VENABLE LLP

product liability update

A PUBLICATION OF VENABLE'S PRODUCT LIABILITY AND TOXIC TORTS GROUP

JANUARY 2008

AUTHORS

Bruce R. Parker
Baltimore, MD
brparker@venable.com
410.244.7534

James C. Fraser
Baltimore, MD
jcfraser@venable.com
410.244.7420

David S. Gray
Baltimore, MD
dsgray@venable.com
410.244.7682

William F. Piermattei
Baltimore, MD
wfpiermattei@venable.com
410.244.7473

FDA Subcommittee Finds That FDA Cannot Perform Its Mission

In December 2006, FDA Commissioner Andrew von Eschenbach, M.D., directed the FDA's Science Board to create a subcommittee to assess whether the FDA's science and technology capabilities can support current and future regulatory needs. The Science and Technology Subcommittee conducted that assessment and reported its conclusions in a November 2007 report entitled *FDA Science and Mission at Risk*.[i] The Subcommittee determined that "science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." Inevitably, plaintiffs' counsel in pharmaceutical and medical device products liability litigation will attempt to use the Report as a sword against federal preemption arguments and the "FDA defense."[ii] The pharmaceutical industry and its defense counsel therefore should become familiar with the Report, and begin developing strategies for rebutting plaintiffs' arguments about the Report.

Major Findings of the Report

The Report contains three "major findings." The first major finding was that the "FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak." One key basis for this finding was the Subcommittee's determination that the FDA is incapable of adequately regulating medical products that are developed based on "new science." For example, the science of genomics will play an ever-expanding role in the risk-benefit evaluation of drugs, vaccines and new drug target identification. The FDA is receiving a growing number of submissions where the use of genomic data may separate and identify patients with genetic profiles who may be more likely to benefit from a proposed treatment. However, according to the Subcommittee, the FDA's ability to analyze genomic data "is strained by lack of expertise, lack of adequate IT and bioinformatics systems, and difficulty in integrating science directly and seamlessly into the [FDA's regulatory] reviews."

Another basis for the first major finding was the Subcommittee's view that the FDA has insufficient capacity in surveillance modeling, risk assessment and analysis. According to the Subcommittee, there are "scientific gaps in surveillance and biostatistics" at the FDA. The Subcommittee determined that it would be necessary for the FDA to develop new statistical approaches to address "the deluge of data" on drug and medical device safety that will become available electronically from networks of care providers, such as the Veterans Administration and the Centers for Medicare and Medicaid. The Subcommittee also found that the FDA lacks the statistical and biomathematical expertise necessary to effectively evaluate products and assist sponsors in designing valid studies. The Subcommittee noted that the FDA traditionally has performed risk

benefit assessments "informally," but that "more formal methods" are needed for optimal decision-making. The Subcommittee nevertheless determined that the FDA currently lacks the quantitative expertise for this task and the FDA will need to "develop increased awareness of and expertise in design and analytical methods" to perform risk-benefit analyses.

The Subcommittee's second major finding was that the "FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability." The Subcommittee noted that, "despite the significant increase in workload during the past two decades, in 2007 the number of appropriated personnel remained essentially the same – resulting in major gaps of scientific expertise in key areas." According to the Subcommittee, the increased workload and declining level of resources has led to the loss of some of the FDA's best scientists.[iii] The Subcommittee noted that some single faculty labs at universities have budgets and staff that exceed those of some major FDA centers and that the FDA's salary cap makes it difficult to keep qualified scientists from leaving the FDA for careers in academia or the private sector. The Subcommittee also noted that FDA personnel are given "little or no time" to "attend scientific conferences to ensure that they keep up with new developments in the field." The Subcommittee further determined that, in the future, the FDA will need to strengthen its collaborations with outside scientists because the "FDA will not be able effectively to recruit and retain all the scientific expertise it needs in house."

The Subcommittee's third and final major finding was that the "FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate." According to the Subcommittee, although the FDA has made important improvements in its IT resources, "significant gaps remain" and these gaps are "putting the FDA's mission at risk." For example, the Subcommittee noted that clinical trial data and adverse event reports are stored in hard copy format in warehouses, and that such data storage methods "promote errors in regulatory science due to the inability to access, integrate and analyze data." Indeed, FDA staff repeatedly emphasized to the Subcommittee "the incredible missed opportunities that exist due to the inability to conduct safety and efficacy studies as a consequence of these deficiencies in storage, search and core scientific tools." The Subcommittee also found that the FDA lacks the IT resources necessary to manage the complex data types, data models, and analytical methods associated with "new science." Finally, the Subcommittee found that the FDA has inadequate processes for the recruitment and retention of IT staff.

Arguments on Preemption

Plaintiffs may be inclined to cite the Report as a reason for trial judges to deny defense arguments that certain causes of action are preempted by federal law. For example, in a case in which a plaintiff claims that a drug manufacturer's FDA-approved label should have contained a specific warning, the manufacturer may contend that the claim is preempted because the FDA had previously determined that such a warning was inappropriate. *See, e.g., Tucker v. SmithKline Beecham Corp.*, 2007 WL 2726259 (S.D. Ind. Sept. 19, 2007). A plaintiff may respond that such a claim should not be deemed preempted because the Report calls into question the FDA's ability to do risk-benefit analyses of products.

Such an argument, however, is without merit. The doctrine of preemption does not arise from the notion that federal regulatory agencies are perfect. Instead, the doctrine is grounded in the Supremacy Clause of the United States

Constitution and the principle that, when state and federal laws conflict, federal law controls.[iv] *Maryland Pest Control v. Montgomery County, Maryland*, 884 F.2d 160, 162 (4th Cir. 1989) ("The Supremacy Clause is grounded in the allocation of power between federal and state governments," and "is, in effect, a limit on a state's power to interfere with matters of national concern."); *see also Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1346 (Fed. Cir. 1999) ("The concept of preemption originates in the Supremacy Clause of the Constitution, and focuses on the conflict between state and federal law."). Thus, even if it were true that the FDA needs more resources and personnel to improve its ability to regulate the pharmaceutical industry, the fact remains that courts must dismiss any state causes of action that would create a standard of conduct for a manufacturer that conflicts with a federal standard. *Rose v. Arkansas State Police*, 479 U.S. 1, 3 (1986) ("There can be no dispute that the Supremacy Clause invalidates all state laws that conflict or interfere with an Act of Congress."); *see, e.g. Price v. Cook*, 2007 WL 2154766 (W. Va. Cir. Ct. July 9, 2007) (state failure-to-warn claim preempted because the FDA explicitly rejected label warning proposed by plaintiff). Indeed, despite the Report, the FDA continues to support industry's preemption arguments in pharmaceutical cases on the grounds that some state law claims conflict with federal law. *See, e.g.*, Brief for the United States as Amicus Curiae in Supporting Petitioners in *Warner-Lambert v. Kimberly Kent*, No. 06-1498, Supreme Court of the United States (filed in November 2007) (arguing that state law fraud-on-the-FDA claims are preempted).[v]

Arguments on the FDA Defense

Protecting the FDA defense may prove a somewhat tougher task. As an initial matter, defense counsel must mount a vigorous challenge to the admissibility of the Report. Plaintiffs are most likely to argue that the Report is admissible under the "public records and reports" exception to the hearsay rule. Fed. R. Evid. 803(8). In response, defense counsel must stress that while the Report is critical of various aspects of the FDA, the Report does not specify any particular products for which the FDA's safety reviews were inadequate. The Subcommittee even was directed to conduct a "high level review' because it was not feasible for the Subcommittee to conduct specific evaluations of individual programs. See Report at Appendix A-3. As a result, the Report would be irrelevant (or at least more prejudicial than probative) on the issue of whether the product at issue was defective. Cf. Toole v. McClintock, 999 F.2d 1430, 1434 (11th Cir. 1993) (ruling that it was error to admit FDA report on risks of breast implants and noting that the report dealt with breast implants in general and contained no findings about the defendant manufacturer's implants at issue in the case).

Moreover, defense counsel must argue that the Report should be excluded because admission of the Report would inevitably lead to a "mini-trial" on the trustworthiness of the Report's conclusions. See Bright v. Firestone Tire & Rubber Co., 756 F.2d 19, 23 (6th Cir. 1984) (excluding government report on safety of Firestone tires because "[i]t would be extremely difficult and time consuming to evaluate the report's trustworthiness by examining all the data on which it was based."); City of New York v. Pullman, Inc., 662 F.2d 910, 915 (2nd Cir. 1981) (holding that trial court did not err in excluding government report because "admission of the report would have been likely to protract an already prolonged trial with an inquiry into collateral issues regarding the accuracy of the report and the methods used in its compilation").

If a court nonetheless admits the Report, some defense counsel can focus on the few bright spots that the Subcommittee identified. For example, the Subcommittee acknowledged that user fees (e.g., those fees paid by regulated

product manufacturers) have supported some FDA initiatives, and the Subcommittee singled out the leadership of Center for Biologics Evaluation and Research ("CBER") as outstanding. To the extent that products liability litigation may involve a product that FDA reviewed, monitored, or otherwise evaluated with the assistance of user fees, or that was reviewed by CBER (i.e., vaccines), defense counsel must highlight these aspects of the Report. Otherwise, defense counsel can emphasize the FDA and defendant manufacturer's efforts to assure the safety and efficacy of the products at issue. Support for the FDA defense can be found in, among other places,

- the actions that FDA actually took with regard to the specific product at issue or the specific health outcome that the plaintiff allegedly experienced, thereby lessening the impact of the Subcommittee's broad criticisms;
- the transparency of the defendant manufacturer's actions, the clinical data provided to the FDA, and/or the adverse event data provided to the FDA;
- the principle that, with regard to the matters at issue, FDA appreciated the risks, if any, associated with the product at issue and the actions of the manufacturer defendant;
- the decision of the FDA to approve the product at issue, leave the product on the market, and/or approve the proposed warning, even after the disclosure of the alleged "warts;"
- any support that the defendant manufacturer, outside scientific community, or other regulatory agencies provided in support of such a determination;
- the defendant manufacturer implementing any suggestion that the FDA provided; and
- the reliability of the purportedly cutting edge techniques on which a plaintiff and supporting experts rely, insofar as the FDA and industry may have decided against employing those techniques due to their unreliability.

Such evidence bolsters the persuasiveness of a defendant manufacturer's compliance with FDA regulations and the absence of any adverse regulatory action with regard to the defect on which a plaintiff may base a pharmaceutical products liability claim—notwithstanding the FDA's arguable budgetary, personnel, and IT shortfalls.

Venable attorneys Bruce Parker, James Fraser, David Gray and William Piermattei contributed to this bulletin. The Product Liability and Toxic Torts Group at Venable represents clients in a broad range of industries in litigation stemming from product liability and toxic tort claims. Additional information about the group can be found at http://www.venable.com/practice.cfm?action=view&practice_id=310.

Venable office locations

BALTIMORE, MD
750 E. PRATT STREET
NINTH FLOOR
BALTIMORE, MD 21202
t 410.244.7400
f 410.244.7742

LOS ANGELES, CA
2049 CENTURY PARK EAST
SUITE 2100
LOS ANGELES, CA 90067
t 310.229.9900
f 310.229.9901

NEW YORK, NY
ROCKEFELLER CENTER
1270 AVENUE OF THE
AMERICAS
TWENTY-FIFTH FLOOR
NEW YORK, NY 10020
t 212.307.5500
f 212.307.5598

ROCKVILLE, MD
ONE CHURCH STREET
FIFTH FLOOR
ROCKVILLE, MD 20850
t 301.217.5600
f 301.217.5617

TOWSON, MD
210 ALLEGHENY AVENUE
TOWSON, MD 21204
t 410.494.6200
f 410.821.0147

TYSONS CORNER, VA
8010 TOWERS CRESCENT DRIVE
SUITE 300
VIENNA, VA 22182
t 703.760.1600
f 703.821.8949

WASHINGTON, DC
575 SEVENTH STREET NW
WASHINGTON, DC 20004
t 202.344.4000
f 202.344.8300

[i] A copy of the Report, including appendices, can be found at www.fda.gov/ohrrns/dockets/acJ07/briefing/2007-4329b_02_ 00_index.html. The Subcommittee was comprised of three members of the Science Board and other experts from industry, academia and other governmental agencies. A list of the Subcommittee members and its advisors can be found in Appendix A-7 of the Report.

[ii] As used in this Article, the term "FDA defense" refers to a regulated product manufacturer's argument to a jury that, because the FDA found the product to be safe and effective, the manufacturer should not be held liable under negligence or strict liability theories.

[iii] The Report notes that, over the last two decades, Congress has enacted 125 statutes that broadened the FDA's regulatory responsibilities. Virtually all of those statutes required the FDA to develop scientific knowledge and conduct research. However, none of the statutes included an appropriation of funding to accomplish the statutory mandates. From 1980 to 2007, the FDA gained through appropriation only 646 employees. During that period, the FDA lost more than $300 million dollars in its budget due to inflation.

[iv] The Supremacy Clause provides that "the Laws of the United States ... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, [the] Laws of any State to the Contrary notwithstanding.' U.S. Const., Art. VI, Cl. 2. The phrase "Laws of the United States" includes federal regulations. City of New York v. F.C.C., 486 U.S. 57, 63 (1988).

[v] Available at www.abanetorg/publiced/preview/briefs/pdfs/07-08/06-1498_PetitionerAmCuUSA.pdf