



# Southard v. Temple University Hospital, 781 A.2d 101 (Pa. S. Ct. 2001)

Topics Covered: Professional Liability, Informed Consent

**Outcome: Very Favorable**

## Issue

The issue in this case was whether physicians should be required to disclose, in addition to the medical risks, that medical devices to be surgically implanted in a patient's spine had not received FDA approval for such use.

## AMA Interest

The AMA supports a reasonable interpretation of a physician's obligation to obtain a patient's informed consent.

## Case Summary

Southard, a former patient, along with his wife, sued Temple University Hospital and his physicians. He alleged that the defendants, during spinal surgery, implanted pedicle bone screws in his spine without obtaining his consent to the procedure. His basic argument was that he was not advised that the United States Food & Drug Administration had not approved pedicle bone screws for such use, and this omission was material. The trial court entered partial summary judgment against the Southards on this issue, and they appealed.

The appellate court noted that the Food and Drug Act specifically states that it is not intended to limit a physician's right to use non-FDA approved medical devices in their practices. Moreover, the FDA had formally acknowledged that the use of bone screws in the pedicles of the spine is "considered to be the standard of care by the surgical community." Furthermore, the court observed that in other cases physicians had not been required to inform their patients of the FDA's non-approval of pedicle screws for use in spinal surgery. Nevertheless, the court felt that the jury should have been allowed to decide whether, by not disclosing to Southard the FDA's position on pedicle screws, the physicians had committed a material omission. It therefore reversed the order of summary judgment and remanded the case.

The Pennsylvania Supreme Court accepted the physicians' argument and reversed the intermediate appellate court decision.

## Litigation Center Involvement

The Pennsylvania Supreme Court granted allocatur on the issue of informed consent. PMS and the Litigation Center filed an amicus brief in support of the physicians.

The PMS/Litigation Center brief argued that the physicians were only obliged to warn Southard of the medical risks of the surgery, which they had done. However, physicians are not lawyers, and Southard had not come to the defendants for legal advice. A bare statement that the FDA had not approved pedicle screws for use in spinal surgery would, standing alone, probably have been misleading and would certainly not have helped reach an understanding of the medical risks of the surgery. Physicians lack the expertise to provide a meaningful explanation of the FDA position or of FDA procedures. A ruling against the physicians would have impaired the general quality of health care, because it would, in some instances, induce physicians to be unduly conservative in their recommendations.