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Let It Bleed: The Federal Preemption Doctrine and the Sale of Blood Plasma

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"Let It Bleed:" The Federal Preemption Doctrine and the Sale of Blood Plasma

by Michael L. Perlin

Hillsborough County, Florida
v.
Automated Medical Laboratories, Inc.
(Docket No. 83-1925)

Argued April 16, 1985

ISSUE

At first glance, *Hillsborough County v. Automated Medical Laboratories, Inc.* appears to be just one more idiosyncratic fact pattern serving as the basis for yet another foray by the Court into the land of preemption—that law professors' dream of a doctrine. By way of explanation, the Supremacy Clause of the Constitution (Article VI, cl. 2) requires that when Congress exercises a constitutionally-granted power, that federal law will override or "preempt" any conflicting state law. Following a path of cases that has inquired into such esoterica as bacon packaging, the interstate shipment of avocados and smoke abatement codes for maritime vehicles, this case involves a preemption challenge to county ordinances controlling the collection and sale of blood plasma. A few clues in one of the many *amicus* briefs (filed jointly by the American Blood Resources Association and the Florida Association of Plasmapheresis Establishments) [ABRA brief], however, reveals what may be the true story-behind-the-story: how public awareness of Acquired Immune Deficiency Syndrome (AIDS) has dramatically changed the way the blood banking community is perceived. While this "issue" does not surface explicitly in the *parties'* briefs, the number (and variety) of *amici* underscore its full import.

FACTS

Federal law authorizes broad regulation of blood and blood products (both as biological products and as drugs) and mandates that manufacturers and vendors of blood products be licensed by the Secretary of Health and Human Services (HHS); such licenses are issued only upon a showing that the manufacturer or vendor's establishment and products meet certain safety, purity and potency standards established by HHS.

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Pursuant to federal statute (42 U.S.C. section 262), the Food and Drug Administration's (FDA) Office of Biologics Research and Review regulates various types of blood products and blood banking activities, including blood plasmapheresis procedures and standards. Plasmapheresis is defined as "the procedure in which blood is removed from the donor, the plasma is separated from the elements and at least the red cells are returned to the donor." Plasma derivatives include hepatitis vaccine, albumin and antihemophilic factor. In addition to providing for FDA inspection of plasmapheresis facilities, the regulations establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities and establish human blood product standards; they also mandate testing for hepatitis-positive plasma *after* plasmapheresis is completed.

On November 6, 1980, Hillsborough County (county) adopted Ordinances 80-11 and 80-12 to regulate aspects of the blood plasma sale business. These ordinances imposed a license tax on blood plasma donor centers, conditioned the issuance of a license on a center's agreeing to provide "reasonable and continuing access" to County Health Department (department) personnel for inspections and to continually update information regarding centers' owners, employees, equipment and facilities. They also required that potential donors undergo medical examinations and obtain a "certificate of good health" prior to participating in the plasmapheresis process, and that donor centers provide daily information to the department on the health of individual donors (including results of a breathalyzer analysis and hepatitis tests); supplemental regulations required that each potential donor present to the department a good health certificate along with a sworn affidavit that he or she has not been treated for chronic or acute alcoholism within the prior twelve months.

Automated Medical Laboratories, Inc. (AML) is a Florida corporation that operates eight blood centers (including Tampa Plasma Corporation [TPC] in Hillsborough County) which collect blood plasma from paid donors by plasmapheresis; it subsequently sells the plasma to pharmaceutical concerns for manufacturing products such as those listed in the federal regulations. After the county adopted the ordinances in question, AML filed suit against the county and its department, challenging both the ordinances and the supporting regulations on a variety of constitutional grounds—in-

cluding federal preemption under the Supremacy Clause.

Following a bench trial, the district court sustained all but one aspect of the scheme; it struck down only those portions of the ordinance and regulations dealing with the breathalyzer requirement, holding that the county had not demonstrated that that provision would serve the public interest to any greater degree than the federal regulations. The Eleventh Circuit affirmed on this question, and reversed on all others, holding that the FDA's blood plasma regulations preempted all provisions of the county's ordinances and regulations. (722 F. 2d 1526 (11th Cir. 1984)) It found the federal regulatory scheme "comprehensive," and reasoned that its "pervasiveness" made it clear that there was "no room for local ordinances to supplement it;" the federal interest was "dominant" and the additional requirements imposed on donor centers were unduly and impermissibly "burdensome and expensive."

BACKGROUND AND SIGNIFICANCE

Like all preemption cases, there's something illusory about *Hillsborough County*: is this a case where a local government seeks to oust or usurp federal authority by adopting local ordinances that conflict with local law (as AML insists) or, on the other hand, is it one where a local government exercises its traditional police powers to supplement minimum requirements of federal agencies by adopting nonconflicting health and safety standards that respond to local needs (as the county argues)? How the Court chooses to read the question will likely preordain its answers.

The Court is no recent stranger to preemption cases: in its last two terms, it has grappled with the doctrine in at least eight other cases. Under these cases and their predecessors—especially *Fidelity Federal Savings and Loan v. de la Cuesta* (458 U.S. 141 (1982))—if there is no express congressional intent to preempt, preemption will be implied: 1) when a scheme of federal regulation is so pervasive as to make it reasonable to infer that Congress left no room for the states to supplement it, or 2) where Congress has not entirely displaced state regulation in a specific area, state law may be preempted to the extent that it actually conflicts with federal law. Such conflict arises when complying with both federal and state regulations is a physical impossibility or where state law stands as an obstacle to accomplishing and executing the full purposes and objectives of Congress.

Here, the trial focused on four provisions of the local ordinances apparently not explicitly dealt with in the federal regulations: 1) establishing a countywide plas na vendor system, 2) requiring that prospective plasma vendors submit to a hepatitis pretest, 3) providing for local enforcement by the department, and 4) requiring that prospective vendors undergo a breath analysis to determine blood alcohol content. Before the Supreme Court, the county relies heavily on a statement by a prior FDA commissioner that the federal regulations "are not intended to usurp the powers of state or local authorities to regulate plasmapheresis procedures in their localities." This lends strong support to the county's stance that its major concern is *vendor* protection, while the federal government's primary focus is *plasma* protection. Significantly, it is substantially supported in this approach by *amicus* the United States which takes the position that, with the "potential exception" of the county's requirement that a "certificate of good health" be obtained (which *might* clash with FDA's hepatitis collection regulations), the county's "supplementary" ordinances would cause no "inevitable" disruption of federal blood policy especially in light of the FDA's disclaimer. It notes further, though, that the "potential exception" need not concern the Court because AML might lack the requisite standing to challenge that provision.

On the other hand, AML reads the relevant federal laws and regulations as so pervasive and so comprehensive a scheme as to "leave no room for state regulation of the plasmapheresis industry." In the areas of product purity, donor safety and adequate plasma supply, federal interest is "so dominant that local legislation is precluded." AML concludes: while the concern for donor safety is a "shared" local-federal interest, "given the federal ... regulatory intent to establish a uniform, comprehensive national program in this area ..., it is apparent that Congress intended uniform national standards that would foreclose the imposition of different or more stringent local requirements."

As indicated, the role of *amici* is especially provocative in this case. In addition to the United States, a consortium of governmental groups—the National Association of Counties, the International City Management Association, the National Conference of State Legislatures, the National League of Cities and the U.S. Conference of Mayors—filed in support of the county (NAC brief). Besides the ABRA brief, briefs were filed on behalf of AML by the Grocery Manufacturers of America, Inc. (GMA) and by the American Blood Commission—a nongovernmental organization consisting of thirty-three national groups (including the American Medical Association, the American Heart Association, the American Red Cross, the AFL-CIO and a plethora of disease-specific societies and foundations) established pursuant to an invitation of the Secretary of Health Education and Welfare to establish a "National Blood Policy" (ABC brief). Through these briefs, the story-behind-the-story peeks out from the somewhat leaden curtain of preemption doctrine: The ABC brief—which, somewhat floridly, characterizes blood as the "river of life"—is explicit:

> Anything that causes public hesitancy to contribute blood and blood products of any kind is dangerous, and today it has become doubly harmful. The widely publicized devel-

opment of a new disease, AIDS (Acquired Immune Deficiency Syndrome) and its suspected connection with blood and derivatives, has contributed to public fears about blood donations. Although experts consider those fears are unwarranted, they threaten the delicate tie of individual donors to the system of voluntary donations that underlies the National Blood Policy. Consequently, the national interest requires the avoidance of any obstacle that is not needed for the protection of public health.*

How the Court's ultimate decision relates to *this* perception will undoubtedly be *Hillsborough County's* ultimate legacy.

ARGUMENTS

For Hillsborough County *(Counsel of Record, Joe Horn Mount, P. O. Box 1110, Tampa, FL 33601; telephone (813) 272-5670)*

1. Federal law and regulations reveal an intent not to preempt local plasma laws.
2. Local plasma laws supplement and reinforce federal laws in all critical areas; federal uniform standards cannot imply exclusivity in the area of plasma vendor protections.

For AML *(Counsel of Record, Larry A. Stumpf, Suite 1000, Flagship Center, 777 Brickell Avenue, Miami, FL 33131; telephone (305) 371-2600)*

1. No finding of an express intent to preempt is needed in an area such as this where the federal system is pervasive and comprehensive.
2. Enforcement of local legislation would result in an irreconcilable conflict with federal regulations and would be a substantial obstacle to the full attainment of congressional objectives in blood regulation.

AMICUS BRIEFS

In Support of the County

As indicated above, the United States filed an *amicus* brief in substantial support of the county; the NAC brief is entirely supportive.

In Support of AML

As indicated above, the ABRA, the ABC and the GMA all filed briefs in support of AML.

*Just one week before oral argument in *Hillsborough County*, a California trial court ruled that a manufacturer may be held strictly liable for contaminated blood products in a case alleging that a hemophiliac's AIDS-related death was caused by a blood clotting agent; that decision is believed to be the first to accept the argument that "medical service" immunity laws (state statutes generally shielding blood suppliers from breach-of-warrant and strict, liability suits) should not apply to AIDS cases.