

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROLLIN PAUL GOODMAN, in his Individual Capacity, <i>Plaintiff-Appellant,</i> v. UNITED STATES OF AMERICA, <i>Defendant-Appellee.</i>

No. 01-35240
D.C. No.
CV-97-00456-EFS
OPINION

Appeal from the United States District Court
for the Eastern District of Washington
Edward F. Shea, District Judge, Presiding

Argued and Submitted
June 11, 2002—Seattle, Washington

Filed August 2, 2002

Before: Betty B. Fletcher and Ronald M. Gould,
Circuit Judges, and Mary H. Murguia,* District Judge.

Opinion by Judge Gould

*The Honorable Mary H. Murguia, United States District Judge for the District of Arizona, sitting by designation.

COUNSEL

Julie A. Anderson, Lynch, Hensley & Anderson, Wenatchee, Washington, for the plaintiff-appellant.

Joseph H. Harrington, Assistant United States Attorney, Spokane, Washington, for the defendant-appellee.

OPINION

GOULD, Circuit Judge:

This case, brought under the Federal Tort Claims Act (“FTCA”), 28 U.S.C. §§ 1346 and 2671, raises jurisdictional and substantive issues. JoAnn Goodman, who was diagnosed with incurable melanoma cancer, participated in a clinical research study at the National Institutes of Health (“NIH”) and died from a toxic reaction to one of the medicines used in the study. Her husband, Rollin Paul Goodman (“Paul Goodman”), filed an unsuccessful administrative complaint for the wrongful death of his wife. Thereafter, he filed a fed-

eral complaint under the FTCA alleging medical malpractice. The complaint was amended two times to correct deficiencies and to allege that the NIH failed to obtain JoAnn Goodman's informed consent. After a four-day bench trial, the district court entered judgment for the United States, holding that the United States did not breach its duty to obtain informed consent from JoAnn Goodman. We have jurisdiction and we affirm.

I.

In 1990, JoAnn Goodman, then a thirty-six year old wife and mother who resided in the eastern part of the State of Washington, was diagnosed with advanced melanoma in her scalp. The cancer was excised, but because of the depth of the tumor, JoAnn Goodman's prognosis was poor. By 1995, the cancer had spread to JoAnn Goodman's liver. Despite extensive chemotherapy, the tumors in JoAnn Goodman's liver did not decrease.

In March of 1995, JoAnn Goodman and her treating physician discussed the possibility that Mrs. Goodman might participate in an experimental clinical study at the National Cancer Institute ("NCI") of the NIH, in Bethesda, Maryland. The study was conceived and directed by the NIH's Dr. Douglas Fraker. This experimental clinical study required patients to undergo a major surgery called isolated liver perfusion ("ILP"). This involved isolating the liver from the rest of the body and then administering increasing doses of a cancer fighting drug, Melphalan, in combination with Tumor Necrosis Factor ("TNF") directly to the tumor.¹ Dr. Fraker wrote the

¹Originally, the research study identified TNF and Interferon-gamma as the cancer-fighting agents to be used. The first 17 patients in the study were treated with these agents, at which time the focus of the study was to determine the maximum safe tolerable dose of TNF. That dose was determined to be 1.0 milligrams per kilogram. After analyzing the results, the study discontinued the use of Interferon-gamma and began to use Mel-

protocol for the ILP and submitted it for review to the Institutional Review Board (“IRB”) of the NCI.² It received approval from the IRB. The IRB also approved the consent form for patients, such as JoAnn Goodman, who chose to participate in the ILP study.

On April 14, 1995, JoAnn Goodman and her father-in-law traveled from Washington state to Maryland to discuss with NIH doctors whether JoAnn Goodman was eligible to participate in the ILP study. There, they met with Dr. Fraker and Dr. H. Richard Alexander, another doctor involved with the study. JoAnn Goodman discussed the ILP procedure with the NIH doctors. A copy of the consent form was given to her and it was explained.

After her April trip to the NIH, JoAnn Goodman returned home to Washington where she underwent further tests to see if her cancer had spread to other areas. The tests revealed that JoAnn Goodman now had three tumors in her liver. But the cancer had not yet spread to other areas. On June 8, 1995, JoAnn Goodman’s treating physician noted in his chart that:

[JoAnn Goodman] is not able to work, wants to be active, and has a strong personal preference for going ahead with the isolated liver perfusion study. She understands quite well, I think, that it may have only a small chance of helping her, since she has a rapidly growing disease.

phalan, in combination with TNF, this time escalating the dose of Melphalan with the primary goal of determining the maximum safe tolerated dose of Melphalan combined with TNF. The dose of Melphalan escalated as follows: patients 18, 19 and 20 received 1 mg/kg of Melphalan, patients 21, 22 and 23 received 1.5 mg/kg of Melphalan and patients 24, 25, 26, and 27 (JoAnn Goodman) received 2.0 mg/kg of Melphalan. The dosage of TNF remained constant for all patients, at 1mg/kg.

²The IRB reviews and monitors a new protocol for a proposed study before patients can participate in the study.

Shortly thereafter, JoAnn Goodman returned to the NIH where she was prepared for her ILP surgery.

The day before the surgery, Dr. Alexander discussed with JoAnn Goodman the procedure, the plan for dose escalation, and the experience of the three prior NIH patients who had undergone the ILP procedure at the same dosage levels of the drugs. JoAnn Goodman was, once again, presented with a consent form to participate in the experimental protocol for ILP.³ JoAnn Goodman signed the form. The next day, she under-

³This form was identical to the one given to JoAnn Goodman in April during her initial visit to the NIH and it contained the following language:

Isolated liver perfusion is a major surgical procedure performed in the operating room. During the operation the blood vessels to and from the liver are controlled so that very high concentrations of chemotherapy drugs can be delivered to your liver where the tumor is located. By isolating the liver from the rest of the body large amounts of drug that would be toxic if given by arm vein can be used. The type of drugs used in this study are experimental agents called Tumor Necrosis Factor (TNF) and melphalan.

...

Tumor necrosis factor and melphalan have not been used for isolated liver perfusion in patients before. The treatment you will receive is designed to determine if TNF and melphalan cause side effects when used in isolated liver perfusion and to determine what dose of these drugs can be used safely in this procedure. Your liver tumor might decrease in size in response to the treatment, although the chance of response cannot be predetermined since we have no experience using this type of treatment. Since the treatment drugs are isolated to the liver, this treatment will only effect [sic] tumor in the liver.

...

The side effects of TNF and melphalan in the liver are not completely known but may include liver failure, abnormal blood clotting, or jaundice. The operative procedure itself may cause clotting or blockage of blood vessels to and from the liver leading to liver failure or accumulation of fluid in your abdomen or lower body.

went the experimental ILP procedure involving the combined use of Melphalan and TNF. The surgery lasted ten hours.

Tragically, the dosage of Melphalan used during the surgery caused liver toxicity and veno-occlusive disease (“VOD”). VOD is a syndrome where the small blood vessels in the liver are blocked, leading to a lack of circulation and death of the tissue. None of the NIH’s prior ILP patients had suffered from VOD. Over the next six weeks, JoAnn Goodman suffered and was given the pain reliever drug, Toradol. JoAnn Goodman died on August 5, 1995.

II.

In May, 1996, Paul Goodman, in his individual capacity, filed an administrative claim with the U. S. Department of Health and Human Services (“HHS”), for the wrongful death of his wife. On the claim form, Paul Goodman wrote, among other things, that his wife “died of things and/or mistakes while at the NIH where she was receiving treatment.” Paul Goodman also wrote that the Toradol given to JoAnn Goodman after the ILP surgery “was a mistake and more than likely complicated her condition.” Paul Goodman’s administrative claim also stated that “things . . . were overlooked in the procedure and [JoAnn Goodman] should not have died.” In May, 1997, the HHS denied Paul Goodman’s claim stating:

There is no evidence that the death of Mrs. Jo Ann [sic] Goodman was a result of negligence on the part of NIH physicians. Mrs. Goodman underwent an experimental treatment for liver cancer, which involved a risk of death. Mrs. Goodman was well informed of this risk when she gave her consent to undergo the experimental treatment. Her death was the result of a disclosed complication of the treatment rather than any act or omission of NIH physicians.

On November 20, 1997, the Estate of JoAnn Goodman (“Estate”) filed a complaint against the United States in the Eastern District of Washington. The government moved for summary judgment on the basis that the Estate could not produce a medical expert to support its malpractice claim.⁴ The Estate conceded that point and the district court permitted the Estate to amend its complaint and add a claim for lack of informed consent. The government then moved to strike because, in its view, the Estate did not bring the informed consent claim before the administrative agency and thus failed to exhaust administrative remedies. On April 9, 1999, the district court denied the government’s motion and held that the court retained jurisdiction over the informed consent claim. The district court then granted the United States summary judgment on the medical malpractice claim. At this point, only the informed consent claim remained a triable issue.

On June 1, 1999, the Estate filed a motion to amend the first amended complaint by abandoning its claim and substituting Paul Goodman as Plaintiff. The district court granted this motion. The United States then moved for summary judgment on the basis that, among other things, Paul Goodman — who had brought the administrative claim — did not file suit in federal court and thus failed to timely commence a lawsuit. The district court denied this motion.

On September 28, 1999, the United States, once again, filed a motion for summary judgment alleging that under Maryland law (1) the United States owed no duty to Paul Goodman and (2) Paul Goodman was unable to prove that JoAnn Goodman’s injury was foreseeable. The district court denied the government’s motion. A four-day bench trial was held in March 2000, and in December 2000 the district court rendered

⁴Under Maryland law, a medical expert witness is essential to prove a causal connection between an alleged negligent act and any alleged damage in complicated medical malpractice cases. See *Craig v. Chenoweth*, 194 A.2d 78, 79 (Md. 1963).

findings of fact and conclusions of law favorable to the government and entered judgment in favor of the United States.

Paul Goodman appeals, claiming, *inter alia*, that the NIH doctors failed to warn JoAnn Goodman of the foreseeable risks involved in the ILP surgery and failed to obtain legally effective informed consent.

III.

At the threshold we address whether the jurisdictional requirements of the FTCA have been satisfied. The government alleges that the district court erred in asserting jurisdiction over the case. It argues two grounds barring jurisdiction: (1) the government asserts that the amended complaint was time barred because Paul Goodman, in his individual capacity, did not file a federal complaint within six months of the agency's decision; and (2) the government contends that the informed consent claim was not brought before the administrative agency and, therefore, Paul Goodman failed to exhaust administrative remedies.

A.

The government argues that Paul Goodman's amended complaint is time barred under the FTCA because Paul Goodman, in his individual capacity, did not file a federal complaint within six months of HHS' decision to deny his administrative claim. We disagree.

A district court does not have jurisdiction to hear a tort claim against the United States unless the claimant files a complaint in federal court within six months after final agency decision. *See* 28 U.S.C. § 2401(b). Under the "relation back" provisions of Federal Rule of Civil Procedure 15(c)(2), a party may amend a pleading despite an applicable statute of limitations in situations where "the claim . . . asserted in the amended pleading arose out of the conduct, transaction, or

occurrence set forth . . . in the initial pleading.” Moreover, an amended complaint substituting a plaintiff “relates back” to the initial complaint if the plaintiff is a real party in interest. See 6A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure*: § 1501 (2d. 1990). Federal Rule of Civil Procedure 17(a), which addresses real parties in interest, provides that an action shall not be dismissed

on the ground that it is not prosecuted in the name of the real party in interest until a reasonable time has been allowed after objection for ratification of commencement of the action by, or joinder or substitution of, the real party in interest; and such ratification, joinder, or substitution shall have the same effect as if the action had been commenced in the name of the real party in interest.

This sentence in Rule 17(a) “is designed to avoid forfeiture and injustice when an understandable mistake has been made in selecting the party in whose name the action should be brought.” 6A Wright & Miller, § 1555 at 412;⁵ *U.S. for Use and Benefit of Wuff v. CMA, Inc.*, 890 F.2d 1070, 1074 (9th Cir. 1989) (stating that “[t]he purpose of this portion of Rule 17(a) is to prevent forfeiture of an action when determination of the right party to sue is difficult or when an understandable mistake has been made”).

In this case, Paul Goodman’s administrative claim was denied on May 21, 1997. On November 20, 1997 — one day short of the six month period from the denial of the administrative claim — Paul Goodman, as the personal representative

⁵Wright & Miller further states that “[a] literal interpretation of the last sentence of Rule 17(a) would make it applicable to every case in which an inappropriate plaintiff has been named.” 6A Wright & Miller, § 1555 at 415. However, the treatise goes on to caution that “the rule should be applied only to cases in which substitution of the real party in interest is necessary to avoid injustice.” *Id.*

of the Estate of JoAnn Goodman, filed a complaint in federal court. Under the applicable Maryland law,⁶ however, only relatives of the victim, in their individual capacities, could bring a wrongful death action. To remedy the Estate's pleading mistake, the district court allowed the Estate to amend its complaint and substitute Paul Goodman, in his individual capacity, for Paul Goodman as the Personal Representative of the Estate.

Here, the district court, fully advised of the circumstances, concluded that Paul Goodman is the real party in interest. Under the unusual facts of this case, we do not disagree. Paul Goodman's attorney made an understandable pleading error by filing the original complaint on behalf of the Estate, and there may have been uncertainty about the correct plaintiff because of uncertainty about applicable law. To hold that Paul Goodman, in his individual capacity, is time barred would go against the purpose of the last sentence of Rule 17(a), that is, to prevent forfeiture of a claim when an honest mistake was made. There can be little doubt that the government was alerted to the interests involved of both the Estate and the surviving spouse. Limiting our ruling to the unusual circumstances of this case, we hold that the district court did not err

⁶Paul Goodman contends that because his wife was treated as part of an experimental procedure at a federal facility, the district court should have applied the federal regulations governing people involved in federal experimental procedures instead of Maryland law to the informed consent claim. See 45 C.F.R. §§ 46.111(a)(4), 46.116. We reject this contention. Under the FTCA, the liability of the United States is determined "in accordance with the law of the place where the [allegedly tortious] act or omission occurred." 28 U.S.C. § 1346(b). Moreover, "[i]n an action under the FTCA, a court must apply the law the state courts would apply in the analogous tort action, including federal law." *Rhoden v. United States*, 55 F.3d 428, 431 (9th Cir. 1995). In an analogous state case, a Maryland court would apply Maryland common law to determine whether legally effective informed consent was obtained. Thus, the liability of the United States in this case is determined by whether the NIH doctors complied with Maryland's common law doctrine of informed consent. The district court correctly applied Maryland law.

in treating Paul Goodman as the real party interest pursuant to Rule 17(a). And in light of Rule (15)(c)(2), we hold that substitution of Paul Goodman properly related back to the filing of the original complaint, thus satisfying the jurisdictional requirements of Section 2401(b).

B.

We next consider the United States' argument that the district court did not have subject matter jurisdiction to hear plaintiff's informed consent claim because, in its view, that claim was not brought before the administrative agency and, therefore, plaintiff failed to exhaust administrative remedies.

[1] In a claim for damages against the United States, an independent cause of action must first be submitted for administrative review before that claim can be filed in federal court. *See* 28 U.S.C. § 2675(a). Where such a claim is not first presented to the appropriate agency, the district court, pursuant to Federal Rule of Civil Procedure 12(b)(1), must dismiss the action for lack of subject matter jurisdiction. *See McNeil v. United States*, 508 U.S. 106 (1993).

[2] But the prerequisite administrative claim need not be extensive. The person injured, or his or her personal representative, need only file a brief notice or statement with the relevant federal agency containing a general description of the time, place, cause and general nature of the injury and the amount of compensation demanded. *See Warren v. United States Dep't. of Interior Bureau of Land Mgmt.*, 724 F.2d 776, 779 (9th Cir. 1984); *Avery v. United States*, 680 F.2d 608, 610 (9th Cir. 1982) (“[A] skeletal claim form, containing only the bare elements of notice of accident and injury and a sum certain representing damages, suffices to overcome an argument that jurisdiction is lacking.”). Furthermore, the notice requirement under section 2675 is minimal, and a plaintiff's administrative claims are sufficient even if a separate basis of liability arising out of the same incident is pled in federal court.

[3] Notwithstanding our general rule establishing a liberal notice requirement, this case presents an issue not previously decided by us: whether an administrative claim that alleges negligent care and treatment by hospital personnel necessarily presents an informed consent claim for purposes of satisfying the notice requirements of section 2675(a). The majority of circuits that have addressed the issue have held that to adequately exhaust administrative remedies with respect to an informed consent claim, a medical malpractice claim is not necessarily sufficient; instead, “the administrative claim must narrate facts from which a legally trained reader would infer a failure to obtain informed consent.” *Murrey v. United States*, 73 F.3d 1448, 1453 (7th Cir. 1996); *Bush v. United States*, 703 F.2d 491, 495 (11th Cir. 1983). In *Frantz v. United States*, 29 F.3d 222, 224 (5th Cir. 1994), the Fifth Circuit, however, held that “[b]y its very nature, the informed consent claim is included in the [plaintiff’s] allegation of [medical] negligence in their administrative claim.⁷”

[4] In *Murrey*, the Seventh Circuit addressed whether an administrative claim asserting medical negligence during surgery gave sufficient notice of an informed consent claim. The *Murrey* court recognized that informed consent is a species of negligence, however, it held that “to base a suit on lack of informed consent [a plaintiff] was required to include, or at least allude to, the issue of informed consent in the administrative claim.” *Murrey*, 73 F.3d at 1451. Although the Seventh Circuit concluded that in *Murrey*, the administrative claim provided sufficient facts to notify the government of the

⁷In a three-judge panel opinion, the Fourth Circuit adopted the Fifth Circuit’s rule, with one judge dissenting. *Drew v. United States*, 217 F.3d 193 (4th Cir. 2000). Subsequently, however, the Fourth Circuit granted rehearing en banc and vacated the opinion on September 8, 2000. The full court on rehearing was equally divided but affirmed the judgment. *Drew ex rel. Drew v. United States*, 231 F.3d 927 (4th Cir. 2000) (en banc). The Fourth Circuit En Banc Court did not, however, issue a written opinion that could serve as persuasive authority here.

informed consent claim, it explicitly refused to go as far as *Frantz*.⁸ See *Murrey*, 73 F.3d at 1453.

We agree with the Seventh Circuit that the *Frantz* rule is too broad and may give inadequate respect to the values of fair notice. For example, if an administrative claim alleged death or disfigurement caused by a drunken or intentionally malicious surgeon, no reasonable person would construe such a notice as including a claim of lack of informed consent.

Though rejecting the broad rule of *Frantz*, we conclude that our existing prior general precedent on notice supports an interpretation of Paul Goodman's administrative claim as including lack of informed consent under the unusual circumstances presented, and is not inconsistent with the Seventh Circuit's approach.

We have prior precedent supporting a generous notice interpretation in *Rooney v. United States*, 634 F.2d 1238 (9th Cir. 1980). There, the plaintiff fell at a government construction site and was treated at a military medical facility. In his administrative claim, the plaintiff described the fall, but only alleged that he received negligent medical care from the United States.⁹ Before the district court, however, plaintiff filed an amended complaint alleging that the fall itself was the result of the government's negligence. In that case, we rejected the government's contention that plaintiff's administrative claim did not encompass any claim for liability from the fall and held that the administrative claim more broadly put the government on notice for claims arising from injuries

⁸The administrative complaint in *Murrey* included an attachment that stated that Murrey was fearful of surgery and that the doctors "assured him and his family that surgery was the only available therapy, and that it would extend his life by 15 years." *Murrey*, 73 F.3d at 1452.

⁹In *Rooney*, the plaintiff's administrative claim stated: "The claimant . . . sustained injuries as a result of a fall and subsequent medical care . . . The United States of America . . . negligently and carelessly treated, transported and cared for the claimant." 634 F.2d at 1242.

sustained as a result of the fall. *See also Broudy v. United States*, 722 F.2d 566 (9th Cir. 1983) (holding plaintiff's administrative complaint alleging negligent exposure to radiation established subject matter jurisdiction for plaintiff's civil claim alleging failure to warn of radiation exposure).

[5] Taking into account our prior precedent, and considering the precise nature of the notice here given, the government's response to it and the claim later asserted, we are led to conclude that Paul Goodman's informed consent claim was fairly included in his broad but untutored allegation of mistakes at NIH causing his wife's death in his administrative claim. Paul Goodman's administrative claim filed with HHS alleged, *inter alia*, in plain human terms that: "things . . . were overlooked in the procedure and [JoAnn Goodman] should not have died," that his wife died of "mistakes." In federal court, represented by counsel, Paul Goodman alleged with specificity in the second amended complaint that the NIH doctors failed to obtain legally adequate informed consent. Paul Goodman was not required to provide HHS with a preview of the details of his federal complaint, nor required to describe in more than minimal detail the factual predicate for his claim. *See, e.g., Broudy*, 722 F.2d at 568-69; *see also Burchfield v. United States*, 168 F.3d 1252, 1255 (11th Cir. 1999) (stating, "[w]e do not require the claimant to provide the agency with a preview of his or her lawsuit by reciting every possible theory of recovery . . . or every factual detail that might be relevant"). Administrative claims are often filed by lay persons and they are routinely considered by the government in good faith. In this setting, no good purpose would be served by imposing an intricate pleading requirement.

[6] We have strong reason to think the government well understood the general scope of Paul Goodman's claim. To say in plain English that "things . . . were overlooked in the procedure" and that his wife "should not have died," could imply that the claimant's wife agreed to a procedure involving a greater standard of care than what she received. But more

importantly, in responding to and denying Paul Goodman's administrative claims, HHS expressly addressed the issue of informed consent, viewing their own procedure as exculpatory. In its denial, HHS told Paul Goodman that:

Mrs. Goodman was well informed of this risk when she gave her consent to undergo the experimental treatment. Her death was the result of a disclosed complication of the treatment rather than any act or omission of NIH physicians.

From this we conclude that the government was fairly on notice that the informed consent claim was before it. We need not, and explicitly do not, hold that all medical malpractice claims will necessarily include a claim of lack of informed consent. We hold only that the specific language of the administrative claim filed by Paul Goodman reasonably included such an informed consent claim and the government was on fair notice of it, as evidenced by the government's response that the decedent had been well informed of the risks when she consented. Paul Goodman properly exhausted his administrative remedies with respect to his informed consent claim and the district court correctly asserted jurisdiction over it.¹⁰ We conclude there was jurisdiction and the district court properly permitted Paul Goodman's claim to go to trial.

¹⁰The government argues that even if we hold that Paul Goodman exhausted his administrative remedies, under Maryland common law, only the patient herself can bring a claim for lack of informed consent and Paul Goodman, as surviving spouse, could not properly bring a wrongful death claim based on the *decedent's* lack of informed consent. It is well-established under Maryland law that a surviving spouse can bring a wrongful death action based on medical malpractice, but we have not found, nor does any party cite case law regarding, whether a surviving spouse may bring a wrongful death action based on lack of informed consent. *See Slate v. Zitomer*, 341 A.2d 789 (Md. 1975) (holding that a surviving spouse can bring a wrongful death action based on medical malpractice); *see also* Md. Code Ann., Cts. & Jud. Proc. § 3-904(a). However, the district court concluded and we agree that courts have indicated

IV.

Having addressed the threshold jurisdictional issues, we now address the merits of Paul Goodman's claims that the NIH doctors failed to: (1) inform JoAnn Goodman of the foreseeable risks of the ILP surgery, such as VOD; and (2) obtain a supplemental written consent form in light of the fact that earlier ILP patients had suffered complications from the surgery.

A.

We first address Paul Goodman's argument that NIH doctors failed to warn JoAnn Goodman of the foreseeable risks of ILP surgery, including the possibility that she could suffer VOD. This argument is unpersuasive.

Under Maryland's informed consent doctrine, a physician has a duty "to explain the procedure to the patient and to warn him [or her] of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to

that Maryland law permits wrongful death claims by a patient's spouse based on the patient's lack of informed consent. A Maryland appellate court in *Lapelosa, Inc. v. Cruze*, 44 Md. App. 202 (1979), considered a loss of consortium claim by a patient's wife based on medical malpractice arising from the patient's lack of informed consent. The patient died before trial, but the wife was allowed to continue to litigate the action. The Fourth Circuit has also allowed both a patient and her spouse to sue for lack of informed consent under Maryland law. *Lipscomb v. Memorial Hosp.*, 733 F.2d 332 (4th Cir. 1984) (allowing a patient and her husband to bring patient's claim for lack of informed consent, in a case based on Maryland law). We decline to create a Circuit split and accept the Fourth Circuit's and the Maryland appellate court's implicit finding that under Maryland law a plaintiff can bring a claim based on his or her spouse's lack of informed consent. We hold that under Maryland law, Paul Goodman could properly bring the wrongful death claim based on his wife's lack of informed consent.

undergo such treatment.” *Sard v. Hardy*, 379 A.2d 1014, 1020 (Md. 1977). This duty to explain and warn requires the physician to disclose “the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment.” *Id.* (emphasis added).

Here, the NIH doctors adequately informed JoAnn Goodman of the known material risks associated with the surgery. Furthermore, the record supports the conclusion that the NIH doctors were not, and could not reasonably have been, aware that VOD would occur at the dosage level used in JoAnn Goodman’s ILP procedure.¹¹ As the district court explained after hearing examination of many witnesses, including medical experts, “no expert testimony disputed that position and no other patient in an earlier group participating in [the ILP] study had experienced VOD.” It is tragic when death occurs following risky medical procedures based on complications. But in the battle against deadly diseases, progress often will be made only when medical experimentation is permitted. Doctors must give fair warnings of risks that are known or that reasonably should have been known by them. However, here, the NIH doctors were not required to warn JoAnn Goodman, as she embarked bravely on an experimental procedure that might have helped her and others, of an unperceived risk of which they reasonably were not aware.

B.

Next we address Paul Goodman’s contention that further supplementation of the written consent form was required. According to Paul Goodman, the written consent form should have incorporated the complications experienced by the three

¹¹In the Dutch study relied on by Dr. Fraker, Melphalan had been administered in higher doses without causing VOD in any of that study’s patients.

earlier patients at the NIH who underwent the same ILP procedure as JoAnn Goodman. Again, we find this argument unpersuasive. As the district court recognized, “there is no legal requirement that the consent form developed for [the ILP] study must be amended as each group of patients proceeds through the study.” To hold that the signed consent form was inadequate would require the NIH to update its already detailed consent form every time a patient experiences any sort of complication from an experimental procedure. The NIH was not required to update the consent form under these circumstances. The consent form and procedures were medically reasonable and legally adequate.

V.

The district court had jurisdiction to decide Paul Goodman’s claim. The district court held a full and fair trial on the factual and legal issues pertinent to whether JoAnn Goodman was fairly warned of the risks of the experimental ILP procedure that preceded her tragic death. The factual determinations crediting the NIH doctors’ testimony are significant, and such decisions are routinely and properly entrusted to the trier of fact, here the district court, which saw the witnesses who were examined and cross-examined by diligent counsel on both sides. We cannot properly reverse the dispositive factual findings, and we conclude that there was no error in the law applied by the district court. We affirm the decision of the district court denying the claim for lack of informed consent.

AFFIRMED.