US government opens racketeering case against tobacco industry

Anne Harding *New Jersey*

The US government's civil racketeering case against the tobacco industry, originally filed under the Clinton administration, finally went to trial on Tuesday in the District Court of Washington, DC.

Dr David Kessler, the former chief of the Food and Drug Administration, will be the government's first witness.

Under the Racketeer Influenced Corrupt Organizations Act (RICO), a law passed in 1970 to prosecute organised crime, the Department of Justice is charging tobacco companies with conspiring to conceal the health risks and addictive powers of cigarettes. The government is seeking the "disgorgement" of \$280bn (£156bn; €230bn) that it says the industry earned by selling ciga-

rettes to people who got addicted before the age of 21 since the enactment of the act.

The government had also sued for the recovery of billions of dollars spent by Medicare and other federal health plans to treat smoking related illness since 1954, when the conspiracy allegedly began. US District Judge Gladys Kessler dismissed this part of the suit in 2000.

William Ohlemeyer, vice president and associate general counsel of Philip Morris USA, told reporters at a pretrial briefing last week that the government had no case. Under the "forward looking" RICO statute, according to Mr Ohlemeyer, the US government must prove that tobacco companies continue to act fraudulently and will do so in the future, but he said Philip

Morris has changed its ways since signing on to the Master Settlement Agreement in 1998.

"Say what you will about the company's past, I am quite confident that we have a very persuasive defence as to what we are doing today and what we intend to do in the future," Mr Ohlemeyer said.

Under the agreement, Philip Morris and six other tobacco companies agreed to pay US states \$246bn to reimburse Medicaid for treating smoking related illness, to disband industry trade groups charged with conspiring to hide the dangers of smoking, and to reform cigarette marketing.

"They would like you to believe they've changed, but they really haven't," Dr Richard Hurt, director of the Nicotine Dependence Center at the Mayo Clinic, said in an interview with the *BMJ*. Dr Hurt was the first state witness in the 1998 Minnesota tobacco trial, one of the suits that led to the Master Settlement Agreement.

Dr Hurt said that the industry was still engaged in deceptive practices, such as marketing cigarettes as "light" and "ultra light," and was working behind the scenes to fight legislation aimed at banning smoking in the workplace.

The government has also named five other companies as being part of the conspiracy to conceal the health risks and addictive powers of cigarettes. These are R J Reynolds, British American Tobacco, Brown and Williamson Tobacco, Lorillard Tobacco, and the Liggett Group. It also cites two industry trade groups, one of which, the Tobacco Institute, was dissolved under the terms of the Master Settlement Agreement. The case is expected to last six months.

The tobacco companies have filed an appeal challenging the government's legal authority to seek the \$280bn disgorgement. A federal appeals court will hear oral arguments on the case in November. □

Routine colonoscopies miss more than 10% of polyps

Scott Gottlieb *New York*

A study of adults who did not have signs of colon disease found that traditional optical (flexible) colonoscopies missed more than a tenth of precancerous polyps that were identifiable with virtual colonoscopy, a new "virtual" procedure using computed tomography to form three dimensional images of the colon.

In the study, researchers led by Dr Perry Pickhardt of the University of Wisconsin Medical School, Madison, evaluated 1233 asymptomatic adults (mean age 57.8 years) who had virtual colonoscopy and optical colonoscopy on the same day (*Annals of Internal Medicine* 2004;141:352-9).

The study identified 1310 polyps at optical colonoscopy, 511 (39%) of which measured 5 mm or greater.

Of these 511 polyps, 55 (11%) were found only on "second look" optical colonoscopy, after

Adenomas in the colon (above) are more likely to be missed in certain locations, such as behind a fold or near the anal verge

unblinding of the virtual colonoscopy results. Twenty four (44%) of these 55 lesions were non-adenomatous, including 16 hyperplastic polyps. Of the 31 missed neoplasms, 10 adenomas that measured only 5 mm were excluded from further analysis because of their diminutive size.

The 21 missed adenomas measuring more than 6 mm occurred in 20 patients (17 men and 3 women; mean age 58.2 years).

Thus the "miss" rate for adenomas on optical colonoscopy compared with virtual colonoscopy was 10.0% (95% confidence interval 6.3% to

14.9%) (21 of 210 adenomas measuring 6 mm or more).

At 8 mm and 10 mm thresholds, the adenoma miss rates on optical colonoscopy were 10.5% (5.2% to 18.5%) (10 of 95 adenomas) and 11.8% (4.4% to 23.9%) (6 of 51 adenomas) respectively.

Most clinically important adenomas that were missed on optical colonoscopy were located behind a fold or near the anal verge.

An accompanying editorial in the same issue (pp 401-3) notes that the study relied on a state of the art computed tomography scanner for performance of the virtual colonoscopy that is not available in most centres, as well as using radiologists specially trained in this technique.

"Optical colonoscopy is a sensitive diagnostic tool for detecting colorectal neoplasia. However, despite the utmost attention to technique, even experienced colonoscopists will occasionally miss significant lesions," the authors wrote. "By using VC [virtual colonoscopy] as a separate standard of reference, our study confirms that distinct locations on OC [optical colonoscopy] examination represent relative blind spots where clinically significant polyps can sometimes be missed." □