

Embryo mix-up debacles: Is there liability?

A discussion of IVF-related injuries and the evolving legal considerations

Joseph S. Sanfilippo, MD, MBA, and Steven R. Smith, MS, JD

IN THIS ARTICLE

Opening case
this page

Legal
considerations
page 40

Future
challenges
page 43

CASE Embryo mix-up with 2 couples

A lawsuit was recently filed in California by a couple after the woman carried and gave birth to “the wrong child.” This was the second full-term pregnancy for the couple. The couple had undergone an unsuccessful in vitro fertilization (IVF) cycle in October 2018. The next IVF cycle in 2019 led to the birth of a daughter on September 24, 2019, who is the subject of this case.¹

At the time of birth, the couple suspected something was wrong because the baby had “jet-black hair and a complexion that was darker” than their complexions. The couple eventually obtained a DNA test, which confirmed in November 2019 that this was not their biological child.¹

A few weeks later, they learned that another woman who went to the same IVF clinic gave birth to a female baby 1 week after their daughter was born. Similarly, that baby did not

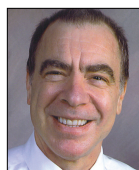
resemble the parents, and DNA testing confirmed the baby belonged to the first couple. The couples ultimately exchanged the babies.¹

The legal claim filed against the IVF center and its owner (an obstetrician) was for breach of contract, medical malpractice, and infliction of emotional distress, including experiencing “disassociation” on the part of the couple(s). Each couple felt they did not get to experience the birth of their biological child, and, of course there was considerable distress in the process of learning that the child was not theirs and exchanging the birth child for the biological child. In addition, the couple who filed the suit had another child (now age 7 years), who begged them to keep the baby to whom they gave birth. The couple also reported experiencing panic attacks as a result of the events.¹

Medical considerations

As of 2018, more than 8 million IVF babies had been born, with the first in 1978 in the United Kingdom.² Advances in science and technology have improved the process. Storage tanks now have alarms and several safeguards to monitor the level of liquid nitrogen and immediately notify key personnel if levels are low (FIGURES 1 and 2). Preimplantation genetic testing is also readily available to assess the embryo prior to transfer into the uterus and identify various genetic problems.

Guidelines for embryo straw labelling are provided by the College of American Pathologists and the Centers for Disease Control and Prevention. The American Society for Reproductive Medicine (ASRM) also provides guidelines. When an error occurs, disclosure



Dr. Sanfilippo is Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh, and Academic Division Director, Reproductive Endocrinology and Infertility, Magee-Womens Hospital, Pittsburgh, Pennsylvania. He also serves on the OBG MANAGEMENT Board of Editors.

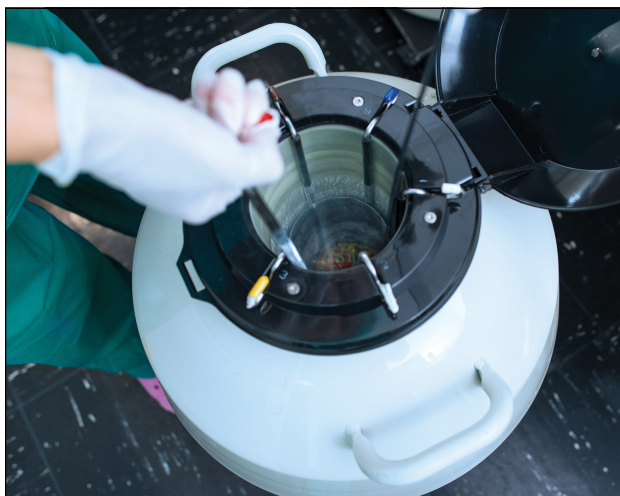


Mr. Smith is Professor Emeritus and Dean Emeritus at California Western School of Law, San Diego, California.

The authors report no financial relationships relevant to this article.

doi: 10.12788/obgm.0170

FIGURE 1 Storage tank for embryos and oocytes



bluecinema/E+/Getty Images Plus

FIGURE 2 Cryo tank with liquid nitrogen, and storage canes



camaralenta/iStock / Getty Images Plus

is recommended and ethical and legal counsel should be involved. Failing to disclose can lead to professional penalties.⁴

Unfortunately, despite these advances and guidelines, embryo mix-ups like the one in the above case do occur and receive public notice (See “Cross country embryo mix-up cases” on page 41).^{5,6} A report from the University of Nevada assessed liability for embryo mix-ups in US fertility practices from 2000 to 2020.⁷ They evaluated 184,015 IVF cycles with 176 claims. Payments were made to plaintiffs in 21 cases, resulting in \$15 million of awarded damages (average award was \$199,188).⁷ The most common problem was in the embryology laboratory with an overall incidence of 0.03% of the total number of IVF cycles.⁷ To avoid damages, the authors emphasized the importance of following labeling guidelines when storing embryos, considering a 2-step read-back method prior to embryo transfer, and offering genetic testing when a discrepancy is noted in the record (TABLE , page 40).⁷

Other medical liability considerations

Embryo mix-ups are not the only source of problems and potential liability in IVF. At the 2021 Association of Sexual and Reproduc-

tive Medicine Annual Meeting, Applebaum et al presented results from a comprehensive review of malpractice litigation involving IVF in the United States.⁸ Using the legal database NEXIS Uni they identified 50 cases between 1986 and 2020 (32% of which were filed in New York state). Common thematic elements among patient allegations were embryology errors (eg, lost or destroyed embryos or incorrect sperm or egg donor), errors in preimplantation genetics, surgical or medical errors/complications, or misdiagnosis (eg, sexually transmitted disease screening or malignancy).⁸ Overall, the most common plaintiff complaint was negligence (26 cases) due to informed consent-related issues (9 cases), wrongful life or birth (9 cases), or negligent or intentional infliction of emotional distress (5 cases).⁸

In 48% of cases, the verdict was in favor of the defendant; it was for the plaintiff in 36% of cases and ongoing proceedings or partial judgement accounted for the remaining cases.⁸ Damages ranged from \$4,171.45 to \$50 million. The authors emphasized specific defense strategies, including the importance of careful labeling and handling of embryos, prompt disclosure when an error does occur, and awareness of the specific state statute(s) of limitations for medical malpractice claims.⁸

CONTINUED ON PAGE 40

TABLE IVF practice suggestions⁶

- Develop and implement standardized labeling policies and strategies
- Foster strong communication between the embryologist and reproductive endocrinologist
- Employ a 2-person verification step or read-back method immediately before embryo transfer
- Disclose information in a timely manner to all patients in cases of embryo mix-up
- Review all patients potentially impacted when a mismatched embryo is identified
- Consider offering genetic testing to all patients with any discrepancy found in their record
- Establish IVF practices as a separate, independent business entity such as a limited liability company or professional limited liability company
- Add embryologists, laboratory directors, and other non-physician staff under a rider to the IVF clinic's or physician's malpractice policy by adding an endorsement to the policy
- Accepting an offer to settle for policy limits helps deter the risk of financial liability if the case goes to trial and the award amount exceeds policy limits

Abbreviation: IVF, in vitro fertilization.

Legal considerations

The case at the beginning of this article is a “mix-up” case, in which an IVF center implanted the wrong embryo, resulting in the birth parents not being the biological parents.¹ As in that case, there may be (but are not always)^{6,9} 2 mix-ups, so that 2 couples have each other's biological children. These cases may go unnoticed by the birth parent if the physical appearance is not unexpected and the parents never do genetic testing, or if the IVF center does not discover the error and inform the parents. Infrequently the cases make the news or the courts.^{10,11}

News accounts are not trials, and we do not suggest that all the facts discussed in news reports on the case described here are complete—or even accurate in the details reported. They are generally 1-sided, so there are other perspectives. To consider the legal issues, however, we will assume *for discussion only* that the facts are as they have been reported in the news coverage—with the understanding that the discovery and trial processes would undoubtedly bring to light many other important facts or corrections.

Negligence

Although there are several potential bases for liability (ie, contract or warranty claims, a form of product liability/defect) in mix-up and other artificial reproductive technology (ART), negligence or malpractice seem most likely.¹² “Negligence” here is intended to be simple negligence but may also include gross negligence or recklessness.

Although the incidence of errors in ART is unknown, there is limited evidence that suggests it is not a rare event. One study suggested >20% of fertility clinics knew of errors in processing or handling donor samples and embryos for implantation.¹³ Another study in the United Kingdom found that 1 in 1,000 IVF embryos were implanted in the wrong woman.¹⁴

Was there negligence? The first question in a malpractice or negligence-type action is, was there a professional relationship between the plaintiff who is claiming harm and the professional or organization defendant? The next question is whether the defendant was reasonably careful given the circumstances—that is, did the physician meet the “standard of care”? This is sometimes described as whether the professional's actions would be acceptable (ie, reasonably prudent within the profession or specialty). If there was negligence, then the next question is, did that negligence *cause* an injury to the plaintiff?¹⁵

Determining the standard of care. The nature of the expected standard of care is dependent, in part, on the potential consequences of an error. For example, the care required when there is a significant risk of death from an error would be considerably more cautious than for an error that might result in small property damage. In this case study, a mix-up error is likely to be less severe than death, but is very substantial in terms of emotional harm and disruption. Thus, considerable care and attention would be expected to avoid these errors. They should be a “never” event. Institutions and physicians should give considerable attention to their processes and procedures to avoid the possibility of a mix-up error.¹⁶

Where did the negligence occur? There is an old tort doctrine “*Res ipsa loquitur*” (RIL) that means, “The thing speaks for itself.”

Although there are several technical rules around the application of RIL as a presumption of negligence, it comes down to the proposition that some injuries do not occur without negligence. A traditional medical example is the sponge left in a patient during surgery—ordinarily that does not happen without some negligence. For RIL to be applied, usually the mechanism by which the injury occurred had to be under the control of the defendant (or the agents of the defendant).

The “mix-up” of embryos is an example of the kind of error that would not likely occur without negligence.¹⁷ But the embryo may not be in the exclusive control of any 1 institution. For example, the mistake could be made by the IVF center (or its employees), a separate facility that has processed or cryogenically stored the genetic materials, and independent physicians (not employees or agents of the center). Therefore, it is necessary to pinpoint where the negligence occurred and who is legally responsible. In some cases, a health care provider must take steps to ensure that its contractors have sufficient safeguards to avoid unnecessary harms. For example, an IVF center that uses an external cryogenic storage facility may have some obligation to know that the genetic material returned to the center is the same material that the center provided the storage facility in the first place and is properly identified.¹⁸

Assessing damages

From the facts as we have them, it appears that there must have been negligence that caused the mix-up of the embryos in the original case. It also appears reasonably clear that the negligence resulted in harm to both sets of parents and their families. This would suggest that the families should recover substantial damages. But that, somewhat surprisingly, may not be the case.¹⁹ Several legal principles may limit the availability or size of damages in mix-up cases. Also, it is worth remembering that there are differences in how states treat the different types of damages in these cases. Although the case was filed in California, we’ll take a more national view of the damages issue.

Cross country embryo mix-up cases

More than 2 couples

In a second case from California, a couples’ son was born to another couple in New York—along with another boy from a third couple. The woman in New York thought she had carried biological twins but genetic testing confirmed the twins were not related to the couple or to each other (the second couple filed a separate medical malpractice and negligence lawsuit in New York). All 3 couples had sought care at the same IVF clinic. The babies were eventually returned to their biological parents.¹

Different races

In a New York case, a Korean couple had twin White boys after consenting to a single embryo transfer. Meanwhile a couple in Los Angeles who went to the same in vitro fertilization clinic gave birth to a child that did not match their appearance. Both couples had undergone embryo transfers on the same day. The court arranged for the Korean couple to surrender their twins to their biological parents when they were 6 months of age in exchange for their biological child.²

References

1. Couple claims clinic implanted their embryo in wrong woman. Associated Press. July 10, 2019. <https://apnews.com/article/de32d537c6e34808b28834c23f00e272>. Accessed January 6, 2022.
2. In the matter of accusation against Steven L. Katz. Case no. 03-20001-122617.OAH no. N2004080093. Sacramento, CA. Medical Board of California Department of Consumer Affairs 2005.

Not all harm is treated as equal. The first problem facing plaintiffs in mix-up cases may be the fact that they have suffered only emotional harm, without any physical injury. Traditionally, the courts have been reluctant to allow recovery in negligence for purely emotional injuries. Also “intentional” infliction of emotional distress does permit financial recovery, but generally “negligent” infliction of emotional harm traditionally has not. In part, this was because of the fear of unwarranted (and difficult-to-assess) claims of emotional harm that are not related to a physical harm. Some states developed a “zone of danger” exception (eg, where someone was almost hit by a car) or allowed some emotional injury recovery if there were “physical manifestations” of the emotional harm. In short, depending on the state’s rules, negligence that causes purely emotional harm may not be compensable.²⁰

CONTINUED ON PAGE 42

FAST TRACK

When assessing damages for embryo “mix-up” cases, emotional and physical injuries as well as institutional negligence is assessed by the court

State-based malpractice “caps.” Another limitation on emotional injuries is the “caps” on malpractice damages enacted by several states (including California, where this mix-up case occurred). Therefore, if a mix-up case is determined to be a malpractice case under state law, emotional suffering damages (which are non-economic damages) may be limited to the cap—\$250,000 in California, for example—even if the state allows damages for emotional injuries without physical injuries.

The rare exception. Very careless labeling or handling of the identity of the embryo could at the extreme be considered gross negligence or recklessness. There are relatively inexpensive and easy procedures that could easily avoid what is likely to be significant harm to families (including emotional upset).²¹ Institutions that callously fail to use those procedures might be seen by some courts as reckless, or in outrageous cases, even intentional. An example would be the University of California Irvine Center for Reproductive Health case, in which physicians intentionally (without consent) used patients’ ova, fertilized them, and then implanted them in other patients, with at least 15 births, many lawsuits, and multimillion dollar settlements.²² In “intentional” cases, limitations on emotional injuries would usually not be major barriers to recovery of damages. However, those are legal stretches, and recovery is the exception rather than the rule.²³

Additional legal concerns with IVF

Reproduction negligence cases include a large range of errors and injuries—not just embryo mix-ups. Courts have struggled with when it is appropriate to allow damages, even when there have been clear injuries. For the most part courts have been reluctant to find liability in many areas of new IVF technology.¹² One problem in determining how to assess damages is determining how incidental benefits should be used to offset some or all of the damages. For example, how should the joy of having a child offset the costs of raising the child?

There are more than a dozen kinds of current and likely future claims arising from

problems with ART. It is tempting to conclude, “Oh, what a tangled legal web we weave when first we practice to artificially conceive.” There are various groupings of such claims, with several examples of cases presented in this article. It is not possible to consider those in detail in this article. As a general proposition, however, “our legal system treats wrongfully disrupted plans concerning reproduction like one of those life adversities that people are expected to abide without remedy.”²⁴

This is not to say, however, that there is no compensation for IVF-related injuries. Applebaum and colleagues found more than 100 cases in the 35 years covered by the study (1984-2020).⁸ However, only 50 of those cases fit the criteria for inclusion in their data. The successful cases for the plaintiffs involved medical or surgical error, while it appeared that various forms of wrongful life or birth were much less successful. It would be a mistake to conclude from these data that there are not, and will not be, meaningful risks of liability in the areas of IVF and ART more generally.

First, claims that fit with existing legal doctrine are producing liability. About half of the claims (25 over the 34 years) examined by Applebaum et al resulted in liability. Admittedly, that number was small because ART use was increasing. Where the claims fit well-recognized legal forms of damages and forms of action (primarily negligence), the liability could be substantial. A remarkable example of this is the case of *Wuth v Lab. Corp* (see “Liability for genetic testing errors”),²⁵ which was the largest verdict (\$50 million) in the Applebaum and colleagues’ study.⁸ The large verdict was due to the failure of the testing company and a medical center to properly perform and assess a genetic test, which resulted in the birth of a child with an unbalanced chromosome translocation.^{8,25} The child’s serious disabilities would require a great deal of expensive care. Although the jury held the testing laboratory and medical center liable, they did not find liability against the physician.²⁵ Ultimately, this case would be considered a failure of genetic testing rather than an IVF case.

Future challenges

The future is likely to bring substantially expanded IVF/ART liability for several reasons. ART is becoming more common. Although courts have struggled with how to apply existing liability rules to the new technologies and related novel legal claims, the absence of established legal principles into which IVF injuries fit will not last forever. The legal system eventually finds ways of adjusting old rules or adopting new ones to cover injuries from new technology.

Although IVF injuries that most people feel deserve compensation currently are not cognizable in law, that will undoubtedly change. Either the courts will find new ways of assessing ART claims, or state legislatures and Congress will step in with legislation. To date, Congress has been relatively “hands off” on the ART processes, with the Fertility Clinic Success Rate and Certification Act of 1992 being a notable exception.²⁴ This law requires ART programs to report success rates and directs the Centers for Disease Control and Prevention (CDC) to publish reported success rates and laboratory incidents. It also establishes a model state laboratory certification program.²⁴ The CDC has an outline of the work under the statute,²⁶ as well as state-specific data regarding ART²⁷ and lists of publications in key areas.²⁸ In addition there are various state laws related to record-keeping, donor qualifications, licensing, and family law issues.²⁹ Ultimately, physicians,

Liability for genetic testing errors

Although not technically an in vitro fertilization (IVF) case, *Wuth v Lab. Corp.* involved an infant born through IVF with a translocation defect chromosome 2 (ie, deleted material) and extra chromatin on 9. The father's family history included birth defects, including a female cousin with profound developmental disabilities, seizures, and antisocial behavior. He had undergone genetic testing that revealed an asymptomatic balanced, 2;9 translocation. As part of the IVF process, the couple had a genetic consultation and were told there was a 50% chance that the fetus would have an unbalanced 2;9 translocation given the father's family history and that chorionic villus sampling or amniocentesis could detect this in the fetus.¹

Amniocentesis had been performed, with the specimen sent to Lab. Corp. The result was “normal male karyotype.” However, when the baby was born, it was immediately apparent that he had severe physical defects and subsequently cognitive defects. Genetic testing of the child revealed an unbalanced 2;9 translocation. The couple filed a suit for wrongful birth and wrongful life, which went to a jury. The child was awarded \$25 million and the parents/family were awarded another \$25 million in general damages. The verdict reflected errors in genetic (laboratory) testing.

Reference

1. *Wuth v Lab. Corp. of Am.*, 189 Wash. App. 660, 359 P.3d 841 (2015).

scientists, and legal professionals can perform a valuable role in helping to fashion IVF liability principles that are workable and reasonable, that will not interfere with the progress of medicine, and that will ensure that those injured through carelessness or bad medicine receive compensation. ●

References

1. Mark J. California couple sues fertility clinic following IVF embryo mix-up. *Washington Post*. November 9, 2021. <https://www.washingtonpost.com/nation/2021/11/09/in-vitro-fertilization-ivf-mix-up-daphna-cardinale>. Accessed January 5, 2022.
2. More than 8 million babies born from IVF since the world's first in 1978. *Science Daily*. July 3, 2018. <https://www.sciencedaily.com/releases/2018/07/180703084127.htm>. Accessed January 11, 2022.
3. ESCO Medical. In vitro fertilization (IVF) as fertility treatment. <https://www.esco-medical.com/resource/in-vitro-fertilization-ivf-as-fertility-treatment>.
4. Vigdor N. “We had their baby, and they had our baby”: couple sues over embryo “mix-up.” *NY Times*. November 9, 2021. <https://www.nytimes.com/2021/11/09/us/fertility-clinic-embryo-mixup.html>. Accessed January 11, 2022.
5. Couple claims clinic implanted their embryo in wrong woman. *Associated Press*. July 10, 2019. <https://apnews.com/article/de32d537c6e34808b28834c23f00e272>. Accessed January 6, 2022.
6. In the matter of accusation against Steven L. Katz. Case no. 03-20001-122617.OAH no. N2004080093. Sacramento, CA. Medical Board of California Department of Consumer Affairs 2005
7. Rasouli MA, Moutos CP, Phelps JY. Liability for embryo mix-ups in fertility practices in the USA. *J Assist Reprod Genet*. 2021;38:1101-1107. doi:10.1007/s10815-021-02108-1
8. Applebaum J, Berger D, O'Neill K. Can a reproductive endocrinologist be sued for 50 million dollars? A comprehensive review of malpractice litigation involving in vitro fertilization in the U.S. *Fertil Steril*. 2021;116(3s):e19. doi:10.1016/j.fertnstert.2021.07.059
9. *Andrews v Keltz*, 838 N.Y.S.2d 363, 365 (Sup. Ct. 2007).
10. Chichi DV. In vitro fertilization, fertility frustrations, and the lack of regulation. *Hofstra L Rev*. 2021;49:535-568. <https://www.hofstralawreview.org/wp-content/uploads/2021/04/bb.2.chichi.pdf>. Accessed January 11, 2022.
11. Lewin T. Sperm banks accused of losing samples and lying about donors. *NY Times*. July 21, 2016. <https://www.nytimes.com/2016/07/22/us/sperm-banks-accused-of-losing-samples-and-lying-about-donors.html>. Accessed January 11, 2022.

CONTINUED ON PAGE 44

12. Bender L. To err is human ART mix-ups: labor-based, relational proposal. *J Gender Race Justice*. 2006;9:443-508. <https://surface.syr.edu/cgi/viewcontent.cgi?article=1050&context=lawpub>. Accessed January 11, 2022.
13. Baruch S, Kaufman D, Hudson KL. Genetic testing of embryos: practices and perspectives of U.S. in vitro fertilization clinics. *Fertil Steril*. 2007;89:1053-1058. doi:10.1016/j.fertnstert.2007.05.048
14. Liebler R. Are you my parent? Are you my child? The role of genetics and race in defining relationships after reproductive technological mistakes. *DePaul J Health Care Law*. 2002; 5:15-56. <https://via.library.depaul.edu/cgi/viewcontent.cgi?article=1202&context=jhcl>. Accessed January 11, 2022.
15. Crockin SL, Altman AB, Edmonds MA. The history and future trends of art medicine and law. *Fam Court Rev*. 2021;59:22-45. doi:10.1111/fcre.12550
16. Fernandes JS. Perfecting pregnancy via preimplantation genetic screening: the quest for an elusive standard of care. *UC Irvine L Rev*. 2014;4:1295-1326. <https://www.law.uci.edu/lawreview/vol4/no4/Fernandes.pdf>. Accessed January 11, 2022.
17. VanGessel MM. Wrongful surrogacy: the need for right of action in cases of clear negligence. *U Toledo L Rev*. 2015;46:681-706.
18. Reich J, Swink D. Outsourcing human reproduction: embryos and surrogacy services in the cyberprocreation era. *J Health Care L Policy*. 2011;14:241-298. <https://core.ac.uk/download/pdf/217156567.pdf>. Accessed January 11, 2022.
19. Strasser M. Prenatal tort slippage. *Health Matrix*. 2021;31:221-262. <https://scholarlycommons.law.case.edu/healthmatrix/vol31/iss1/9>. Accessed January 11, 2022.
20. Heide IH. Negligence in the creation of healthy babies: negligent infliction of emotional distress in cases of alternative reproductive technology malpractice without physical injury. *J Med L*. 2005;9:55-94.
21. Novo S, Nogués C, Penon O, et al. Barcode tagging of human oocytes and embryos to prevent mix-ups in assisted reproduction technologies. *Hum Reprod*. 2014;29:18-28. doi: 10.1093/humrep/det409
22. Yoshino K. UCI Settles Dozens of Fertility Suits. *LA Times*. September 11, 2009. <https://www.latimes.com/archives/la-xpm-2009-sep-11-me-uci-fertility11-story.html>. Accessed January 11, 2022.
23. Fox D. Reproductive negligence. *Columbia L Rev*. 2017;117:149-242. <https://columbialawreview.org/wp-content/uploads/2017/01/149.pdf>. Accessed January 11, 2022.
24. 42 U.S.C.S. §263a-1-263a-7; Public Law 102-493. <https://www.govinfo.gov/content/pkg/STATUTE-106/pdf/STATUTE-106-Pg3146.pdf>. Accessed January 11, 2022.
25. *Wuth v Lab. Corp. of Am.*, 189 Wash. App. 660, 359 P.3d 841 (2015).
26. Centers for Disease Control and Prevention. The Fertility Clinic Success Rate and Certification Act. December 14, 2020. <https://www.cdc.gov/art/nass/policy.html#act>. Accessed January 11, 2022.
27. Centers for Disease Control and Prevention. State-specific assisted reproductive technology surveillance. December 17, 2020. <https://www.cdc.gov/art/state-specific-surveillance/index.html>. Accessed January 11, 2022.
28. Centers for Disease Control and Prevention. Key findings. March 12, 2021. <https://www.cdc.gov/art/key-findings/index.html>. Accessed January 11, 2022.
29. Cohen EN. 5 Treatise on Health Care Law §22.04, (ed. Hooper, Lundy & Bookman, & Robert W. Lundy, Jr. RW.) (Matthew Bender-LexisNexis)