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Experimental and Investigational Treatments and Procedures under ERISA Group Health Plans

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While most group health plans contain an exclusion for medical and investigational procedures, the scope and the pace at which medical procedures and treatments are tested in the 21st century makes this an extremely difficult standard to apply. There is no bright-line test, experts frequently disagree as to when the line has been crossed, and in some instances the stakes are literally life and death. This article discusses some potential pitfalls for plan administrators and offers suggestions on how to address this difficult aspect of group health care administration.

An exclusionary clause[1] frequently found[2] in a group health plan under ERISA is one for experimental and investigational[3] treatments and procedures.[4] The permissibility of such clauses is recognized under US Department of the Treasury[5] and Department of Labor[6] regulations, as well as the particular procedural rules for appealing adverse benefit determinations based upon the experimental or investigational nature of the treatment.[7] There can be no dispute

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that experimentation in medicine is necessary: "if physicians are limited strictly to previously established procedures, all innovation and progress in the field of medicine would cease."[8] Courts have stated that "it is a recognized fact that, if the general practice of medicine is to progress, a certain amount of experimentation must be carried on."[9] Nonetheless, courts have no quarrel with the rationale for such exclusions[10] but have difficulty in defining and applying these terms.[11]

While it is hornbook law that the lack of definition of contract terms does not require a finding of ambiguity,[12] "in the context of a major medical insurance policy," the term "experimental" and, in this case, the phrase "considered experimental" is ambiguous when it is undefined.[13] In 1988, the US Court of Appeals for the Ninth Circuit commented that "Given the plethora of surgical procedures, the broad term experimental could include many areas. In the context of modern medicine, the term experimental seems clearly ambiguous."[14] The quickening pace of medical developments since 1988 has done nothing to reduce the ambiguity, and at least one court is of the view that cases interpreting the terms experimental, investigational, and educational "provide no meaningful definitions."[15] As a Michigan court explained in *Taylor v. Blue Cross/Blue Shield*:[16]

> A reasonable person could interpret "experimental" to mean a medical procedure which is designed solely for testing a hypothesis without contemplation that any benefit whatsoever would be gained by the patient or could mean a medical procedure which is designed primarily for providing a benefit to their patient but which would have the side effect of testing a hypothesis.[17]

In the absence of a plan definition, a court may apply the plain meaning of experimental[18] or investigational.[19] It is clearly a best practice to define these terms, but plan sponsors should be aware that "the concept can be captured by a verbal formula, but only at a high level of generality.... These definitions, although easy to state, are hard to apply."[20]

One of the reasons that the definitions are difficult to apply "is the nature of medical research," under which "that which one day may be experimental may the next day be the state of the art treatment."[21] As the US Court of Appeals for the Seventh Circuit explained in *Smith v. CHAMPUS*:[22]

> [A]t issue here is the point where a treatment that has been experimental in the past crosses the line into general acceptance—the point at which the medical value of a treatment is no longer generally disputed. Perhaps no such line exists. We are probably dealing more with a zone of perceived effectiveness rather than a precise dividing line.[23]

As one commentator has observed: "Of course, whether or not a treatment is still experimental is often hotly debated. Every procedure needs to begin somewhere. The point at which it shifts from being new and experimental to usual and customary is unclear. Thus, distinguishing between experimental and nonexperimental treatments is not a matter of black and white but often involves varying shades of grey."[24] While line-drawing is inherently a difficult process, plans need to be cognizant of the litigation risk. As one court observed " medical research progresses so rapidly, however, that an experimental procedure may quickly become recognized: an insurance provider who does not look beyond the label 'experimental' may be liable for failure to adequately address a treatment."[25]

Because of the difficulty of this line-drawing exercise, precedents in this area are of limited value,[26] at least to attorneys,[27] and courts are uncomfortable in addressing the issue, exacerbated by the life or death nature of the resolution of these cases.[28] US District Court Judge Daniel Tinder summarized the problems facing courts in these difficult situations:

> Plaintiff Judy Harris well deserves, and in a perfect world would be entitled to, all known medical treatments to control the disease from which she suffers. In ruling as this court must, no personal satisfaction is taken, but that the law was followed. The court will have to live with the haunting thought that Ms. Harris, and perhaps others insured by the Mutual of Omaha Companies under similar plans, may not ultimately receive the treatment that they need and deserve. Perhaps the question most importantly raised about this case and similar cases is who should pay for the hopeful treatments that are being designed in this rapidly developing area of medical science.[29]

In a similar vein, a number of courts have expressed the view[30] shared by commentators[31] that courts are not the proper forum for addressing these issues. As the Seventh Circuit states in *Fuja v. Benefit Trust Life Ins. Co.,* "Cases of this nature pose most difficult policy questions of who should bear the burden of paying for expensive medical treatments that are, as of the time of treatment, of unknown efficacy .... Cases of this nature pose troubling social as well as ethical issues that go well beyond the legal issues."[32]

APPROACHES TO ADDRESS AMBIGUITY

Issuers and plan administrators have adopted several approaches to cure the inherent ambiguity of the term experimental. One approach is to enumerate particular conditions for which a given procedure is experimental[33] or write into the plan specific exclusions for these conditions

without reference to their experimental nature.[34] A second approach is to specify who will decide the meaning of the term "experimental."[35]

The US Court of Appeals for the Third Circuit expressed its belief that "the term experimental basically hinges on the safety and effectiveness of the procedure in question, as demonstrated by its use on an applicable number of patients."[36] It set forth a nonexclusive list of factors for determining whether a procedure is experimental:

(1) Judgment of other insurers and medical bodies;

(2) Experience with the procedure (while this is often measured by numbers, it can be more complex); and

(3) The demonstrated effectiveness of the procedure,[37] taking into account the long-term survival rate associated with the procedure, the likelihood of recurrence of the disease, and the post-operative mortality rate, with effectiveness determined taking into account the rates with no treatment or an alternative treatment,"[38] while recognizing, consistent with the fact sensitive nature of this inquiry[39] that "there will always be particular factors in the case that may affect application of the factors we have outlined."[40]

In *Martin v. Blue Cross and Blue Shield of Virginia,* the US Court of Appeals for the Fourth Circuit stated that the appropriate inquiry in determining whether a procedure is experimental or investigational includes:

(1) A review of the plan language,

(2) The consent form,

(3) The protocol,

(4) The available medical literature, and

(5) The number of prior patients subject to the treatment.[41]

With respect to plan language, and consistent with the doctrine of reasonable expectations,[42] the draftsperson of exclusionary clauses must make them conspicuous, plain, and clear, "placing them in such a fashion as to make obvious their relationship to other policy terms."[43] As another court expressed this point, "the definition of experimental or investigational should be sufficiently concrete to … permit insureds to predict with certainty."[44]

There is a wide variation in plans and policies as to the manner of defining experimental or investigational, and there is no consensus definition of experimental treatment,[45] although common features of an "experimental or investigational" definition will include lack of US Food and Drug Administration approval,[46] no proven benefit to the particular diagnosis or treatment of the participant's particular condition[47] or without contemplation of any benefit;[48] not in accordance with generally accepted standards of medical practice;[49] or provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.[50]

As in other matters involving contract interpretation, participants may benefit from imprecise drafting that did not reflect the intent of the plan sponsor.[51] In other instances, because "an insurer who denies benefits under a plan governed by ERISA must rely on the express language of the plan itself,"[52] plans act arbitrarily in treating an exclusion as experimental based on criteria not set forth in the plan,[53] even if the definition is one an insurer uses in other medical plans that it administers.[54] For example, in *McHenry v. Pacific Source Health Plan,* the district court stated "That a given mental disorder has no absolute cure is not a basis for rejecting treatments which purport to alleviate or ameliorate its symptoms … the fact that applied behavior analysis (ABA) therapy is not effective for every autistic child is not a reasonable basis for concluding that it is experimental or investigational. It is possible for a treatment to be both well-established and of limited efficacy in treating a neurological disorder."[55]

Also, without regard to the standard of review, plan language must be given a reasonable interpretation. Thus, the phrase "widely used" can only mean widely used among the population of patients who suffer from the disorder for which the treatment is designed, and not the population at large.[56] Additionally, the plan language must provide the opportunity for meaningful review. Thus, in *Bucci v. Blue Cross and Blue Shield of Connecticut*[57] the district court rejected defendant's argument that the experience with the proposed regimen was too limited and it had been used in too few cases to permit a meaningful assessment of its efficacy. It explained that "under defendant's theory, whatever number its experts selected, without any obligation to justify the minimum number required, it could deny benefits with impunity. Such an imprecise standard would permit no meaningful review, even under the deferential standard. Denial by application of such a standard cannot be other than arbitrary and capricious and cannot stand."

With respect to the number of procedures performed, while it bears on the question of whether a procedure is experimental,[58] the number of treatments or procedures performed may not always indicate that a procedure is experimental,[59] particularly when the disease is rare. For example, in *Lafferty v. Provident Health Plans,* Provident argued that

the proposed treatment for primary central nervous system lymphoma (PCNSL) was experimental because it was under continued scientific testing and research. The district court acknowledged the accuracy of the factual statement. However, "all treatments for PCNSL are under continued research and treatment because the disease is so rare there have been no Phase III trials for its treatment. In short, there is no gold standard of treatment for PCNSL. Given that there are no Phase III trials for any treatment for this type of cancer, I cannot find that Provident has established that BBBD [blood-brain barrier disruption] enhanced treatment is experimental simply because it is under continued testing and research."[60]

In *Pirozzi v. Blue Cross Blue Shield of Virginia*[61] in concluding that HDCT-ABMT [high dose cytoxan, cisplatin, carmustine with autologous bone marrow transplant] was experimental, Blue Cross Blue Shield relied heavily upon the fact that treatment was not provided in a Phase III clinical trial. The district court disagreed with this analysis, explaining that "the absence of extensive data comparing HDCT-ABMT is relevant, but neither determinative nor ultimately persuasive of the treatment's status as an experimental medical practice."[62]

With respect to consent forms, while language in a consent form may support a finding that a procedure is experimental,[63] reference to a plaintiff's treatment as being part of a study does not necessarily mean that it was experimental or investigational.[64] In a similar vein, participation in a clinical trial does not necessarily indicate that a procedure is experimental or investigational,[65] nor does use of a protocol by itself indicate that a procedure is experimental or investigational.[66] Thus, in *Adams v. Blue Cross and Blue Shield of Maryland,*[67] the district court, in rejecting an insurer's reliance upon the existence of a protocol to support its conclusion that HDCT-ABMT is experimental, explained that many of today's accepted medical treatments are offered under a research protocol. "Given the definition of experimental under the plan, the fact that a treatment is offered as part of an experimental protocol designed to facilitate the collection of data does not necessarily mean that the treatment is by definition experimental."[68] As the Seventh Circuit observed, if use of a protocol made a procedure experimental, "much of medicine might be swept within the ambit of the experimental exclusion provision as there is ongoing investigation across the whole range of medicine including many well-established treatments."[69]

With respect to peer-reviewed medical literature and acceptance by governmental agencies,[70] there is no dispute as to the relevancy of these materials, but, as noted previously, the pace of modern medical research generally eclipses peer-reviewed medical literature, and as is true of the other relevant factors, it is not a *per se* requirement.[71]

As is the case with other issues that are dependent upon plan interpretation, the standard of review is critical.[72] As a technical matter, upon review, "the proper inquiry is not the reasonableness of the

treatment itself, but the reasonableness of defendant's interpretation that it was not covered by the plan."[73] The standard of review of an appellate court depends upon the issue presented. If resolution of an issue depends upon language in the plan document, the review by the court of appeals is *de novo*.[74] However, when a ruling depends upon the evaluation of issues extrinsic to the document, the standard upon review is clear error.[75]

CONCLUSION

Some issues of plan administration are by their nature inherently difficult; determining whether a procedure is experimental or investigational is one of those areas. The inherent difficulty of the determination is often exacerbated by the seriousness of the illness for which treatment is being sought. The plan should, however, at a minimum, seek to set forth in as clear terms as possible those treatments that will be treated as experimental, and confirm that the experts who are making the determination are following the standards that are set forth in the plan.

NOTES

1. Although the types of medical procedures or drugs considered experimental or investigational are boundless, the most commonly litigated issues have involved high dose chemotherapy with peripheral stem cell rescue (HDC/PSCR) treatment for breast, ovarian, and brain care patients. *See* Edward C. Connette, "Challenging Long Term Disability and Health Benefit Denials under ERISA," reported in July 27, 2000, Benefits Link *Health and Welfare Plans Newsletter*. Because experimental and investigatory treatments are an exclusion from coverage, if a participant satisfies the burden of proof that a procedure or treatment is covered under a group health plan, the issuer would have the burden of showing that an exclusion applies. *See, for example, Intel. Corp v. Hartford Accident & Indemnity Co.,* 962 F. 2d. 1551, 1557 (9th Cir. 1991); *Dubaich v. Connecticut General Life Assurance Company,* 2013 WL 3946108 (C.D. Cal. 2013); *Kekis v. Blue Cross and Blue Shield of Watertown, Inc.,* 815 F. Supp. 571,578 (N.D.N.Y. 1995); *Velez v. Prudential Health Care of New York, Inc.,* 943 F. Supp. 332 (S.D.N.Y. 1996); *Bolden v. Humana Ins. Co.,* 46 F. Supp. 2d 1199 (D. Ariz. 2006); *Leonhardt v. Holden Business Forms Co.,* 828 F. Supp. 657 (D. Minn. 1993); *Elsworth v. Consolidated Edison of New York, Inc.,* 10 F. Supp. 2d 427 (S.D.N.Y. 1998); *Lafferty v. Provident Health Plans,* 706 F. Supp. 2d 1104 (D.Ore. 2010). An initial certification of a procedure does not mean that it may not be later denied as experimental. *Miami Children's Hospital v. Century Medical Health Plan, Inc.,* 57 F. 3d 1040 (11th Cir. 1995).

2. Julia Field Costich, "Denial of Coverage for Experimental Medical Procedures: The Problem of De Novo Review under ERISA," 79 *Kentucky L.J.* 801, 807 (1991) (stating that health insurance policies commonly exclude benefits for medical procedures found to be '"experimental" or "investigational" in nature), cited in Judith C. Broston, "The Conflict of Interest Standard in ERISA Cases: Can It Be Avoided in the Denial of High Dose Chemotherapy Treatment for Breast Cancer," 3 *DePaul Journal of*

Health Care Law, (Fall 1999), fn.21; Michael J. Brandt, "The Paradox of Technological Progress in Health Insurance Contracts: Experimental Treatment Clause and Breast Cancer," 2 *Conn. Ins. Law Journal* 243, 247 (1996) (majority of insurance policies contain some form of coverage limitation for treatments not considered standard or commonly used by practitioners); Barbara L. Atwell, "Mainstreaming Complementary and Alternative Medicine in the Face of Uncertainty," 72 *UMKC Law Rev.* 593 (2004) ("experimental treatments are expressly excluded in the typical health insurance contract,"); Jennifer Belk, "Comment: Undefined Experimental Treatment Exclusions in Health Insurance Contracts: A Proposal for Judicial Response, 66 *Wash. Law. Rev.* 809, 812 (1991) (explaining that experimental therapies are excluded in most health insurance policies); Joseph B. Clamon, "Does My Health Insurance Cover It: Using Evidence-Based Medicine and Binding Arbitration to Determine What Therapies Fall Under Experimental Exclusions in Health Insurance Contracts," 54 *Drake Law Rev.* 473, 475 (2006); *Cf.* In a 2004 article in the *Journal of Legal Medicine,* James R. Hubler and Jay Weaver, " Health Insurance and Professional Liability Insurance," pp.179, 181 commented that "in recent years, insurers have begun to include in their policies blanket exclusions for 'experimental' or 'medically unnecessary' services."

3. Experimental and investigational procedures may be a subset of "medically necessary" procedures. *Reimann v. Anthem Ins. Co.,* 2008 US Dist LEXIS 88562 (S.D. Ind. 2008) discussed in Roy Harmon III, "Proposed Cancer Treatment Deemed Experimental," *Health Plan Law,* Nov. 5, 2008. It makes a difference whether the definition under the plan is experimental *and* investigational, or experimental *or* investigational. While the two terms may be related—and this is solely a plan design issue—plans generally provide the exclusion for experimental or investigational and, in some instances, educational. *See Steil v. Humana Kansas City, Inc.,* 124 F. Supp. 2d 660 (D. Kan. 2000) (denial of coverage reversed, because even if the procedure was investigational, it was not experimental) and *Kulakowski v, Rochester Hospital Service Corporation,* 779 F. Supp. 710 (W.D.N.Y. 1991) (the policy provided an exclusion for experimental and investigational treatments and procedures but the defendants' own expert testified that the procedure was not experimental but investigational). *See also Lafferty v. Provident Health Plan, supra* n.1 ("Given the use of the word 'and' in the Policy's definition of experimental and investigational, the court cannot conclude that establishing one of 5 criteria made the procedure experimental/investigational.").

4. For certain nongrandfathered health plans, the scope of procedures that might be excluded as experimental or investigational has been reduced by the Affordable Care Act (ACA). Section 300gg–8 of the ACA provides that if a group health plan provides coverage to a qualified individual, then the plan may not deny the qualified individual participation in an approved clinical trial for treatment of cancer or other life-threatening disease. An approved clinical trial means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is (1) federally funded or (2) conducted under an investigational new drug application reviewed by the US Food and Drug Administration (FDA) or a drug trial that is exempt from having an investigational new drug application. Phase I, Phase II, Phase III, and Phase IV refer to a progression of standardized experiment formats employed by the FDA for the purpose of testing drugs on human patients. Phase I studies are geared toward determining a treatment's dose-limiting toxicities, and usually involve a spectrum of diseases and dose levels. Phase II studies are designed to test efficacy and usually involve a scheduled dose given to patients with a defined disease and clinical status. Phase III studies are designed to compare the efficacy of a treatment to that of standardized treatment by "randomizing" patients with a defined clinical status into one treatment or the other. Phase IV "post-marketing studies" are designed to collect additional information about a treatment. *See Whitney v. Empire*

Blue Cross-Blue Shield, 920 F. Supp. 477 (S.D.N.Y. 1996), *fn.*3. For examples of the types of definitions that will be affected by this ACA provision, *see Wolf v. Prudential Insurance Co. of America*, 50 F.3d. 793 (10th Cir. 1995) (experimental or investigational includes all phases of clinical trials); *Santucci v. Hyatt Corp.,* 955 F. Supp. 927 (N.D. Ill. 1997) (Experimental or investigational includes any service under study or in a clinical trial to evaluate its toxicity, safety, or efficacy for a particular diagnosis or set of indicators. Clinical trials include but are not limited to phase I, II, and III clinical trials) and *Harris v. Mutual of Omaha Co.,* 992 F.2d. 706 (7th Cir. 1993) (experimental or investigational means, *inter alia,* any treatment that is the "subject of ongoing phase I, II, or III clinical trials."); *Nationwide Children's Hospital v. D.W. Dickey & Son, Inc.,* 48 EBC 2024, 2010 WL 419931 (S.D. Ohio 2010) (experimental or investigational includes the subject of an ongoing phase I or phase II clinical trial).

5. Treas. Reg. § 54.9802-1(b)(2)(i)(B).

6. Labor Reg. § 2590.702(b)(2)(i)(B).

7. Labor Reg. § 2560.503-1(h)(3)(iii) provides that in deciding an appeal of an adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug, or other item is experimental, investigational, or not medically necessary or appropriate, the appropriate named fiduciary shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment. Similarly, the minimum standards for state external review process include procedures for adverse benefit determinations involving experimental or investigational treatment substantially similar to what is provided under Section 10 of the NAIC Uniform Model Act. Labor Reg. § 2590.715-2719(c)(2); Treas. Reg. § 54. 9815-2719(c)(2).

8. Cyril H. Wecht, "Research and Experimentation," *Legal Medicine* (6th Ed. 2004), 237, 251.

9. *Id.*

10. The primary reasons that insurers use exclusion provisions are to limit their financial liability, keep the cost of insurance down, and encourage the rendering of safe and effective medical treatments and the elimination of worthless procedures. *See* Melody J. Harness, "What Is Experimental Medical Treatment: A Legislative Definition is Needed," 44 *Cleveland State Law Review* 67, 75 (1996). *See also* James R. Hubler and Jay Weaver, "Health Insurance and Professional Liability Insurance," *Legal Medicine* (6th Ed. 2004) 179, 181, (experimental exclusions are meant to limit liability for expensive and, at times unproven, services); *Tilley v. Hoffman Enclosures, Inc.,* 280 F.3d. 1192 (8th Cir. 2002) ("The plan in an effort to maximize benefits to all covered persons limits or excludes payments for experimental procedures. Exclusion of payments for experimental procedures has the advantage of providing better coverage for more people."); *Reimann v. Anthem Insurance Co., supra* n.3, (denying coverage for experimental/investigational procedures is an "established mechanism for keeping medical costs under at least minimal control for all those who pay for health insurance"). *Cf. Schnitler v. Blue Cross Blue Shield of Nebraska,* 787 F. Supp. 903 (D. Nebr. 1991) ("an application for benefits implicates the rights of other members of the plan."). Of course, when a state law mandates that coverage be provided, a contradictory exclusionary provision would be invalid. *Sluter v. Blue Shield of Michigan,* 979 F. Supp. 1131 (E.D. Mich. 1997). *See also Johnson v. District 2 Marine Engineers Beneficial Association,* 857 F. 2d 514 (9th Cir. 1988) ("not unusual for the cost of experimental procedures to be extremely high. Exorbitant cost may be some indication of the experimental nature of a uniquely expensive procedure.").

11. Part of the definitional problem may stem from the fact that, as one expert witness observed, "medicine is always investigational and experimental in the sense that we have a potential for doing better and should investigate the potential." *Reilly v. Blue Cross and Blue Shield of Wisconsin,* 846 F.2d. 416 (7th Cir. 1988) *cert. den.* 486 US 856 (1988). *See also Estate of Goldstein v. Fortis Benefits Company,* 1996 WL 18977 (N.D. Ill. 1996) ("Clinical research is ongoing and even the most tried and true procedures are constantly being reevaluated"); Lars Noah, "Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy," 28 *American Journal of Law and Medicine* 361, 362 (2002) ("To a greater or lesser extent, all medical interventions have an experimental quality to them."); Barbara L. Atwell, "Mainstreaming Contemporary and Alternative Medicine in the Face of Uncertainty," *supra* n.2 at 593, 605 ("one could argue that medicine is, in many respects, one enormous ongoing experiment").

12. *Bossemeyer v. Healthcare America Plans, Inc.,* 953 F. Supp. 1176 (D. Kan. 1991).

13. *Dahl-Emmers v. Mutual of Omaha Like Ins. Co.,* 986 F.2d. 1379, 1382–1383 (11th Cir. 1993), *cert. den.* 114 S. Ct. 440 (1993). *See also Johnson v. District 2 Marine Eng. Benef. Association, supra* n.10; *Pirozzi v. Blue Cross and Blue Shield of Virginia,* 741 F. Supp. 586, 589 (E.D. Va. 1990); *Wolf v. Prudential Ins. Co., supra* n.4 (in *dicta*, stating it is inclined to agree that "experimental" is ambiguous"), cited in *Steil v. Humana Kansas City, Inc., supra* n.4; *Heasley v. Belden and Blake Corporation,* 2 F.3d. 1249 (3rd Cir. 1993) (courts interpreting the word "experimental" in similar health plans "have found it resistant to precise definition"); *Reed v. Walmart Stores,* 197 F. Supp. 2d 883 (E.D. Mich. 2000). *See also* Jennifer Ruderick Ecklund and Andrew Cookingham, "Strategies for Responding Effectively to a Denial of Treatment as Experimental or Investigational" 8 *Journal of Health and Life Sciences Law* 8, 21, *fn.*45 (June 2015); *Cf.* Wecht, "Research and Experimentation," *supra* n.8 (one of the difficulties in balancing the interest of a patient to be free from abuse and the societal interest in the advancement of medicine is the difficulty of defining experimentation).

14. *Johnson, supra* n.10.

15. *Farley v. Benefit Trust Life Ins. Co.,* 1991 WL 631009 (E.D. Mo. 1991).

16. *Taylor v. Blue Cross/Blue Shield*, 205 Mich. App. 664, 517 N.W. 2d 864 (1994).

17. *Id.* at 568, quoted in *Steil, supra* n.4.

18. *See Steil, supra* n.4 ("experimental ordinarily is defined as relating to a test performed to demonstrate a known truth, examine the validity of a hypothesis, or ascertain the efficacy of something completely untried."); *Pirozzi, supra* n.13 (defining experimental as "relating to an experiment" and defining experiment as "a test performed to test the efficacy of something previously untried"). *Cf. Farley, supra* n.15 (the ordinary meaning of experimental, investigational, or educational is "if the procedures and/or its effects are unknown or indefinite and if the physician administers that treatment in an effort to learn more about that procedure and its effects").

19. *See Schnitker v. Blue Cross Blue Shield of Nebraska,* 787 F. Supp. 903 (D. Nebr. 1991) (treatment is considered investigative when the service, procedure, drug, or treatment has progressed to a limited known application, but has not received recognition as being proven and effective in clinical medicine); *Clark v. K-Mart,* 1992 WL 106935 (3rd Cir. 1992) (investigational means that "the available evidence does not permit conclusions about the effectiveness of the treatment compared with its alternative."); *Escalante v. California Physicians Service dba Blue Shield of California* (C.D. Cal. 2015) ("investigational" means "any treatment, therapy, procedure, drug or drug usage, facility or facility usage, equipment or equipment usage, device or device

usage, or supplies which are not recognized in accordance with generally accepted professional medical standards as being safe and effective for use in the treatment of the illness, injury, or condition, at issue.").

20. *Heasley, supra* n.13.

21. *Holden v. Prudential Ins. Co.,* 951 F.2d. 89 (5th Cir. 1993). *See also Gripkey v. Mail Holders and CHAMPUS,* 1994 WL 276265 (D.S.C. 1994); *Smith v. CHAMPUS,* 97 F.3d 950 at 956–957 (7th Cir. 1996) ("the pace of medical science is ever quickening; yesterday's exotic experiment is today's miracle cure"); *Jenkins v. Blue Cross Blue Shield of Michigan,* 1994 WL 901184 (N.D. Ohio 1994) ("medical science moves at a rapid pace, and what was experimental or investigational five years ago may be considered accepted practice today"); *Estate of Goldstein, supra* n.11 ("Medical research proceeds so rapidly … that an experimental procedure may quickly become recognized"); *McElroy v. Blue Cross-Blue Shield of Oregon,* 825 F. Supp. 1064, 1071 (N.D. Ga. 1993); *Cf. Sluter, supra* n.10 ("oncology is a rapidly changing and rapidly developing field").

22. *Smith*, *supra* n.21.

23. *Id.* at 956–957. *See also Bossemeyer v. Healthcare America Plans, Inc.* 953 F. Supp. 1176 (D. Kan. 1996) ("the nature of cutting edge medical technology is that opinions may differ as to whether a certain procedure has crossed the threshold from experimental, investigational, unproven or educational to general acceptance by the medical community and demonstrated efficacy"); *Heasley, supra* n.13 (experts for both parties agreed that it was difficult to identify precisely when a procedure ceases to be experimental and becomes accepted); *Estate of Goldstein, supra* n.11 ("A line is eventually crossed and a procedure becomes recognized and accepted within the medical community. Much of the litigation over excluded coverage questions when that line is crossed."); *Cf. McElroy, supra* n.21 ("the notion of conventional treatment versus experimental or investigational procedures as applied to the rapidly evolving field of oncology … is a facile but somewhat superficial distinction.").

24. Atwell, *supra* n.2 at 593, 595. *See also* Noah, *supra* n.11 at 361.

25. *Estate of Goldstein, supra* n.11.

26. Harness, *supra* n.10 at 67, 90 (court decisions have no precedential value); Clamon, *supra* n.2 at 473, 485–486 ("the result of these often emotional decisions has been contradictory and has resulted in inconsistent conclusions by courts that provide little or no precedential value to use in resolving future controversies."). As an illustration of the passage of time in determining whether a treatment is experimental, the dissent in *Clark, supra* n.19 noted that "the 3 cases holding the HDCT-ABMT experimental or investigational all addressed treatments proposed or undergone in 1989 or earlier, where the 5 cases to the contrary all addressed treatments after 1989."). For a fuller listing of cases dealing with the experimental or investigational nature of high dose chemotherapy with bone marrow transplants, *see Jenkins, supra* n.21. *See also Holder v. Prudential Insurance Co.,* 951 F. 2d 89 (5th Cir. 1992) ("Had [plaintiff] undergone a similar treatment more recently under an accepted protocol, the case may have turned out differently."); *Cf. Dozsa v. Crum and Foster, Inc.,* 716 F. Supp. 131, 139 (D. N.J. 1989) (may take "time for literature to catch up with accepted practice and what doctors are actually doing"), quoted in *Marro-K-III Communications Corp.*, 943 F. Supp. 247 (E.D.N.Y. 1996) and *McElroy, supra* n.21 ("new and successful treatments for cancers are occurring so quickly that peer-reviewed medical journals cannot keep pace with the rapidity of these breakthroughs, typically lagging behind from one to three years."). A second reason that case law dealing with this issue is of limited utility is the narrow issue presented. As the US Court of Appeals for the Seventh Circuit indicated in *Harris, supra* n.4, "the cases offer little help to our legal analysis. At bottom, the case is one of contract interpretation. Accordingly, it is controlled by the

specific language of the contract into which Ms. Harris and Mutual entered." *See also Whitney, supra* n.4 (although many cases address the issue of whether HDC/ABMT is experimental, "these cases provide little assistance, since by virtue of the task, they each are specifically focused on the contract language at issue."). *But see Helman v. Plumbers and Steamfitters Local 166 Health & Welfare Trust,* 803 F. Supp. 1407 (N.D. Ind. 1992) ("recent cases have determined that a finding that ABMT is experimental cannot stand."). The inherently difficult nature of the line drawing is not the only reason that precedents tend to be of limited value. Additionally, "any determination of whether a particular procedure is experimental will necessarily turn on the facts of the case," which is why "bright line rules in a plan run the risk of over and under inclusiveness." *Heasley*, *supra* n.13. *See also Sheppard and Enoc Pratt Hospital v. Travelers Ins. Co.,* 32 F. 3d 120, 125 (9th Cir. 1994); Harness, *supra* n.10 at 76 ("cases are difficult to harmonize because the decisions are very fact-specific."); and Stephen Plitt, "A Framework for Adjusting Medical Claims Involving Possible Experimental Treatment," *Claims Journal*, Oct. 27, 2011 (determination whether a procedure is experimental is fact-intense.). Further, the issue may focus on whether a treatment is experimental with respect to an individual's particular disease, that is, the issue is the efficacy of a procedure for a participant's particular condition. *See Pirozzi, supra* n.13 (HDCT with ABMT is not an experimental treatment for metastasized breast cancer); *DiDomenico v. Employees Coop Industrial Trust,* 676 F. Supp. 903, 908 (N.D.Ind. 1987) (liver transplants are not experimental for adults as well as children); *Heasley, supra* n.13; *Elsworth, supra* n.1 ("while HDC may be beneficial for other cancers, it is experimental with respect to the type of cancer suffered by Ms. Elsroth, particularly where the cancer has progressed to such an advanced stage."); *Specialty Surgery of Middleton v. Aetna,* 2014 WL 2861311 (D.N.J. 2014) (facet joint injections are considered experimental and investigational when used to treat back and neck pain); *Morse LLC v. Beckman Coulter,Inc.,* 455 F. Supp. 2d 1339 (S.D. Fla. 2006) (cyberknife stereotactic radiosurgery is experimental and/or investigational treatment for patients with solitary liver metastatis from a primary colon cancer); *Burton v. Blue Cross and Blue Shield of Kansas City,* 2014 WL 3767683 (D. Kan. 2014) (IMRT [intensity modulated radiation therapy] is experimental or investigative for ovarian and liver cancer); *Clark, supra* n.19 (HDC/ABMT is beneficial in treating lymphoma and certain other malignancies); *Johnson, supra* n.10 ("a gastroplasty may not be experimental when performed to cure obesity, but it may be when performed to cure already prevalent medical problems"); *Martin v. Blue Cross and Blue Shield of Virginia, Inc.,* 115 F.3d 1201, 1207 (4th Cir. 1997), *cert. den.* 118 S. Ct. 629 (1997).

27. Although court decisions regarding the experimental nature of certain treatments may be of limited precedential value as a legal matter, in *Pitman v. Blue Cross Blue Shield of Oklahoma,* 24 F.3d. 118 (10th Cir. 1994), fn.8, the US Court of Appeals for the Tenth Circuit noted that Blue Cross Blue Shield had conceded that it had changed its policy on the experimental nature of HDC/ABM because of too many adverse decisions.

28. *Reimann, supra* n.3. In *Smith, supra* n.21, Circuit Judge Manion commented upon "the incompetence of courts to decide when exactly that line or zone" between experimental and generally accepted practice "has been traversed. Such decisions are judgment calls for medical scientists and health care professionals, not judges." *See also Whitney, supra* n.4 and *Prowell v. UPS Flexible Benefits Plan,* 2011 WL 5110291 (D. Md. 2011) at *p8) ("Whether a given treatment is experimental is a question not directly addressed by any evidence in the record and in that regard requires medical knowledge in order to answer.") In response, the Seventh Circuit suggested alternative ways to resolve the issue "to reduce the incidence of suits in which one 'expert' testifies that a procedure is experimental and another equally qualified 'expert' testifies to the opposite effect. This so-called battle of the experts occurs all too frequently in federal court." *Fuja v. Benefit Trust Life Ins. Co.,* 18 F.3d 405 (7th Cir. 1994). *See also Bucci v.*

Blue Cross Blue Shield of Connecticut, 764 F. Supp. 728, 733 (D. Conn. 1991) (a court must choose between two sets of experts who often use a "floating standard which can rise or fall in any fact situation and which is not reviewable against identifiable criteria.")

29. *Harris, supra* n.4. *See also Robertson v. Blue Cross and Blue Shield of Texas,* 2015 WL 1715072 (D. Mont. 2015) (Blue Cross Blue Shield "examined the needs of the Plan and ignored the needs of Lana Robertson, a process protected by the rules of law.") *Whitehead v. Federal Express Corporation,* 878 F. Supp 1066 (W.D. Tenn. 1994) ("Despite the overwhelming sympathy and emotional support any person would feel for a cancer patient such as plaintiff, the court does not have a lawful basis to require payment under the circumstances") and *Thomas v. Gulf Health Plan, Inc.,* 688 F. Supp. 590, 594–595 (S.D. Ala. 1988) ("The sympathy the court indeed feels, however, does not and cannot alter the fact that the treatment sought to be covered under the plan is clearly experimental and that, as such, it is specifically excluded under the terms of the plan.").

30. *Hooper v. Demco, Inc*. 37 F.3d 287 (7th Cir. 1994); *Bechtold v. Physicians Health Plan,* 19 F.3d 322 (7th Cir. 1994); *Fuja, supra* n.28.

31. Harness, *supra* n.10 at 90 ("The legal system is a very costly and inefficient mechanism for judging the current state of medical technology"); Clamon, *supra* n.2 at 476 ("courts are ill-equipped to resolve this issue"); *See also* Richard S. Saver, "Reimbursing New Technologies: Why Are Courts Judging Experimental Medicine," 44 *Stanford Law Review* 1095 (1992), cited in Judith C. Broston, "The Conflict of Interest Standard in ERISA Cases: Can It Be Avoided in the Denial of High Dose Chemotherapy Treatment for Breast Cancer," 3 *DePaul Journal of Health Care Law* (Fall 1999), fn.73; Gina Mazzuella Plaue, "Third Party Reimbursement for Participation in Cancer Clinical Trials," 16 *Journal of Contemporary Health Law and Policy* (2000) 305332 ("Routinely, judges are placed in the position of essentially making decisions about the experimental status of medical procedures about which the judges possess no specialized expertise.").

32. *Fuja, supra* n.28.

33. "The problem with enumerating specific experimental procedures as being excluded from the policy or plan is that the list is inherently under-inclusive given the advancement of medical knowledge and technology." Plitt, *supra* n.26.

34. *Heasley, supra* n.13, describing these different approaches. *Wilson v. Group Hospital and Medical Service,Inc.,* 791 F. Supp. 309, 311 (D.D.C. 1992) (latter approach).

35. *See Dahl-Ehmers, supra* n.13 (courts have found the ambiguity of experimental and investigational removed by specifying who will determine its meaning and application); *Fuja v. Benefit Trust Life Ins. Co.,* 809 F. Supp. 1333, 1336 (N.D. Ill. 1992) (procedure or treatment will not be covered if it is "deemed experimental, educative, or investigatory in nature by any appropriate technological assessment body established by any state or federal government"); *Zuckerberg v. Blue Cross and Blue Shield,* 108 AD 56 (1986), *aff'd* 67 NY 2d 688 (1986) (procedure will be covered if an appropriate government agency, federal or state, recognizes it as sufficiently effective to justify any risks that may be involved); *Bossemeyer, supra* n.23; *Boland v. Kings County Medical Blue Shield,* 798 F. Supp. 638 (W.D. Was. 1992) (when a collective bargaining agreement provided that a procedure would be experimental if so determined by Blue Cross Blue Shield, the court would not review the reasonableness of the determination made by Blue Cross Blue Shield).

36. *Heasley, supra* n.13.

37. The effectiveness of a procedure also cannot be determined on a one-off basis. *See Peruzzi v. Summa Medical Plan,* 137 F.3d 431 (5th Cir. 1998) ("that a procedure

achieves the desired result does not preclude the conclusion that it was not at an experimental stage of development."); *Loyola University of Chicago v. Humana Ins. Co.,* 996 F.2d 895 (7th Cir. 1993) ("the experimental nature and research of the Jarvik heart implantation are not diminished just because the procedure was the only choice and happened to be successful.... The fact that a procedure is medically necessary does not obviate the possibility that it may also be experimental."). Also with regard to effectiveness, a decision to determine experimental basis on a success ratio *per se* may be arbitrary, as may a 50 percent success ratio for IVF. *Reilly, supra* n.11; *Cf. Rollo v. Blue Cross Blue Shield of New Jersey,* 1990 WL 312647 at *6 (D. N.J. 1990) (relying upon English studies in concluding that ABMT was not experimental for plaintiff's tumor treatment), discussed in Plitt, *supra* n.26.

38. *Heasley, supra* n.13. The three factors referenced in this opinion are commonly called the Heasley factors. *See* Plitt, *supra* n.26. *See also Pirozzi, supra* n.13.

39. *See Heasley, supra* n.13 at fn.26.

40. *Heasley, supra* n.13.

41. *Martin*, *supra* n.26.

42. *See* Salkin, "The Reasonable Expectations Doctrine," 17 *Journal of Deferred Compensation* 1 (Spring 2012).

43. *Saltarelli v. Bob Barker Group Medical Trust*, 35 F.3d 382, 385 (9th Cir. 1994), cited in *Bolden, supra* n.1.

44. *See Hinman v. John Alden Ins. Co.,* 2010 WL 466155 (D. Ore. 2010) (rejecting defendant's contention that the failure to exclude HDCT/PSCR while excluding HDCT/ABMT was one of semantics).

45. Harness, *supra* n.10 at 67, 79.

46. *Hinman, supra* n.44; *Smith v. Newport News Shipbuilding Health Plan, Inc.,* 148 F. Supp. 2d 637 (E.D. Va. 2001); *McElroy, supra* n.21); *Gardner v. Group Health Plan,* 2011 WL 1321403 (E.D. N.C. 2011).

47. *Elsworth, supra* n.1; *Hinman, supra* n.44.

48. *Taylor, supra* n.16.

49. *Elsworth, supra* n.1; *Kekis v. Blue Cross Blue Shield, supra* n.1; *Hinman v. John Alden Life Ins. Co. supra* n.44; *Adams v. Blue Cross Blue Shield of Maryland*, 757 F. Supp. 661 (D.Md. 1991); *McElroy v. Blue Cross Blue Shield of Oregon,* 757 F. Supp. 661 (D.Md. 1991); *Wilson v. CHAMPUS,* 866 F. Supp. 931 (E.D. Va. 1994); *Bucci, supra* n.28; *Hasty v. Central States SE & SW Areas Health and Welfare Fund,* 851 F. Supp. 1250 (N.D. Ind. 1994); *Perozzi v. Blue Cross Blue Shield of Virginia,* 741 F. Supp. 586, 590 (E.D.Va. 1990); *Marro, supra* n.26; *Wheeler v. Dynamic Engineering, Inc.* 850 F. Supp 459 (E.D.Va. 1994); *Whitney, supra* n.4. *Cf. Westover v. Metropolitan Life Ins. Co.,* 771 F. Supp. 1172 (M.D. Fla. 1991) (a procedure does not cease to be experimental in terms of generally accepted medical standards, merely because it may be widely used, nonharmful, and performed by a licensed physician with the consent of the patient.)

50. *Hinman, supra* n.44; *Kulakowski, supra* n.3 (a procedure under controlled scientific testing and research with questions... as to safety and efficacy). *See also* n.3, *supra*.

51. *Mattie v. Health Services of Savannah,* 893 F. Supp. 1559 (S.D. Ga. 1999). *See also Bailey v. Blue Cross and Blue Shield of Virginia,* 67 F.3d 53 (4th Cir. 1995).

52. *Elsroth v. Consolidated Edison Co. of NY, Inc.,* 10 F. Supp. 2d 427 (S.D.N.Y. 1998).

53. *See Velez, supra* n.1 ("While Prudential based its determination on its assessment that HDC-ABMT was not superior to the standard treatment, that is not the requirement of the plan's criteria"); *Zervos v. Verizon NY, Inc.,* 277 F. 3d 635 (2nd Cir. 2002) (arbitrary and capricious to treat a treatment as experimental because it is not considered superior, while the plan only required that the treatment be considered effective and considered to be appropriate by the relevant plan community); *Chiles v. Coventry Health Care, Inc.,* 2004 WL 1057591 (E.D.La. 2004) (testing may reveal whether a technology is experimental in the colloquial sense of the term, but it is not the test specified in the Group Membership Agreement); *Whittington v. Blue Cross Blue Shield of Maryland, Inc.,* 757 F. Supp. 661 (D.Md. 1991) (Blue Cross Blue Shield's definition of the term experimental is arbitrary and capricious because it is inconsistent with the terms of the plan); *Leonhardt, supra* n.1; *Pirozzi, supra* n.13 ("nothing in the plan requires that a treatment be the subject of multiple completed double blind [studies to escape the experimental treatment exclusion]"); *Smith, supra* n.46 (nothing in the policy requires there to be a completed Phase III study); *Gripkey, supra* n.21 (rejecting an argument denying coverage of a treatment because it was not covered in a phase III clinical trial, when that requirement was not written in the policy and stating that "The per se application of these rules to all decisions to decide whether or not a procedure is experimental is arbitrary and capricious"); *Farley, supra* n.15; *Cf. Bolden, supra* n.1 (plan cannot require a phase III trial when a phase III trial cannot be held because of the few individuals affected.) There is a humanitarian exemption when the number of affected persons is less than 4,000. *See also Pirozzi, supra* n.13 ("Many treatments become accepted without phase III studies, because these studies, by their nature, are difficult to conduct.").

54. *Dozsa, supra* n.26 at 137–138.

55. *McHenry v. Pacific Source Health Plan*, 679 F. Supp. 2d 1226 (D. Ore. 2010).

56. *Bolden, supra* n.1.

57. *Bucci*, *supra* n.28. *Bucci* was distinguished in *Hinman, supra* n.44, when the "definition of experimental and investigational is sufficiently concrete to be applied according to objective standards." What a plan or policy should set forth is "a particular test, or . . . a particular threshold of statistical success in terms of cure or survival rate." *Pirozzi, supra* n.13. *See also Pinckney v. Blue Cross and Blue Shield of Tennessee,* 40 EBC 1081 (M.D.Tenn. 2007) (general references to a medical journal that are not tied to a person's medical condition, needs, and therapy leave plaintiff and court without the essential tools to determine whether the ERISA administrator made a reasoned decision.").

58. *Heasley, supra* n.13. *See, for example, Holder, supra* n.26 (one reason treatment is experimental is that protocol administered to patient was given to only 20 or 30 women nationwide); *Martin, supra* n.26 (HDC/PCSR experimental when fewer than five women had received the treatment for ovarian cancer); *Hendrick v. Central Reserve Life Ins. Co.,* 39 F.3d 507, 514 (4th Cir.1994) (HDC/PSCR is experimental when plaintiff was the first person in the state to receive the treatment for small cell lung cancer).

59. *Heasley, supra* n.13.

60. *Lafferty, supra* n.1; *See also Zalkin v. Coventry Health Care of Nebraska, Inc.,* 2010 WL 1052263 (D. Nebr. 2010) (court questioned Coventry's argument that a treatment was experimental simply because appellant suffered from a rare condition for which there is no standard of care).

61. *Pirozzi*, *supra* n.13.

62. *Id.* at 593594. *See also Wilson, supra* n.49; *Leonhardt,* 828 F. Supp. 657 (D. Minn. 1997); *Dozsa, supra* n.26 at 131, 137–138.

63. *Kopicki v. Fitzgerald Automotive Family Employee Benefit Plan,* 121 F. 2d 467 (D.Md. 2000); *Martin, supra* n.26 (consent form stated that proposed treatment was investigational part of research study and only used for a few patients); *Hendrick, supra* n.58 at 507, 513–514 (consent form stated that the treatment might not help the plaintiff and that his only benefit may be contributing to the advancement of science); *Fuja, supra* n.28. (consent form repeatedly states that the subject was part of a research project, research study, or research protocol and that the safety and efficacy of this two-step approach in in the treatment of breast cancer will be evaluated.); *Sweeney v. Gerber Products Company Medical Benefits Plan,* 1989 WL 160541 (D. Nebr. 1989) (consent form and protocol replete with the terms "study," "research," "investigation" and "experiment"); *Parsons v. Sisters of Charity of Leavenworth Health Systems, Inc.,* 2011 WL 3047622 (D.Mont. 2011) (consent form stated that the procedure was experimental, for research, and "risky, of no proven benefit, and may not work"); *Loyola University of Chicago, supra* n.37 (consent form stated that "the artificial heart prepared for use in my case is an experimental device not yet approved by the FDA for routine use as such its implantation constitutes research."); *Fuja, supra* n.28. (consent form described the protocol as " research project," "research study," and "research protocol"); *Benisek v. Rush Prudential HMO, Inc.,* 1999 WL 498632 (N.D.Ill. 1999) (consent form indicated that "you are being asked to participate in this research study"); *Edens v. Central Benefits National Life Ins. Co.,* 900 F. Supp. 928 (W.D. Tenn. 1995) (informed consent referred to "this experimental study" and "the experimental aspects of this study"); *Children's Hospital Medical Center of Akron,* 2014 WL 1333186, 57 EBC 2657 (N.D. Ohio March 31,2014) (when the informed consent form described the treatment as research, a clinical trial, and experimental, it was a reasonable interpretation of informed consent that the treatment was experimental).

64. *Kekis, supra* n.1; *Jenkins, supra* n.21 (arbitrary and capricious to conclude that merely by using the term study, a treatment is rendered experimental or investigational).

65. *Wilson, supra* n.49 (appellee's own expert witness testified that under clinical trials the procedure is nonexperimental and noninvestigational.); *Wheeler v. Dynamic Engineering and CHAMPUS,* 850 F. Supp. 459, 469 (E.D.Va. 1994) ("the reasons he wants the procedure carried out within a clinical trial is so that proper records will be kept to improve the administration of the procedure to patients.").

66. *Pirozzi, supra* n.13; *Kulakowski, supra* n.3.

67. *Adams, supra* n.49.

68. *Id.* at 675, cited in *Kekis, supra* n.1, fn.5.

69. *Reilly, supra* n.11.

70. *Kopicki, supra* n.63; *Hendricks, supra* n.58 at 507, 512–513; *See also Wilson v. CHAMPUS*, 65 F. 3d. 361, 366 (4th Cir. 1996) (defendant's decision that HDC/PSCR was experimental was arbitrary and capricious, in light of "the abundant evidence and medical opinions that HDC/PSCR was gaining widespread acceptance within the medical community"), quoted in *Kopicki, supra* n.63 at 467; *Stein v. Oxford Health Plans, Inc.,* 56 EBC 1014, 2013 WL 3762898 (E.D.N.Y. 2013) (multiple independent peer review physician opinions stated that the procedure was experimental); *Jacobs, Jr. v. Guardian Life Ins. Co. of America,* 730 F. Supp. 2d 830 (N.D.Ill. 2010) (multiple peer review opinions stated that treatment was both experimental and not medically necessary); *Martin, supra* n.26. A failure to consult with medical authorities as to whether a proposed treatment is experimental is arbitrary and capricious. *DiDomenico, supra* n.26; *Burdette v. Mees,* 933 F.2d. 1001 (4th Cir. 1991). *See also Hawkins v. Mail Handlers and CHAMPUS,* 1994 WL 214262 at *4 and *5 (W.D.N.C. 1994 (CHAMPUS criticized for making a decision on outdated data); *Cf. White v. Caterpillar, Inc.,* 765 F. Supp. 1418 (W.D. Mo. 1991),

aff'd 985 F.2d. 564 (8th Cir. 1991) (arbitrary and capricious for administrator to rely upon five-year-old DATTA report when policy stated that it would only be a guide to determine whether treatment is generally accepted).

71. *Dozsa, supra* n.26 at 131, 138; *Marro, supra* n.26. Recently, state laws and regulations have banned or severely limited the operation of discretionary clauses in insurance policies. *See* Ecklund and Cookinghan, *supra* n.13 at 19.

72. *Peruzzi, supra* n.37; *Simmons v. Blue Cross Blue Shield of Tennessee,* 2005 WL 1638737 (M.D. Tenn. 2005).

73. *Hendricks, supra* n.58 at 507.

74. *Bailey, supra* n.51.

75. *Id. See also* Heasley, *supra* n.13; *Holder, supra* n.26; *Farley v. Benefit Trust Life Ins. Co.,* 979 F.2d 653, 661 (8th Cir. 1992).