discovery will lead to novel diagnostic and therapeutic approaches to neurodegenerative diseases. Researchers now plan to focus on ways to inhibit the formation of the protein aggregates. □

In Huntington's chorea proteins invade the neurone's nucleus

CONOR CAFFEY/SPL

Police free to bug surgeries

John Warden,
parliamentary correspondent, BMJ

Draft Home Office guidelines, issued for consultation last week, seem to give fewer safeguards against the police bugging doctors' premises in Britain than had been expected.

The Police Act 1997 gives the police and customs new powers of "intrusive surveillance," which means they could break into premises and install listening devices in their pursuit of serious crime. A concession by the previous Conservative government made under parliamentary pres-

sure meant that any bugging that could affect legal, medical, or journalistic privilege would have to be approved by a High Court judge acting as a special commissioner (22 February, p 611).

The new Home Office guidelines do not specify any rights of medical privilege or clinical confidence. But cases involving the acquisition of "confidential personal information"—which is stated to cover information relating to physical or mental health—will require the approval of a commissioner.

A Home Office official said that in practice this would bring doctors' surgeries under the protection of commissioners, although they would not be exempt for surveillance. When the case is urgent, surveillance

can begin without the prior approval of a commissioner.

The two other protected categories are specified in the guidelines with more emphasis as "matters subject to legal privilege" and "confidential journalistic material."

The BMA's secretary, Dr Mac Armstrong, said that he is satisfied that confidential medical information is covered by the Home Office guidelines. Last January, a number of doctors, including the president of the General Medical Council and others from the royal colleges, medical schools, and the BMA, said that any infringements of the confidentiality between doctors and their patients could be justified only in the rarest of circumstances. □

Sensitivity of mammography depends on menstrual phase

Kamran Abbasi, *BMJ*

Mammography carried out in the second half of the menstrual cycle may miss breast cancer in women who have used oral contraception or hormone replacement therapy, a Canadian study shows.

Dr Cornelia Baines and her team from the University of Toronto examined data from the Canadian national breast screening study, which recruited 8887 menstruating women aged 40-44 years. They suggest that the higher risk of a false negative result on mammography in menstruating women in the luteal phase (days 15-28) may explain why screening is less efficacious in the under 50s (*Cancer* 1997;80:720-4).

The women received annual mammography and physical examination. If the result of mammography was negative and breast cancer was diagnosed

within the subsequent year, then this was deemed to be a false negative result. Although the specificity of mammography was 97%, the results showed sensitivities of 60% in the follicular phase (days 1-14) and 49% in the luteal phase of the menstrual cycle. The difference was due to the higher false negative rate among women who had used hormonal therapies.

Breast screening in the under 50s is controversial because of the lack of supportive evidence, and policy varies from country to country. In Britain, unlike North America, the screening programme is targeted at 50-64 year olds, with mammography only occasionally carried out in younger women with a strong family history of breast cancer.

Professor Martin Vessey, chairman of the Department of

Health's advisory committee on breast cancer screening, said: "Generally, in Britain mammography would not be done in menstruating women. We are not convinced that screening below the age of 50 is the right thing to do, and it has lower sensitivity and specificity than in older women."

"These results are not totally unreasonable as breast tissue is

more dense in the luteal phase. There are two key points here. Firstly, the findings would be of importance in younger women with a family history of breast cancer who undergo mammography, and, secondly, the effect of HRT on mammography is under investigation in Britain, as the current belief is that HRT does interfere with sensitivity and specificity." □

Menstruation may reduce the sensitivity of mammography

Doctors in Wales should speak Welsh

Roger Dobson, *Gwent*

More Welsh language training courses for doctors and other professionals are urged in a report from the Welsh Language Board.

The report says that patients who are unwell or under pressure are more comfortable talking about their problems in their first language but are sometimes unable to do so. The report's author, Professor Colin Williams from the University of Wales, Cardiff, said: "Many people we spoke to told us that they felt much more comfortable using Welsh with doctors, midwives, and dentists, but they were either simply unable to do so, or viewed English as the language of authoritative comment and judgment and so didn't choose to use Welsh."

"Openings in so many key professions, such as doctors and solicitors, tend to attract unilingual English speakers to areas with a high proportion of Welsh

speakers," he added. There are no figures on the number of Welsh speaking doctors in practice, while estimates on how many people in Wales have Welsh as a first language range up to 400 000 people out of a population of 2.9 million.

One of the findings of the report was that Welsh was not used as much by key staff in the health sector as in other areas, and a major recommendation is that medical and dentistry services in the Welsh language should be made available wherever possible.

Dr Bob Broughton, BMA Welsh Secretary, said: "The Welsh Council of the BMA has a clear policy that the criteria for appointment of all doctors must be those of professional competence and ability to do the medical job." But he added: "We realise that for the under 5s there is an advantage to having some Welsh because in the heartlands they mostly speak Welsh at home until they go to school. We also appreciate that the elderly, and particularly the elderly mentally infirm, often revert to first language, which for many of those aged 65 plus is Welsh in parts of Wales." □

FDA tightens rules on advertising

Deborah Josefson, *San Francisco*

Pharmaceutical companies in the United States must provide more information when advertising directly to the public, the Food and Drug Administration (FDA) has ruled, after mounting concern that a lot of promotional material is confusing. Television and radio advertisements are particularly targeted under the new rules, which come into effect immediately.

The pharmaceutical industry in the United States spends \$600m (£375m) a year promoting its products to the general public. A survey by the Washington based advertising firm Scott and Lieb found that 57% of doctors said that patients often come in holding a drug advertisement in their hand or referring to a drug manufacturer's promotional material. Dr Wendy Schwartz, a family doctor at Georgetown University in Washington, DC, said that on average two patients a day appear in her surgery requesting an advertised drug by name.

The Federal Food, Drug and Cosmetic Act of 1994 required

advertisements for prescription drugs that made medicinal claims to contain a "brief summary" and a "major statement" in which the drug's indications, contraindications, risks, and side effects are clearly stated. These conditions were easily met by print advertisements, but because of time, space, and monetary constraints, television and radio advertisements rarely included this information. Consequently, the FDA exempted them from this requirement so long as their communications did not make any therapeutic claims. As a result, most drug advertisements that are broadcast only mention the drug's name and obliquely allude to its therapeutic indication, urging consumers to ask their doctor about the drug.

The new rules will allow manufacturers to include therapeutic claims so long as adequate provisions are made to disseminate information about the drug's side effects—for example, by supplying freephone numbers or an internet address. □

The campaigner who dreams of a tobacco free world

Matthew Myers was the only public health advocate to sit down with tobacco companies in the United States earlier this year to broker the historic \$300bn (£188bn) deal. He tells Terri Rutter that the battle against smoking is far from over

Matthew Myers says attitudes towards tobacco are finally changing

This week doctors, tobacco control activists, and public health officials gather at the 10th world conference on tobacco or health in Beijing. Matthew Myers, executive vice president of the National Center for Tobacco-Free Kids, will be among them. The venue for the meeting is appropriate, he says, as more people will die in China from tobacco related illness than anywhere else in the world.

Mr Myers has a mission to stop what he passionately believes is indiscriminate murder carried out by tobacco companies. "This is an industry responsible for killing more people than any other," he says. Set up a year ago, the National Center for Tobacco-Free Kids counts among its member organisations (over 120) the American Cancer Society, the American Medical Association, and the American Public Health Association.

Mr Myers, a long time tobacco control advocate, was responsible

for demanding that warning labels on cigarette packages be printed in bold type and prominently placed—a law he wrote in conjunction with the American vice president Al Gore—and he successfully lobbied Congress to double the tax on cigarettes.

In April this year, when representatives from the five largest tobacco companies in the United States sat down with state attorneys general to try to reach a mutually amenable settlement,

■ *"The tobacco industry is responsible for killing more people than any other industry"*

Mr Myers was the only public health advocate to join them (26 April, p 1217). He worked for the provision in the settlement that calls for the industry to pay heavy fines if smoking among young people does not dramatically decrease.

Mr Myers fosters a long bred enmity towards the tobacco industry, which underscores his speech and his work. "This industry has made its livelihood out of exploiting children," he said. "They use nicotine to addict new consumers, knowing that their products kill."

But for all his strong words and his widely acknowledged influence in more than a decade of antitobacco work, not everyone supported his efforts in the settlement talks. While he had his proponents—including the Clinton administration and Richard Scruggs, a lawyer who represented 20 states in the talks and who called Matthew Myers the single most important player in the negotiations—he also had his critics. "The National Center for Tobacco-Free Kids is performing exactly the wrong role," representative Henry Waxman, an antitobacco campaigner, told the *New York Times* while the talks were taking place. "They seem to have forgotten that their original mission was to be advocates, not backroom negotiators."

Mr Myers was not surprised: "Some believe that no one should sit down with the tobacco industry, given their decades of wrongdoing. But if there is an opportunity to bring about fundamental change then it would be irresponsible not to."

Aged 50, he had come a long way to get to that negotiating table. As a law graduate, in 1980 he went to work at the Federal Trade Commission in the division of advertising practices, where he oversaw advertisements produced by tobacco companies. "Three secretaries quit smoking in response to the work we did," he said. "The more you learn about the industry, the more you recognise how reprehensible their behaviour has been." In 1981 he opened a law firm in Washington, DC, and began representing the Coalition on Smoking or Health, an organ-

isation comprising the American Cancer Society, the American Lung Association, and the American Heart Association. Last year this became the National Center for Tobacco-Free Kids.

Mr Myers said that after years of work he is finally seeing a sea

change in attitude towards smoking. Although doctors have been issuing warnings that smoking can cause disease since at least the 1960s, it was only last year that the Food and Drug Administration declared that nicotine is an addictive drug and, under its commissioner Dr David Kessler, that smoking is a paediatric disease. "The tobacco industry has always been treated as any other industry selling a legal product," said Mr Myers. "But this is the only product that kills when it is used as intended." Much more work will be needed, however, for his ultimate goal—"to have no one smoke"—to be achieved.

The proposed \$300bn (£188bn) settlement with the tobacco companies that Mr Myers helped to craft is likely to require more toiling over its fine points before it meets public health demands. The Advisory Committee on Tobacco Policy and Public Health, the group that is reviewing the settlement to advise Congress and which includes Dr Kessler and the former Surgeon General Everett Koop, announced that the settlement was unacceptable. The committee was particularly concerned that the Food and Drug Administration would not be given enough authority to regulate nicotine.

Mr Myers is also not satisfied with its terms. "I think the settlement offers a historic opportunity to bring about public policy change, but only if critical improvements are made," he said. He also points to the necessity for no restrictions to be placed on the Food and Drug Administration, as well as to the issues surrounding the tobacco industry's responsibility to curb smoking in young people.

Although increasing numbers of adults are stopping smoking, the number of teenagers who smoke in the United States is the highest it has been in 16 years. "The most important war is not being won," he said.

It is no coincidence that in 1993—the year that saw a sharp increase in the number of teenagers who started smoking—tobacco companies lowered the price by 40 cents on the three brands that young people predominantly smoke, he said. He hopes that his centre's aggressive public education campaign will go some way to counter that trend (see pp 439, 440). □