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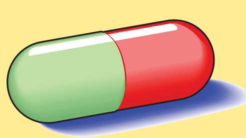

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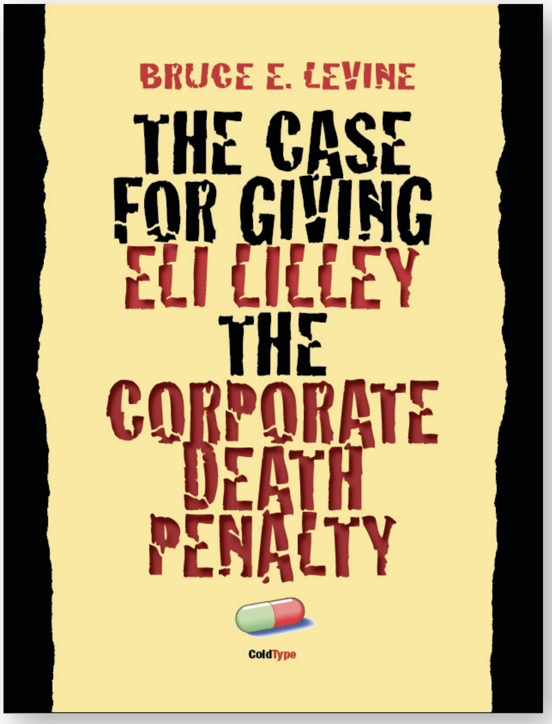

THE AUTHOR

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THE CASE FOR GIVING ELI LILLEY THE CORPORATE DEATH PENALTY

BRUCE E. LEVINE

Eli Lilly & Company's rap sheet as a public menace is so long that for Lilly watchers to overcome the "banality-of-Lilly-sleaziness" phenomenon, the drug company must break some type of record measuring egregiousness. Lilly obliged earlier this year, receiving the largest criminal fine ever imposed on a corporation.

If Americans are ever going to revoke the publicly granted charters of reckless, giant corporations -- well within our rights -- we might want to get the ball rolling with Lilly, whose recent actions appalled even the mainstream media. And with Lilly's chums, the Bush family, out of power, now might be the right time.

On January 15, 2009, Lilly pled guilty to charges that it had illegally marketed its blockbuster drug Zyprexa for unapproved uses to children and the elderly, two populations especially vulnerable to its dangerous side effect. Lilly plead guilty to a misdemeanor charge and agreed to pay $1.42 billion, which included $615 million to end the criminal investigation and approximately $800 million to settle the civil case.

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> **Much of the controversy surrounding Ave Maria has focused on the question of how it can simultaneously be a Catholic enclave and a governmental unit**

One of the eight whistle-blowers in this case, former Lilly sales representative Robert Rudolph, says the settlement will not completely change Lilly's business practices, and he wants jail time for executives. "You have to remember, with Zyprexa," said Rudolph, "people lost their lives."

Rudolph is not exaggerating. Zyprexa, marketed as an "atypical" antipsychotic drug, has been promoted as having less dangerous adverse effects than "typical" antipsychotic drugs such as Thorazine and Haldol. However, on February 25, 2009, the Journal of the American Medical Association reported that the rate of sudden cardiac death in patients taking either typical or atypical antipsychotic drugs is double the death rate of a control group of patients not taking these drugs.

Zyprexa -- though not nearly as well known as Lilly's previous blockbuster Prozac -- is today one of the biggest-selling drugs in the world. Zyprexa has grossed more than $39 billion since its approval in 1996, with $4.8 billion of that in 2007 (and it was projected to equal or surpass that gross in 2008 when earnings are reported).

Lilly has had other Zyprexa scandals, but in this current one, Lilly executives matched Charles Dickens scoundrels. Zyprexa is approved by the Food and Drug and Administration (FDA) for schizophrenia and bipolar disorder, but Lilly illegally marketed it for sleep difficulties, aggression, and other unapproved uses. Lilly sales reps aggressively pushed Zyprexa as a wonderful drug to chill out disruptive children and the elderly who were not schizophrenic or bipolar. The lawsuit against Lilly stated, "In truth, this was Lilly's thinly veiled marketing of Zyprexa as an effective chemical restraint for demanding, vulnerable and needy patients."

Doctors can prescribe drugs for unapproved uses (called "off-label prescribing"), but drug companies are not allowed to market drugs for unapproved uses. Many drug companies break this rule, but Lilly broke it with gusto. "The company made hundreds of millions of dollars by trying to convince health care providers that Zyprexa was safe for unapproved uses," said Laurie Magid, acting U.S. Attorney for the Eastern District of Pennsylvania where the case was prosecuted. Magid said that Lilly was responsible for "putting thousands and thousands of patients at risk."

"The Big Cypress Swamp's flora and fauna are just as sensitive to disruption of natural water flows and fragmentation of habitat as are those of the vast, grassy tracts of Everglades to the east

One marketing effort consisted of the Lilly sales force urging geriatricians to use Zyprexa to sedate unruly nursing home and assisted-living facilities patients. Lilly sales reps distributed a study claiming that elderly patients taking Zyprexa required fewer skilled nursing staff hours than were necessary for patients taking competing medications. Magid stated that Lilly sales reps were "trained to use the slogan five at five, meaning five milligrams at 5 o'clock at night will keep these elderly patients quiet." Illegally marketing Zyprexa for elderly patients was especially troubling for prosecutors because Zyprexa increases the risks of heart failure and life-threatening infections such as pneumonia in older patients.

In addition to targeting the misbehaving elderly, Lilly also targeted annoying kids. New York Times reporters Gardiner Harris and Alex Berenson, who have been covering Eli Lilly and Zyprexa for several years, reported on January 14, 2009, "The company also pressed doctors to treat disruptive children with Zyprexa, court documents show, even though the medicine's tendency to cause severe weight gain and metabolic disorders is particularly pronounced in children … The children receiving Zyprexa gained so much weight during the study that a safety monitoring panel ordered that they be taken off the drug."

Mainstream reporters were so appalled by Lilly's recent actions that some voiced caustic commentaries about the relatively small price Lilly paid for its transgressions. CBS reporter Sharyl Attkisson (January 15, 2009) noted, "Eli Lilly has pled guilty to marketing the sometimes dangerous drug Zyprexa in ways never proven safe or effective … Lilly has agreed to pay $1.4 billion, including the largest criminal fine ever imposed on a corporation. Ironically, that's about as much as the company's Zyprexa sales in the first quarter last year." However, the mainstream media failed to provide the context of Lilly's horrendous history which goes back decades.

The New York Times 2009 article did at least go back as far as 2006, reminding readers of the Times exclusive on another Zyprexa scandal. In December 2006, a whistle blower handed over to the Times hundreds of internal Lilly documents and e-mail messages among top company managers that showed how Lilly had downplayed Zyprexa's association with weight gain and metabolic disorders such as diabetes.

A Rolling Stone piece earlier this year ("Marketing Lilly's Zyprexa, a Phony 'Miracle' Drug") details how Lilly minimized Zyprexa's relationship with dramatic weight gain. In 1995, prior to FDA approval of Zypexa , Lilly's own panel of experts concluded that Zyprexa produced an average weight gain of 24 pounds in a single year (one in six patients gained more than 66 pounds); that kind of weight gain can elevate blood-sugar levels and cause diabetes. This data, however, was not submitted by Lilly to the FDA.

Lilly-Zyprexa scandals didn't just start in 2006. A 2003 Lilly-Zyprexa scandal involved Medicaid and the National Alliance for the Mentally Ill (NAMI), ostensibly a consumer organization. That year, Zyprexa grossed $2.63 billion in the United States, 70 percent of that attributable to government agencies, mostly Medicaid. Zyprexa cost approximately twice as much as similar drugs, and state Medicaid programs, going in the red in part because of Zyprexa, were attempting to exclude it in favor of similar, less expensive drugs. When Kentucky's Medicaid program attempted to exclude Zyprexa -- its single largest drug expense -- from its list of preferred medications, NAMI bused protesters to hearings, placed full-page ads in newspapers, and sent faxes to state officials. What NAMI did not say at the time was that the buses, ads, and faxes were paid for by Lilly.

“The march of suburbia hasn't stopped, but it has slowed. And Florida's real-estate and construction barons are now clamoring for a healthy share of federal bailout money to get them through hard times

The Lilly-NAMI financial connection had already been exposed by Ken Silverstein in Mother Jones in 1999. Silverstein reported that NAMI took $11.7 million from drug companies over a three-and-a-half-year period from 1996 through 1999, with the largest donor being Lilly, which provided $2.87 million. Lilly's funding also included loaning NAMI a Lilly executive, who worked at NAMI headquarters but whose salary was paid for by Lilly.

Beyond Zyprexa, in 2002 fingers were pointed at Lilly for tampering with the Homeland Security Act. On November 25, 2002, soon after George W. Bush signed the Act, New York Times columnist Bob Herbert discovered what had been slipped into it at the last minute, "Buried in this massive bill, snuck into it in the dark of night by persons unknown . . . was a provision that – incredibly – will protect Eli Lilly and a few other big pharmaceutical outfits from lawsuits by parents who believe their children were harmed by thimerosal."

While it was recently revealed that research published in 1998 that linked vaccine use to autism was fraudulent, in 2002 the harmfulness of thimerosal (a preservative that contains mercury and used by Lilly and other drug companies in vaccines) was not clear. Specifically, in 1999 the American Academy of Pediatrics and the Public Health Service had urged vaccine makers to stop using thimerosal, and in 2001 the Institute of Medicine concluded that the link between autism and thimerosal was "biologically plausible." So in 2002, drug companies such as Lilly which had used thimerosal in vaccines were nervous about what scientists and the courts would ultimately determine.

How then did a drug-company protection provision get inserted in the Homeland Security Act? Here's my bet for one of Herbert's "persons unknown." In June 2002, then President George W. Bush had appointed Lilly's CEO, Sidney Taurel, to a seat on his Homeland Security Advisory Council. Ultimately even some Republican senators became embarrassed by the drug-company protection provision, and by early 2003, moderate Republicans and Democrats agreed to repeal that particular provision from the Act.

The year 2002 was a banner one for "Lillygates," with "60 Minutes II" ultimately airing another juicy Lilly scandal. Lilly's patent for Prozac had run out, and the drug company began marketing a new drug, Prozac Weekly. Lilly sales representatives in Florida gained access to patient information records, and, unsolicited, mailed out free samples of Prozac Weekly. Though they primarily targeted patients diagnosed with depression who were receiving competitor antidepressants, at least one such Prozac Weekly sample was mailed to a sixteen-year-old boy with no history of depression or antidepressant use. Law suits followed.

The most cinematic of all Lilly scandals began in 1989 and culminated in1997. One month after Joseph Wesbecker began taking Lilly's antidepressant Prozac, he opened fire with his AK-47 at his former place of employment in Louisville, Kentucky, killing eight people and wounding twelve before taking his own life. British journalist John Cornwell covered the trial for the London Sunday Times Magazine and ultimately wrote a book about it. Cornwell's The Power to Harm is not simply about a disgruntled employee becoming violent after taking Prozac; the book is about Lilly's power to corrupt a judicial system.

"The people who pick the tomatoes go home each day to trailer parks that present a shocking contrast to the condos and McMansions just over the horizon in Ave Maria

Victims of Joseph Wesbecker sued Lilly, claiming that Prozac had pushed Wesbecker over the edge. The trial took place in 1994 but received little attention as America was obsessed at the time by the O.J. Simpson spectacle. While Lilly had been quietly settling many Prozac violence suits, the drug company was looking for a showcase trial that it could actually win. Although a 1991 FDA "Blue Ribbon Panel" investigating the association between Prozac and violence had voted not to require Prozac to have a violence warning label, by 1994 word was getting around that five of the nine FDA panel doctors had ties to drug companies -- two of them serving as lead investigators for Lilly-funded Prozac studies. Thus with the FDA panel now known to be tainted, Lilly wanted a Prozac trial it could win, and it believed that Wesbecker's history was such that Prozac would not be seen as the cause of his mayhem.

A crucial component of the victims' attorneys' strategy was for the jury to hear about Lilly's history of reckless disregard. Victims' attorneys especially wanted the jury to hear about Lilly's anti-inflamatory drug Oraflex, introduced in 1982 but taken off the market three months later. A U.S. Justice Department investigation linked Oraflex to the deaths of more than one hundred patients, and concluded that Lilly had misled the FDA. Lilly was charged with 25 counts related to mislabeling side effects and plead guilty.

In the Wesbecker trial, Lilly attorneys argued that Oraflex information would be prejudicial, and Judge John Potter initially agreed that the jury shouldn't hear it. However, when Lilly attorneys used witnesses to make a case for Lilly's superb system of collecting and analyzing side effects, Judge Potter said that Lilly itself had opened the door to evidence to the contrary, and he ruled that Oraflex information would now be permitted. To Judge Potter's amazement, victims' attorneys never presented the Oraflex evidence, and Eli Lilly won the case.

Later it was discovered why victims' attorneys remained silent about Oraflex. In a manipulation Cornwell described as "unprecedented in any Western court," Lilly cut a secret deal with victims' attorneys to pay them and their clients not to introduce the Oraflex evidence. However, Judge Potter smelled a rat and fought for an investigation, and in 1997 Lilly quietly agreed to the verdict being changed from a Lilly victory to "dismissed as settled."

If Americans want to take on Lilly, they might want to do it during a time when the Bush family is out of power. Sidney Taurel, former Lilly CEO and George W. Bush appointee to the Homeland Security Advisory Council, is not the only Bush family-Lilly connection. George Herbert Walker Bush once sat on the Eli Lilly board of directors, as did Bush family crony Ken Lay, the Enron chief convicted of fraud before his death. Mitch Daniels, George W. Bush's first-term Director of Management and Budget, had actually been a Lilly vice president, and in 1991 he had co-chaired a Bush-Quayle fundraiser that collected $600,000. This is the same Mitch Daniels who is now governor of Indiana, Lilly's home state.

Currently, the public's right to revoke corporate charters is still recognized by the courts, but attorneys general today rarely exercise this option, and then only against small corporations. Loyola Law School Professor Robert Benson, who in 1998 petitioned California's attorney general to revoke the corporate charter of Union Oil of California (Unocal), notes that state attorneys general "don't hesitate to draw this particular arrow from their quivers when the target is some small, unpopular or socially marginal enterprise." But when it comes to egregious large multinationals, Benson concludes, "They don't even want you to know about it because they don't want to appear to be soft on corporate crime."

In his book When Corporations Rule the World, David Korten, former Harvard Business School Professor writes, "In the young American republic, there was little sense that corporations were either inevitable or always appropriate." Early in American history, Americans were very much concerned about any entity achieving too much power, and so in corporate charters there were clear limits placed on: years permitted to exist, borrowing, land ownership, extent of enterprise, and sometimes even on profits. Korten notes that in the first half of the nineteenth century, "Action by state legislators to amend, revoke, or simply fail to renew corporate charters was fairly common."

The Program on Corporations, Law & Democracy (POCLAD) was created in 1994, in part to inform Americans that they can in fact revoke corporate charters. In 1890, POCLAD explains, the highest court in New York State revoked the charter of the North River Sugar Refining Corporation in this unanimous decision: "The judgment sought against the defendant is one of corporate death … the defendant corporation has violated its charter, and failed in the performance of its corporate duties, and that in respects

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The effect is reminiscent of the most tortuously gerrymandered legislative districts, or perhaps Israeli maps of a vision for the West Bank. Ostensibly development-free parts of the RLSA are cut by six-lane thoroughfares that will take residents in to Naples, Fort Myers and Bonita Springs on the coast

so material and important as to justify a judgment of dissolution."

Giant drug corporations -- especially ones that make a killing selling dangerous drugs by hyper-pathologizing people who can't defend themselves -- get my adrenaline going; and so my candidate to get the ball rolling is Lilly, which has now made themselves vulnerable by getting in so much damn trouble. But with Lilly's man Mitch Daniels currently governor of Lilly's home state, Lilly still has pull; and so I won't be upset if some other giant sleazebag corporation receives the death penalty before Lilly.

Given the fact that Americans already have a history of revoking corporate charters, why shouldn't this practice be continued? Yes we did, yes we still can, and so yes let's do it.