LAW & MEDICINE

Mislabeled Drugs: An Update

In an earlier column, I wrote about the case of *Wyeth v. Levine* that was pending before the U.S. Supreme Court (CLINICAL ENDOCRINOLOGY NEWS, December 2008, p. 21). I noted that "in the end, the Levine case presents a clear-cut choice between a drug manufacturer claiming protection because its drug survived Food and Drug Administration scrutiny, versus state tort and product liability laws designed to protect the health and welfare of its citizens when they are injured by those very same pharmaceuticals because of the product's being defective or inadequately labeled. Hopefully, there will be wisdom and equity in the decision rendered by the Supreme Court."

BY MILES J. ZAREMSKI, J.D.

The Supreme Court has now spoken, in a 6-3 decision handed down last month. Its wisdom now sides with those who are injured by mislabeled drugs. The loser is the idea that FDA approval implies preemption from state law.

As detailed in my earlier piece, Diane Levine was a musician who sought relief from migraine headaches and accompanying nausea. As part of her treatment, she was given the drug Phenergan, made by Wyeth. The drug was administered via intravenous push, but entered an artery instead of a vein. As a result, gangrene set in, and her right forearm was amputated. She sued in Vermont state court and won a substantial verdict. The jury's verdict was appealed to the Vermont Supreme Court, which affirmed the state court's decision.

Wyeth then took the case to the U.S. Supreme Court, contending that since Phenergan and its labeling had been approved by the FDA, the company could not be responsible for damages. In other words, the federal Food, Drug and Cosmetic Act (FDCA), which implies that FDA approval prevents the drug company from being sued, preempts any state law. The high court disagreed.

After studying the history of the FDCA, the Supreme Court concluded that a manufacturer "generally may change a drug label only after the FDA approves a supplemental application." But the court said that doesn't mean that changing the labeling on the drug after initial approval would violate federal law, as Wyeth had argued. It is the responsibility of the manufacturer, not the FDA, to ensure correct and proper drug labeling, according to the decision.

The history of the FDCA also showed that Congress did not intend to preempt state law cases that stemmed from a failure to warn patients about particular drugs. Wyeth could not produce specific language from either Congress or the FDA demonstrating that specific labeling standards remained solely and exclusively within the legal purview of the federal government and not state law.

In fact, the court's majority belief was that Congress enacted the FDCA primarily to bolster consumer protection against harmful products, not to provide a legal remedy in the federal courts for consumers harmed by unsafe or ineffective drugs. Instead, the court determined that wronged consumers could get remedies in the state courts.

What does the *Wyeth v. Levine* case say about doctors' prescriptions? Can a physician rely on what is on the label as an absolute defense to, say, a medical malpractice lawsuit involving the administration of a drug that is mislabeled? No. Physicians have duties to patients, independent of the of drug manufacturers' responsibilities to label their products properly. Likewise, if a physician should not be prescribing a drug for one reason or another despite what the label says, continued use of the drug still will expose that physician to potential liability.

Despite the big play given to the decision, the "bark" of *Wyeth v. Levine* is greater than its "bite". ■

MR. ZAREMSKI, *who has written and lectured on health care law for more than 30 years, practices in Northbrook, Ill. Please send comments on this column to cenews@elsevier.com.*

Stem Cell Executive Order Draws Praise, Criticism

BY JOYCE FRIEDEN

President Barack Obama's executive order reversing the Bush administration's restrictions on government-funded stem cell research drew cheers from several diabetes organizations.

Under the previous policy, government funding for embryonic stem cell research was limited to studies using only the few stem cell lines that were in existence in August 2001, when then-President George W. Bush announced the policy. President Obama's executive order, which he signed in March, lifts those restrictions and allows funded research to include embryonic stem cell lines created after that date. However, the order does not lift a current ban on using federal funds to create stem cell lines if the creation involves destruction of human embryos. Federal policy does not affect privately funded stem cell research.

President Obama noted at the signing ceremony that "many thoughtful and decent people are conflicted about, or strongly oppose, [embryonic stem cell] research. I understand their concerns, and we must respect their point of view."

But he added that "in recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values. In this case, I believe the two are not inconsistent.

"After much discussion, debate and reflection, the proper course has become clear," he said. "The majority of Americans—from across the political spectrum, and of all backgrounds and beliefs—have come to a consensus that we should pursue this research. … That is a conclusion with which I agree. That is why I am signing this executive order and why I hope Congress will act on a bipartisan basis to provide further support for this research."

The president said that the government "will develop strict guidelines, which we will rigorously enforce, because we cannot ever tolerate misuse or abuse. And we will ensure that our government never opens the door to the use of cloning for human reproduction."

The American Diabetes Association applauded the executive order. "The ethical use of stem cell research holds the promise of accelerating medical advancements in many fields," Dr. R. Paul Robertson, the association's president for medicine and science, said in a statement. "This brings hope to the nearly 24 million American adults and children with diabetes who face its many complications, including heart disease, amputation, and blindness."

The Juvenile Diabetes Research Foundation (JDRF) also praised the move. "We're very grateful to President Obama for setting in place a policy to fully explore this promising field of science," foundation president and CEO Dr. Alan Lewis said in a statement.

JDRF international chairman Mary Tyler Moore agreed. The order "is a strong signal to patients, scientists, and the nation that we have the government's full support to pursue ethical research that may accelerate progress to new treatments and possible cures for diabetes," she said.

Lawrence Tabak, Ph.D., acting deputy director of the National Institutes of Health, also expressed support for the executive order. "Researchers will now be able to pursue new knowledge about human development, regenerative medicine, and the origins of many of our most devastating diseases," he said in a teleconference. "NIH will do its part to implement new policy and develop guidelines as expeditiously as possible to make sure the best science is funded and the research is conducted in a responsible manner."

But Dr. David Stevens, CEO of the Christian Medical Association, in Bristol, Tenn., cited problems with embryonic stem cell research. First, there is a moral issue: "We understand that embryos are human beings. Every one of us was an embryo," he said. "When you destroy an embryo, you destroy a distinct human being." Also, the prospects for embryonic stem cell research have been overblown, he continued. "We know that embryonic stem cells are difficult to culture and to control. … Even people in this field say that if treatment is going to come out of this, it's probably 20 years away." ■