UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X

ORAL STATEMENT BY THE COURT AT CLASS CERTIFICATION ARGUMENT

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MD-1596

----------X

UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, ERIC TAYAG, and MID-WEST NATIONAL LIFE INSURANCE COMPANY OF TENNESSEE, on behalf of themselves and others similarly situated,

05-CV-4115
05-CV-2948

Plaintiffs,

vs.

ELI LILLY AND COMPANY,

Defendant.

----------X

F+D
7/17/08

LOCAL 28 SHEET METAL WORKERS, on behalf of themselves and others similarly situated,

06-CV-0021

Plaintiffs,

vs.

ELI LILLY AND COMPANY,

Defendant.

----------X

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated,

06-CV-6322

Plaintiffs,

vs.

ELI LILLY AND COMPANY,

Defendant.

----------X

JACK B. WEINSTEIN, Senior United States District Judge:

The court is grateful for the appearance in person and by telephone today of those interested in the Zyprexa litigation and for the excellent briefs and arguments presented.

This is a complex and troubling series of cases. Four years ago, the Judicial Panel on Multidistrict Litigation transferred the *Zyprexa Products Liability Litigation* to this court, expecting it to attempt to complete discovery and resolve as much as possible of the related litigation in federal courts, and, preferably, that in state courts as well.

The related cases are as follows:

1) Some 30,000 cases claiming personal injury due to side effects, including diabetes, obesity, and other diseases, allegedly known to, but concealed by, Lilly, have been settled. Approximately three hundred remain.

About a hundred were filed in the Eastern District of New York. They are being set for group trials in this court, with discovery to be completed within months. These cases will be settled, tried, or dismissed by summary judgment in the near future.

Several hundred other still-open cases were transferred to this court from other federal courts. Discovery is being completed in groups under the auspices of Special Master Peter Woodin. These cases will shortly be settled, dismissed, or suggested for remand back to the transferor court for trial.

Because of statute of limitations concerns, it is unlikely that any appreciable number of new cases will be added to this group. Thus, completion of this central aspect of the multidistrict litigation is near.

2) A putative class action securities suit by parties who purchased Lilly stock has been dismissed on statute of limitations grounds. *See In re Zyprexa Prods. Liab. Litig.*, — F. Supp. 2d —, Nos. 04-MDL-1596, 07-CV-1310, 2008 WL 1923126 (E.D.N.Y. Apr. 30, 2008).

3) Three shareholder derivative suits against Lilly's board of directors and corporate officers have been filed in this court and three others are in Indiana. They are based on the claim that the company leaders should have acted in a way that would have prevented this litigation. These claims have no more than modest merit. It is expected that they will soon be settled in Indiana.

4) A series of actions have been filed for overcharging, based in part on excessive off-label promotion: the central claim is that anyone who paid for Zyprexa is entitled to a refund because of the drug's allegedly fraudulently inflated price. A number of groups have sued or threatened to sue on this theory:

A) Third-party payers, such as insurance plans and union funds. This group is involved in the class certification discussed in the just-issued draft memorandum. *See* Discussion Draft, July 2, 2008, *UFCW Local 1776 & Participating Employers Health & Welfare Fund v. Eli Lilly & Co.*, Docket No. 05-CV-4115, Docket Entry No. 202 (E.D.N.Y.). The draft suggests that a jury might find some merit to the contention that Lilly exaggerated the utility of the drug, both on and off-label, and de-emphasized its dangers, in order to support an excessive price. Evidence of defendant's alleged failure to disclose its products' side effects, its violation of obligations of transparency, and its deliberate encouragement of off-label use, permits—but just barely—a jury finding of liability under RICO. *See In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571 (E.D.N.Y. 2007) (denying summary judgment in this case); *see also In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 230-247 (E.D.N.Y. 2007) (indicating the thin basis for the entire

Zyprexa personal injury litigation).

Each side has severe deficiencies in proof. The defendant's claim of transparency is contradicted by some evidence of possible fraud. The plaintiffs' evidence of damages and their computation of the amount of overpricing is questionable, but is marginally sufficient for a reasonable juror to find a specific amount of overpricing per prescription. *Cf. Zyprexa*, 489 F. Supp. 2d at 247 ("[P]laintiffs have barely—but sufficiently under summary judgment standards—demonstrated that reasonable minds may differ on this [statute of limitations] point."). That Lilly, as the patent-holder for Zyprexa, had the ability through its monopoly power to set any price it wished for the drug may appear to a jury to moot any "overpricing" claim by any plaintiff.

When appropriate, our juries are capable of reasonably denying or limiting awards in mass tort cases *See, e.g., Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris, Inc.*, 178 F. Supp. 2d 198 (E.D.N.Y. 2001), *rev'd and dism'd sub nom. Empire Healthchoice, Inc. v. Philip Morris USA, Inc.*, 393 F.3d 312 (2d Cir. 2004) (jury compensatory damage award far less than the health insurer's claimed increased costs of treatment of smokers resulting from tobacco companies' schemes to distort public knowledge concerning risks of smoking in violation of New York consumer protection law); *see also In re Joint Eastern & Southern Dists. Asbestos Litig.*, 762 F. Supp. 519 (E. & S.D.N.Y. 1991) (cigarette-asbestos damage trial resulting in defense verdict).

From the prospective jury's point of view, a difficulty with the

institutional plaintiffs' overpricing claims—as well as those of the state and federal governments, discussed below—may be that these institutions themselves had a fiduciary duty to ensure that their members were not overusing or overpaying for a medication. Information about Zyprexa's alleged deficiencies and overpricing has been available for years. Food and drug agencies in other countries were not misled. The third-party payers, with their professional consultants and pharmacy benefit managers, arguably should not have been gulled.

Strong evidence that they were not defrauded is provided by the fact that most of the third-party plaintiff representatives still maintain Zyprexa on their formularies and continue to pay for the drug, as they have in the past. By contrast, the Veterans Health Administration in Los Angeles dropped Zyprexa as a first-line drug in 1998 because of its known high costs and adverse side effects; it required that patients first be put on lower-priced Risperdal. *See* Evid. Hr'g Tr. 381, Mar. 31 & Apr. 1, 2008 (testimony of William Wirshing, M.D.).

B) Individuals patients who made full or partial payments directly for Zyprexa have claims similar to the third-party payers', but they are low in amounts and difficult to prove from available records.

C) Various states, through their state Attorneys General, have made overpricing and off-label claims based primarily on state Medicaid payments for Zyprexa. The same problems that apply to the third-party payers will arise in the state suits. It should be noted that, after protracted negotiations in this court, all states have

already received substantial payments in the form of liens and hold-backs on personal injury settlements obtained by individuals who used Zyprexa when they were covered by Medicaid. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006) (Memorandum Order & Judgment Regarding Liens and Disbursement Procedures). In short, the possible claims of the Attorneys General would appear to have as little value as that of the third-party payers.

5) The federal government has a variety of bases for suing for overpricing because of Zyprexa's use in the Armed Forces, Veterans Health Administration ("VA"), Medicare, etc. These claims are of relatively slight value for the same reasons as those of the third-party payers and state Attorneys General. The federal government has already received substantial payments for liens and hold-backs on personal injury settlements by individuals who used Zyprexa when they were covered by Medicare.

The federal government's claims may well be viewed by juries as especially anomalous. A large part of the legal problems attributed to Zyprexa, if they exist, are arguably due to the failure of the responsible federal agencies to prevent abuse. A jury might credit evidence that the government and its responsible agencies did not adequately ensure that the available knowledge of pharmacological efficacy and dangers, to the extent they can and should have been known, were rapidly communicated to prescribing doctors, third-party payers (and their advisors), major purchasers such as Medicare, Medicaid, and the VA, and even patients. Compared to its peer agencies in other parts of the world, the United States Food and Drug Administration ("FDA") has arguably failed

consumers and physicians by overrelying on pharmaceutical companies to provide supporting research for new drug applications; by allowing them, through lax enforcement, to conduct off-label marketing; by acquiescing to industry pressure on drug labels; by not requiring doctors—the main line of defense against misusing prescriptions—to be adequately informed; and by leaving information dispersal and control largely to industry-influenced medical journals and non-governmental associations.

The result of such claimed governmental failures arguably causes overuse and overpricing of pharmaceuticals, resulting in mass litigations such as this one for Zyprexa. That the federal government is prohibited from negotiating with drug companies over the price of pharmaceuticals may be pointed to as indicative of the problems. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1860D(i), 117 Stat. 2066 (2003) (codified at 42 USC § 1395w-111) ("In order to promote competition . . . , the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."). Any claims by the federal government for overpricing might appear to be inequitable by juries.

6) Bruited about is the threat of criminal litigation as a basis for possible fines, restitution, administrative penalties, and other recovery techniques. In the enormous cache of discovery documents it has reviewed, no sign of potential criminal liability has been observed by this court, although of course this court is not privy to ongoing

investigations, if any. At the moment it is enough to say that the threat of criminal prosecution does not substantially enhance the value of civil proceedings before, or potentially before, this or other courts.

Evidence referred to in the Discussion Draft of July 2, 2008, the previous summary judgment opinion in this case, *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp. 2d 571 (E.D.N.Y. 2007), the extensive opinion on summary judgment in several individual personal injury actions, *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 230-247 (E.D.N.Y. 2007), and briefs and arguments, might indicate to a jury fault by others than Lilly. It could suggest to jurors inadequate control of the pharmacological research, development, distribution, delivery, use, and payment systems in the United States: failure of the state and federal protective agencies upon which users of pharmaceuticals primarily depend to protect against overpricing and misuse, and, in particular, the FDA's lack of adequate research and control over marketing; failure of third-party payers, pharmacy benefit managers, and their consultants to exercise control over drug pricing and use; failure of what should be impartial and timely research by governmental and non-governmental organizations; inadequate steps by governmental and non-governmental organizations to promptly publicize efficacy and dangers; and, to some extent, failure of prescribing doctors and other medical personnel to limit appropriately usage and costs. Lilly's alleged lack of transparency, failure to warn, and deceptive or illegal marketing practices are but some of the factors that a juror could find led to this litigation. This congeries of conflicting considerations would tend to minimize a jury's finding of damages and preclude punitive damages.

The court has suggested that the overcharge cases should be settled promptly so that the defendant can get on with its research, production, and sale of pharmaceuticals, appropriately chastened for arguably failing to divulge in a timely fashion what it knew or should have known of efficacy and dangers. In this litigation there is evidence of the enormous contribution by, as well as the endemic shortcomings in, our pharmacological industry and regulatory agencies affecting the health of our people. Mass tort law can exercise only a small part in correcting deficiencies in our health system.

Persons and parties other than those listed on the draft certification opinion may wish to be heard on the class certification issue. The court will receive written submissions on or before August 22, 2008. After considering those submissions, the court expects to file a certification opinion in the Fall.

July 17, 2008
Brooklyn, N.Y.