Oral Statement of Commissioner J. Thomas Rosch FTC Oversight Hearing Committee on Commerce, Science and Transportation United States Senate April 10, 2007

Thank you, Chairman Pryor, Vice Chairman Stevens, and Senator Klobuchar, for this chance to appear before you with Chairman Majoras and my fellow Commissioners.

Today I'd like to talk briefly about the Commission's activities in the health care area. One of the most important priorities of the Commission is, of course, the pursuit of those who make deceptive health care claims. Over the past few years, the agency has brought several successful enforcement actions against marketers that deceptively advertised health-related products that they claimed could, among other things, cause weight loss, decrease pain, cure cancer and increase height in adults and children.¹ For example, marketers for weight-loss products recently settled charges that they had made false or unsubstantiated claims. In settling, they surrendered cash and other assets collectively worth at least \$25 million and agreed to limit their future advertising claims.²

In addition to law enforcement action, the Commission works hard to educate the media and consumers about fraudulent claims. For example, since 2003, we've promoted our "Red Flags" initiative, which asks for the media's help in preventing the dissemination of facially false advertising claims for weight-loss products. As a complement to this initiative, the agency also has created extensive consumer education campaigns to alert consumers about deceptive claims,

¹ Last September, for example, in a case brought by the Commission, a federal district court found that defendants' claims for their purported pain relief ionized bracelets were false and unsubstantiated, and required the individual and corporate defendants to pay up to \$87 million in refunds to consumers. *FTC v. QT, Inc.*, No. 03 C 3578 (N.D. III. Sept. 8, 2006) (final judgment order), *available at* http://www.ftc.gov/os/caselist/0323011/061113qrayfinaljdgmntorder.pdf.

² See FTC Press Release, Federal Trade Commission Reaches "New Year's" Resolutions with Four Major Weight-Control Pill Marketers (Jan. 4, 2007), available at <u>http://www.ftc.gov/opa/2007/01/weightloss.htm</u>.

including "teaser" websites and online games.³

Competition also plays an important role in our health care agenda. Our written statement describes some of our efforts to ensure that healthy competition exists in the markets in which health care providers do business, including our challenges to some practices by physician providers and to hospital and drug company mergers.

I'd like to take a minute to describe our efforts to combat what we consider to be illegal "reverse payments" made by branded drug makers to generic drug makers in patent litigation settlements between branded and generic firms instituted under the Hatch-Waxman Act. As you know, the Eleventh Circuit reversed our decision in the *Schering* case that a substantial reverse payment made seemingly as a *quid pro quo* for the generic to abandon its effort to enter the market before expiration of the branded's patent, was illegal.⁴ We held that the settlement agreement was tantamount to a market division agreement between a competitor (the branded) and a potential competitor (the generic), which the Supreme Court has held is illegal.⁵

The Eleventh Circuit held that we were wrong in *Schering* and that a settlement within the scope of the patent – in other words, a settlement that wouldn't affect the generic's unpatented products or keep the generic from competing beyond the life of the patent – is legal under the patent laws. The Supreme Court declined to review that decision, at the suggestion of the Justice Department which advised that the issue was not ripe for Supreme Court review. In

³ For example, during "National Consumer Protection Week" last year, the FTC unveiled a series of online games that allow consumers to interact with the information and test their knowledge about common scams, such as worthless weight-loss products, bad business opportunities, and fake foreign lotteries. The "Grand Scam Challenge" can be found as part of the NCPW Web site at <u>http://www.consumer.gov/ncpw</u>.

⁴ In the Matter of Schering-Plough Corp., Docket No. 9297, Federal Trade Commission, 2003 FTC LEXIS 187, Dec. 8, 2003; Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005).

⁵ Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990)(per curiam).

the *Tamoxifen* case, which involved facts similar to *Schering*, a divided Second Circuit essentially followed the Eleventh Circuit.⁶

We believe *Tamoxifen* and *Schering* are bad law. More specifically, we continue to believe that most, if not all, reverse payments are illegal if they are made at the same time a generic agrees not to compete as soon as it could if it won its challenge to the branded's patent.

Schering could be reversed in one of two ways. First, the Supreme Court has just asked for the Justice Department's recommendation whether the Court should review the decision in *Tamoxifen*. We are hopeful that the Court will review and reverse *Tamoxifen* in a fashion that will discredit *Schering*.

Second, the Judiciary Committee has reported a bipartisan bill that would generally prohibit reverse payments in the instances I described. Commissioner Leibowitz testified on behalf of the Commission in connection with that bill.⁷

Whether the Supreme Court or the Congress overturns *Schering*, we firmly believe that one or the other should do so because agreements like those at issue in *Schering* can severely hobble competition between providers of drugs and thereby impose a very significant tax on the federal and state governments, as well as consumers, all of which buy drugs and stand to benefit from competition.

I look forward to answering any questions you may have. Thank you.

In Re: Tamoxifen Citrate Antitrust Litigation, 429 F.3d 370 (2d Cir. 2005).

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 $http://www.ftc.gov/speeches/leibowitz/070117 anticompetitive patents ettlements_senate.pdf.$

⁷ See Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: the Benefits of a Legislative Solution, January 17, 2007, *available at*