LSP Group LLC
LAW | SCIENCE | POLICY

Direct Dial: (312) 857-5545
Cellular: (312) 802-4471
E-mail: khartley@lspgrp.com

Via E-Mail

March 28, 2016

Matthew Litton
Employee Benefits Law Specialist
Office of Health Plan Standards & Compliance Assistance
Employee Benefits Security Administration, Room N–5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Angela Nelson, Director
Insurance Market Regulation Division
Missouri Department Of Insurance
P.O. Box 690
Jefferson City, MO 65102-069

Re: "Experimental Exclusions" and Proposed Glossary for Health Insurance Policies

Brief Summary of Comment

This emailed letter and attachments provide comments on the Department of Labor's proposed glossary of terms used for health insurance policies. Ms. Nelson is a recipient because my understanding is the Department of Labor has received ongoing input on this topic from the NAIC Consumer Information B subgroup, chaired by Ms. Nelson. One hope is that her committee and state insurance regulators will focus new attention on new possibilities.

This comment makes two main points. First, it identifies and proves up a significant problem with the past and current use of inconsistent and subjective health care contract terms for when insurers will (or will not) pay for innovative new medical technologies, such as new drugs and diagnostics. Current and past health insurance contracts usually address the topic of innovative new technologies through so-called "experimental exclusions, and through terms regarding "medical necessity." Improved terms and disclosures are badly needed.

The second point is that many of the problems with payments for new technologies could be substantially – and quickly - fixed by expanding the proposed health insurance glossaries to include "check the box" tables that provide concrete, objective pieces of information that can be used to understand and compare the terms of health insurance contracts relevant to payments for new technology, such as new drugs or diagnostics. In short, the suggestion is that insurers would externalize information about objective and subjective factors they already make use of when deciding to pay (or not) for innovative new technologies. The information would be externalized and communicated through relatively simple "check the box tables" that will communicate the objective or subjective factors an insurer will (or will not) apply when asked to pay for a new

technology. Examples of such objective factors would include whether the technology has received approval from FDA, CMS/Medicare, NCCN or other expert groups.

The proposed check the box tables are needed and would be highly useful because decades of litigation over "experimental exclusions" already have proved that objective factors (e.g., FDA approval) are in fact considered by many health insurance companies. Therefore, better glossaries in fact can be built by using "check the box tables" that communicate how the different health insurers actually do (or do not) apply objective factors when deciding to pay (or not) for innovative new medical technologies. Over time, better processes and insurance policy terms also should be created and standardized. But that longer process should not stand in the way of rapid, relatively easy to accomplish use of check the box tables.

Set out below is a brief example of what part of a check box table could look like, and the type of information it can communicate when used in a glossary along with other similar items.

Throughout this comment, the term "technology" should be understood to include therapies, drugs and diagnostics.

Check the Box Table to Show the Impact of FDA and/or CMS Approval for Insurer Approval of New Technology, After Successful Completion of an Approved Phase III Clinical Trial for the New Technology			
Possible grading level	List of objective events that will (or will not) result in payments under a health insurance contract	Yes	No
Platinum	Insurer will pay for a new technology beginning the day after FDA accepts a New Drug Application for the technology, for on label or off label indication, when recommended by a board certified oncologist practicing in an NCCN cancer center		

Overview of Further Sections of this Comment Letter

There are essentially two sections to this comment. The first section points out that the glossary fails to address two critical terms of health insurance policies. The two critical health insurance contract terms not defined in the glossary are terms that address the important topic of when health insurers will pay for new and innovative treatments and diagnostics to find, treat and perhaps cure diseases. Specifically, the glossary does not address the inconsistent and subjective "experimental exclusion" terms that are used by many insurers and plan administrators to block payments for new treatments. This section also shows that similarly subjective terms also are used to define when a treatment is or is not "medically necessary." Two further parts of the section are as follows:

1. The Definition Problems Date Back At Least 20 Years: As shown by law review articles and judicial opinions cited *infra*, the term "experimental" has been widely used and defined in health insurance policy exclusions for at least twenty years, but the definitions used are inconsistent, subjective and unmanageable. Over the years, the numerous lawsuits and rulings explicitly have identified major problems with definitions and application, but the health insurance companies have failed to fix the problem, and so have the state level insurance company regulators. Instead, the terms of yesterday look much like the terms used today.

2. Current Definitions are Inconsistent and Subjective : A 2016 study (*infra*) of 17 health insurer web sites proves that several major health insurers are today using insurance policies - and internal guidelines/policies - that contain literally hundreds of uses of the term "experimental," and the varying terms used are inconsistent, subjective and unmanageable. Total different uses exceeded 4,100 for 17 web sites surveyed. By proceeding in this manner, health insurers (1) implicitly recognize and prove that use of one umbrella term is impractical, (2) deprive doctors of information needed to work well with patients, and (3) health insurers deprive insureds of the power to make meaningful insurance purchasing decisions.[1] The problems are further illustrated by at least 45 federal lawsuits since 2010 where the term "experimental" apparently has been at issue in various contexts. See Exhibit 1 (results from appropriate Boolean word search on Lexis). In addition, many or most health insurers program their software to target and deny and all bills for new technologies by targeting the computer codes used to identify new technologies.

The second section of this comment provides specific suggestions for expanding the glossary, including examples of "check the box" tables. The section also provides additional data and examples of lawsuits demonstrating the need for material changes in the glossaries. As noted earlier, the overall suggestion is to expand and improve glossaries by adding objective, easier to understand "check the box" tables that would present objective fact information useable to compare and evaluate health insurance contracts as to when an insurer will (or will not) pay for innovative medical treatments and diagnostics. Frankly, much of the work could be done especially quickly if health insurers disclosed the substance of the decision trees and software algorithms they use in the computer programs that are the core deciders of most aspects of medical claims processing. However, even then, ordinary Americans and others will still need a simpler version of the factors applied. Therefore, the Department of Labor, health insurers, regulators, and expert medical groups should work together to create standardized "check the box" tables that would present the needed, objective information regarding decision-making on new drugs and diagnostics. Using check the box tables to present objective answers to factual questions would be a notable improvement. The extent of the improvement would be especially

[1] The "methods" for the study are set out in Appendix 1.

large when compared to the failures of the "one size fits all" use of vague and arcane sets of words that produce endless uncertainty and arguments among sick people, health insurers, physicians and hospitals. Check the box tables also could present and compare the use of subjective terms, and whether or when they may (or may not) override objective factors.

The suggested additions to the glossaries could be mandatory or could be presented as an optional "nudge," as defined and explained by Cass Sunstein and others.[2] The "nudge" version could allow health insurers to continue to make their own choices about when to pay for new and innovative treatments, and would offer consumers and expert groups notably more free market, objective information that could be evaluated to compare the benefits offered (or not) by the various different health insurance contracts available for purchase. With objective and standardized information made available through check the box tables, the various different insurance contracts could be objectively compared, evaluated and graded by both consumers and expert groups (e.g., professional medical associations). Indeed, one would hope and expect that expert groups would publish meaningful, annual comparisons and grades to help persons make better choices between health insurance contracts.

Insurers would benefit (or suffer) because their contract offerings could be better understood through the use of improved glossaries and terms. For example, one insurer might choose to attract more purchasers by promising to pay for new and innovative drugs as soon as the FDA approves them. Presumably that insurer would charge more to purchase its health insurance contract. A different insurer, on the other hand, could choose to instead communicate that it will not pay for a drug until approved by the FDA and approved for payment by CMS/Medicare (the timing differences can be large or small, depending on variables). Communicating information of this sort is both practical and useful because lawsuits to date have proved that most health insurers already take into account objective factors such as the presence or absence of approval by FDA or CMS/Medicare. Therefore, use of check the box tables in glossaries would provide a way that both consumers and health insurers could benefit because the tables would force to the surface answers about objective factors, and the answers could then be compared in meaningful ways. That approach would be a significant improvement over the current process of leaving consumers baffled and defeated by the impossibility of comparing inconsistent "one size fits all" insurance contract terms that use vague and inconsistent subjective references to terms such as "medical community acceptance."

Set out at the end of the letter are specific examples of check the box tables that could be used in glossaries to communicate objective information about when a health insurance company would (or would not) pay for an innovative new treatment or diagnostic for cancer. Please understand these tables are provided as examples written by a non-expert; no doubt medical

---

[2] http://www.ft.com/intl/cms/s/2/3421a0be-cece-11e3-8e62-00144feabdc0.html (last visited March 25, 2016)

experts, drug companies, diagnostic companies, and health insurers could quickly generate better check the box tables that could quickly be put into use. And, even if those tables would fall short of perfection, the tables certainly would be a vast improvement when compared to depending only on subjective and vague one size fits all terms, such as "acceptance in the medical community."

In addition, there is a great need to put check the box tables to use quickly. Over 1,500 Americans die every day of cancer, and thousands more are diagnosed with cancer. The same is true for other major diseases, but in differing amounts. For those still living, making better insurance choices is important to obtain quality care and to avoid wasting money on inferior health insurance contracts. Moreover, making better insurance choices also is especially important for additional tens of millions of persons who know they face much higher than usual risks for certain diseases because of factors such as inheriting mutated genes (e.g., mutations in BRCA genes), because of current or past work environments (e.g., coal miners), or because of past actions (e.g., smoking cigarettes). This is a classic situation in which the perfect could become the enemy of good, and that should not be tolerated when so many are dying, sometimes needlessly. Therefore, for the most serious medical conditions (e.g., stage III or IV cancers), check the box tables should be quickly put into use for 2017 health insurance contracts. Frankly, everyone involved should admit that perfection in substance and process will never be achieved if only because molecular biology continues to move forward against some major diseases.

And, to close this introduction, a reminder that the term "technology" should be understood to refer to and include therapies, drugs and diagnostics.

Section I: Past and Current Use of "Experimental Exclusions," and Related Data

The Term "Experimental" Is Critical in Health Insurance Policies

The proposed glossary of health insurance policy terms does not include a definition for the term "experimental." The definition of the term is critical because numerous health insurance policies incorporate an "experimental exclusion" for new therapies and/or diagnostics. Exclusions of this sort are frequently used by health insurance companies to deny persons access to diagnostics and/or therapies tied to precision medicine, among other things. For many years, the exclusions also have been frequently used to deny access to stem cell transplants and other therapies. *See*, *for example*, Natalie L. Regoli, *Insurance Roulette: The Experimental Treatment Exclusion & Desperate Patients*, 22 Quinnipac L. Rev. 697 (2004).[3] *See also* Lee Black, *Experimental Breast Cancer Treatments and Health Insurance Coverage*, Virtual Mentor,

[3] http://www.quinnipiac.edu/prebuilt/pdf/SchoolLaw/LawReviewLibrary/34_22QLR697(2003-2004).pdf)

January 2007, Volume 9, Number 1: 34-37 (describing lawsuits and rulings regarding "experimental exclusions and medical necessity definitions").

The articles cited above prove the further point that definitions of "experimental" have been inconsistent and subjective for decades, and the health insurers have been very aware of the problem, but have failed to find an industry-wide answer to the problem. Thus, in his 2007 article, Mr. Black reviewed and presented some of the definitions in use at that time, as revealed by judicial decisions in instances where lawsuits arose because various insurers had denied coverage under their diverse and inconsistent versions of the "experimental" exclusion. Mr. Black concluded that the definitions used were highly material to outcomes. Among other things, the article stated the following conclusions by Mr. Black:

> "The variety among insurance contract provisions relating to coverage of experimental treatments is astounding. They range from very sparse language which offers little insight into what an insurer considers experimental to very detailed provisions. In general, the less detailed the language, the better the outcome for the patient who challenges a denial. This formula, however, is by no means foolproof. In some instances, even a definition of experimental that seems to allow for flexibility can be viewed by a court as sufficiently precise to preclude a challenge by the patient." (emphasis added)

> "In most cases, the terms of the insurance contract played a larger role in judicial decision making than medical opinion, a fact that had considerable consequence because parties generally interpret contracts in ways that are consistent with their own best interests. For insurance companies, best interests meant denial of a claim (although a poorly reasoned denial could more easily lead to liability). Patients, on the other hand, have an interest in treatment, so experimental procedures were quickly interpreted as "accepted by the medical community" as soon as they had received a few endorsements." (emphasis added)

In his 2007 article, Mr. Black went on to quote some of the various inconsistent terms that were in use in some health insurance policies litigated between 1996 and 2002. Set out below are the quotes, and the cases to which he cited:

> "The following examples of contract language describing coverage for experimental treatment come from legal cases where the denial of coverage for breast cancer treatment was challenged.

> "'Experimental' means those procedures and/or treatments which are not generally accepted by the medical community…". [citing to *Healthcare America Plans v. Bossemeyer*, 953 F. Supp. 1176, 1179 (D. Kan. 1996)].

> "'[C]harges for treatment or service that (are) determined by the Plan Administrator to be experimental, investigational, unnecessary, and/or inappropriate for the condition, even if prescribed and/or ordered by a Doctor' are excluded from coverage." [citing to *Reed v. Wal-Mart*, 197 F. Supp. 883, 885-886 (E.D. Mich. 2002)].
>
> "…Services…are Medically Necessary if they are…commonly and usually noted throughout the medical field as proper to treat the diagnosed condition, disease, Injury, or Illness…" [citing to *Killian v. Healthsource Provident Administrators*, 152 F.3d 514, 516 (6th Cir. 1998)].
>
> "A drug, device or medical treatment or procedure is Experimental…if Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of ongoing Phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis…" [citing to *Lewis v. Trustmark Insurance Co.*, US App 15746, 9 (4th Cir 1999)].
>
> "The last example above is most specific as to what is considered experimental; the second and third are more vague and do not provide a definition of "experimental" that would aid an insured patient in determining what is covered. Herein lies the difficulty for HDC, PSCR and ABMT: especially in the 1990s, these medical procedures were given inconsistent treatment by judicial circuits."

To sum up, Mr. Black's 2007 article highlighted some of the many then-existing denials, lawsuits and other problems flowing from the health insurance industry not adopting consistent, logical terminology as to when insurers will pay for new technology. The next section of this comment demonstrates that almost a decade later, the health insurance industry still has not adopted a consistent, logical term (although a small number of companies have taken a few small but positive steps). The overall point is that the health insurance industry has not proven itself a responsible steward for these terms, and many insurers have failed to fulfill the fiduciary duties owed to each and every insured.

A 2016 Website Review Proves Continuing Use of Inconsistent and Illegal Definitions

We conducted a recent review of health insurer websites to find terms used to define "experimental exclusions." The results shows that most health insurance companies still are using inconsistent and subjective definitions of the term "experimental." In addition, many of the insurance companies do not even provide a glossary with the term, and so it is literally impossible to comparatively assess the terminology prior to purchasing a policy.

Specifically, two tables below summarize results from the 2015 and a 2016 review of 17 websites of health insurance industry companies for information a person theoretically could find regarding the so-called "experimental exclusion" used as part of many health insurance policies. Overall, the survey results show the majority of the insurance company websites (10/17) did not provide a definition of the term "experimental," with 1 of the 10 sites (Anthem) impossible to access without an insurance policy number. For the 7 health insurance company websites that did provide a definition for the term "experimental," the definitions were materially different and inconsistent. Where the term was used, the results showed that some but not all insurers used the term so often that the number of search "hits" returned is vast. In both tables, the far right hand columns show the number of search "hits" returned when searching for the word "experimental."

The 7 definitions of "experimental" that were found on insurer web sites are set out in Table 1, including the full text of each. The middle column contains quotes from the insurer web sites; the diversity of wordings proves the inconsistency and subjectivity of terms used.

Table 1 – 2016 Results - Surveys of Health Insurance Websites for "Experimental"

Insurer and website address for glossary, if found	**If a glossary was present, exactly what words or phrased were returned as the result after searching the glossary for the term "experimental"**	**# of search results returned for the term "experimental"**
2016 Aetna https://www.aetna.com/glossary.html	"Experimental services or procedures These are often newer drugs, treatments or tests. They are not yet accepted by doctors or by insurance plans as standard treatment. They may not be proven as effective or safe for most people."	999
2016 Cigna http://www.cigna.com/glossary	"Experimental Procedures Unproven or investigational treatments that are not in line with generally accepted standards of care."	389
2016 Emblem http://www.emblemhealth.com/en/Members/Resources/Glossary.aspx	"Experimental Procedures Procedures that are mainly limited to laboratory research."	197
2015 HCSC /http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=i2kcy40k&corpBrand=HCSC&corpEntCd=IL1	"Experimental – Investigational or unproven, not yet proven safe or effective."	443
2016 Carefirst Inc. https://member.carefirst.com/individuals/health-insurance-glossary/health-insurance-glossary-	"Experimental Procedures Any service or supply that is in the developmental stage or is in the process of human or animal testing."	15

e.page?alphaId=glossary-e		
2016 Blue Cross Blue Shield of Michigan http://www.bcbsm.com/providers/help/glossary/provider-e.html	"experimental See investigational." "investigational Any procedure, treatment, supply, device or drug that has not received FDA approval or is not yet supported by the clinical community because the scientific evidence available does not demonstrate the effectiveness of the service or technology."	389
2016 Golden Rule Insurance Co.: http://www.goldenrule.com/glossary-terms/experimental-procedures/	"Experimental or Investigational Procedures Health care services, procedures, therapies, devices, or supplies that the insurance company considers medically unproven are considered experimental or investigational procedures. Such treatments are typically excluded from coverage."	2

The "experimental exclusion" terms quoted in the middle column of Table 1 prove the inconsistency of the words used to define the concept, and also reveal the repeated use of subjective terms. The continuing use of so many inconsistent and subjective terms is inherently suspect in an age in which society has created and paid for the ability to obtain expert advice and decisions from expert agencies (e.g., FDA and CMS/Medicare) and private experts groups, such as the National Comprehensive Cancer Network and the American Society of Clinical Oncologist, as well as various other specialty groups of doctors focused on subtypes of the many diseases we call "cancer." A cynic might infer that long ago insurance company lawyers originally drafted the terms to seek maximum wiggle room, perhaps tempered a bit by salespeople concerned about not sounding too harsh. And, one could further infer that too many current insurers and their attorneys and actuaries refuse to adapt and use new words and principles because change is not easy, and would require time, money and fresh thinking.

Whatever the process may have been or may now be at each insurance company, the definitions set out in the middle column of Table 1 reveal patent inconsistency. Some of the terms also say little about the actual role of and weight given to objective factors, such as the weight assigned to decisions or recommendations of expert agencies and private groups. Some fo the terms also use relatively more subjective terms. The situation can and should be changed and improved by expanding the glossaries to include check the box tables that would make those factors better known and much more comparable. Increasing transparency is key to better decision-making. Or, as Justice Brandeis put it, sunshine is the best disinfectant.[4]

[4] See https://sunlightfoundation.com/blog/2009/05/26/brandeis-and-the-history-of-transparency/ (last visited March 27, 2016).

Improving the disclosure of the objective and subjective factors also would be valuable because it would reduce the ability of bad actors to disguise bad decisions. There is at present too much room for mischief in subjective terms, including terms such as "the insurance company considers [a technology] medically unproven," or the insurer may have an unduly narrow view of what it deems "scientific evidence" that it perceives as "available." All of these subjective terms can be used to build up denials premised on the assertion that the doctor and patient failed to "properly" demonstrate the "effectiveness of the "service or technology." All of these subjective words and phrases also create room to shunt aside objective facts, such as the decisions and recommendations of expert groups. Those subjective "one size fits all" words and phrases also fail to provide certainty needed by patients, doctors, hospitals, and makers of drugs and diagnostics. Indeed, the existing phrases used by some of the health insurers would fit comfortably with a conversation between Alice and Humpty Dumpty:

> "When *I* use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean—neither more nor less." "The question is," said Alice, "whether you *can* make words mean so many different things." "The question is," said Humpty Dumpty, "which is to be master—that's all." Lewis Carroll (Charles L. Dodgson), *Through the Looking-Glass,* chapter 6, p. 205 (1934 publication of Carroll's 1872 publication).

By putting in place glossaries that disclose the objective and subjective factors used, and their weight, the Department would reduce the ability of some insurance company masters to unfairly turn subjective words into excuses to deny access to or payments for new technologies.

The need for glossaries and check the box tables is further proven by Table 2, below. Table 2 goes further than Table 1 by providing information from 10 health insurer web sites that (1) did not define the term experimental in a glossary, but (2) did use the term in the health insurance contract, or in guidelines covered by the search box for the insurer's web site. In addition, the far right column of Table 2 shows the number of search hits returned for the term "experimental" at each web site. The number of search hits per web site ranged from a low of 0 to a high of 1,700. There were 4,102 total search hits across all 17 web sites.

Table 2 - 2016 Results of Surveys of Health Insurance Websites for "Experimental"

Insurer #	Insurer and website address for glossary, if found	If a glossary was present, exactly what words or phrased were returned as the result after searching the glossary for the term "experimental"	# of search results returned for the term "experimental"
1	2015 Aetna	"Experimental services or	Aetna.com

	https://www.aetna.com/glossary.html	procedures These are often newer drugs, treatments or tests. They are not yet accepted by doctors or by insurance plans as standard treatment. They may not be proven as effective or safe for most people."	1583
	2016 Aetna https://www.aetna.com/glossary.html	"Experimental services or procedures These are often newer drugs, treatments or tests. They are not yet accepted by doctors or by insurance plans as standard treatment. They may not be proven as effective or safe for most people."	Aetna.com 999
2	2015 CIGNA http://www.cigna.com/glossary	"Experimental Procedures Unproven or investigational treatments that are not in line with generally accepted standards of care."	Cigna.com (191) Medical Library (70)
	2016 Cigna http://www.cigna.com/glossary	"Experimental Procedures Unproven or investigational treatments that are not in line with generally accepted standards of care."	Cigna.com (389) Medical Library (430)
3	2015 Emblem http://www.emblemhealth.com/en/Members/Resources/Glossary.aspx	"Experimental Procedures Procedures that are mainly limited to laboratory research."	Emblemhealth.com 321
	2016 Emblem http://www.emblemhealth.com/en/Members/Resources/Glossary.aspx	"Experimental Procedures Procedures that are mainly limited to laboratory research."	Emblemhealth.com 197
4	2015 Humana https://www.humana.com/learning-center/glossary/?kc=1005011074	Term not in glossary	Humana.com 15
	2016 Humana https://www.humana.com/learning-center/glossary/?kc=1005011074	Term not in glossary	Humana.com 0

5	2015 Kaiser	No general glossary found	Kaiserpermanente.org 85
	2016 Kaiser	No general glossary found	Kaiserpermanente.org 80
6	2015 Blue Cross/Blue Shield of Illinois/http://www.bcbsil.com/insurance-basics/ understanding-health-insurance/ glossary	Term not in glossary	BCBSIL.com 0
	2016 Blue Cross/Blue Shield of Illinois/http://www.bcbsil.com/insurance-basics/ understanding-health-insurance/ glossary	Term not in glossary	BCBSIL.com 0
7	2015 United Healthcare/http://www.uhc.com/searchresult?q=glossary&locale=en	Term not in glossary	UHC.com 29
	2016 United Healthcare/http://www.uhc.com/searchresult?q=glossary&locale=en	Term not in glossary	UHC.com 359
8	2015 HCSC/http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=i2kcy40k&corpBrand=HCSC&corpEntCd=IL1	"Experimental – Investigational or unproven, not yet proven safe or effective."	www.medicalpolicy.hcsc.net 443
	2016 HCSC	It appears changes were made to the HCSC website that render it not possible to make an exact comparison. Upon clicking on the link used in 2015, the searcher is taken to an error message "this web page is not available." ERR_NAME_NOT_RESOLVED.	See notes in middle column of table.
	2016 HSCS alternative search at http://www.hcsc.com/glossary.html	Term not in glossary	

9	2015 Anthem Blue Cross Blue Shield/anthem.com	Cannot find way to search without putting in member number	
	2016 Anthem Blue Cross Blue Shield/anthem.com	Cannot find way to search without putting in member number	
10	2015 Carefirst Inc. Group/https://member.carefirst.com/individuals/search.page?searchWord=glossary&searchBtn.x=0&searchBtn.y=0&actionFieldAudience=search	"Experimental Procedures Any service or supply that is in the developmental stage or is in the process of human or animal testing."	https://member.carefirst.com 10
	2016 Carefirst Inc. https://member.carefirst.com/individuals/health-insurance-glossary/health-insurance-glossary-e.page?alphaId=glossary-e	"Experimental Procedures Any service or supply that is in the developmental stage or is in the process of human or animal testing."	https://member.carefirst.com 15
11	2015 Centene Corp. Group/centene.com	No general glossary found	www.centene.com 0
	2016 Centene Corp. Group/centene.com	No general glossary found	www.centene.com 0
12	2015 Blue Cross Blue Shield of Florida Group/http://www.bcbsfl.com/wps/wcm/connect/34c4f6004f40e071bc3dfe53a65fe90d/SBCUniformGlossary.pdf?MOD=AJPERES	Term not in glossary	http://www.bcbsfl.com 12
	2016 Blue Cross Blue Shield of Florida https://www.floridablue.com/general/glossary#E	Term not in glossary	http://www.bcbsfl.com 17
13	2015 Blue Cross Blue Shield of Michigan/http://www.bcbsm.com/providers/help/glossary/provider-e.html	"experimental See investigational." "investigational Any procedure, treatment, supply, device or drug that has not received FDA approval or is not yet supported by the clinical community because the scientific evidence available does not demonstrate the effectiveness of the service or technology."	bcbsm.com 10
	2016 Blue Cross Blue Shield of	"experimental	

	Michigan http://www.bcbsm.com/providers/help/glossary/provider-e.html	See investigational." "investigational Any procedure, treatment, supply, device or drug that has not received FDA approval or is not yet supported by the clinical community because the scientific evidence available does not demonstrate the effectiveness of the service or technology."	Bcbsm.com 389
14	2015 Assurant Health: http://www.assuranthealth.com/learning-center/ understanding-health-insurance/ glossary-of-health-insurance-terms#gl05	Term not in glossary	Assuranthealth.com 5
	2016 Assurant Health: http://www.assuranthealth.com/learning-center/glossary-of-health-insurance-terms	Term not in glossary	Assuranthealth.com 5
15	2015 Golden Rule Insurance Co.: http://www.goldenrule.com/glossary-terms/experimental-procedures/	Experimental or Investigational Procedures -- Health care services, procedures, therapies, devices, or supplies that the insurance company considers medically unproven are considered experimental or investiga-tional procedures. Such treatments are typically excluded from coverage.	http://www.goldenrule.com 5
	2016 Golden Rule Insurance Co.: http://www.goldenrule.com/glossary-terms/experimental-procedures/	"Experimental or Investigational Procedures -- Health care services, procedures, therapies, devices, or supplies that the insurance company considers medically unproven are considered experimental or investiga-tional procedures. Such treatments are typically excluded from coverage."	http://www.goldenrule.com 2
16	2015 Excellus: https://www.excellusbcbs.com/wps/portal/xl/mbr/searchdisplay?WCM_GLOBAL_CONTEXT=/wps/wcm/connect/default/excellus/member/health+plans/glossary/glo-glossary+of+terms	Term not in glossary	https://www.excellusbcbs.com 9
	2016 Excellus:	Term not in glossary	

	https://www.excellusbcbs.com/wps/portal/xl/mbr/searchdisplay?WCM_GLOBAL_CONTEXT=/wps/wcm/connect/default/excellus/member/health+plans/glossary/glo-glossary+of+terms		https://www.excellusbcbs.com 9
17	2015 Molina Health Care: http://www.molinahealthcare.com/members/common/Search/results.aspx?k=glossary&s=membersentirewebsite&v=en-us	Term not in glossary	http://www.molinahealthcare.com 820
	2016 Molina Health Care: http://www.molinahealthcare.com/members/common/Search/results.aspx?k=glossary&s=membersentirewebsite&v=en-us	Term not in glossary	http://www.molinahealthcare.com 1,700

Together and individually, Tables 1 and 2 prove the existence of an unmanageably large number of inconsistent and subjective insurance company uses of phrases for the term "experimental." There is no possible way a human being – or even a computer – can make a meaningful evaluation of 4,102 uses of the word "experimental" when spread across 17 web sites, not to mention the dozens of other health insurer web sites. The Department's glossary needs to expand and change in order to fix the problems insurers have failed to fix by themselves.

45 Recent Federal Lawsuits Regarding Experimental Exclusions

Additional evidence of the current definitional deficiencies consists evidence of the amount of litigation regarding the application of "experimental" exclusions to deny access to medical therapies and diagnostics. To test the numbers, a Boolean logic word search was run in a legal research database (Lexis) that contains all federal court opinions. The search requested a return of all federal judicial opinions issued on or after January 1, 2010 in which the term "experimental" was used within 5 words of the word "exclusion." The results indicate 45 lawsuits have produced federal judicial opinions using those words since 2010. The search results are attached as Exhibit 1 and include sufficient text to confirm the opinions are on point. The search was limited to opinions in federal court cases because the federal ERISA statute controls many aspects of many benefit plans for employees, and because well-advised litigants are likely to seek a federal trial court forum if possible because federal trial judges have broad powers to issue injunctions.

Some Insurers Set Their Software Program to Target and Refuse to Pay for Innovative New Treatments and Diagnostics

Further evidence of past and current problems lies in the fact that many or most of today's health insurance policies are written - and administered - with the intent and practice of not paying for new treatments and diagnostics, even if they would save the life of that particular insured. More specifically, health insurers routinely deny approval of or payments for new treatments or diagnostics based on practices that are not disclosed in health insurance contracts. The targeting of and refusal to pay for new treatments is a practice understood and commented on by professionals steeped in the arcane but important world of medical billing codes and software. One such person is Debra M. Parrish, a lawyer who represents numerous medical providers and others. In a 2013 article, she explicitly pointed out that "**many, if not most payers, have implemented billing software edits that automatically deny claims**" **for new treatments and diagnostics**. She explained:

> "Most new medical technologies initially are billed to payers with a miscellaneous CPT code (those ending in "99") or a category III CPT code (codes ending with a "T"). Each January and July, the AMA issues new "T codes" to track the adoption of new technologies.
>
> **Many, if not most payers, have implemented billing software edits that automatically deny claims that are billed with a miscellaneous or T CPT code as experimental or investigational. Although the AMA, the entity that issues the CPT codes, has stated it is unreasonable for any payer to assume a service billed with a T code is experimental or investigational, the practice continues. (emphasis added)**
>
> Thus, adopters of new technologies should anticipate denials of services provided with these codes. Despite these initial denials, providers can not only get paid for individual claims, they can change payer policies. The following describes how.
>
> Novitas, the Medicare contractor for Pennsylvania (among other states and the District of Columbia), has a general policy, i.e., a local coverage determination ("LCD") that will deny coverage of a service billed with a category III CPT code as experimental and investigational. (emphasis added).
>
> See Local Coverage Determination 31686. Thus, through this policy, Novitas immediately declares any T-coded service to be non-covered unless and until the policy is revised and the procedure is excluded from the list of non-covered services."[5]

[5] Debra M. Parrish, Appealing Medicare Denials of New Medical Technologies, Western Pennsylvania Healthcare News (January 30, 2013), online at

Ms. Parrish's disclosure should provoke deep questions and thoughts by anyone interested in seeing health insurance contracts work well for policyholders. Indeed, it is difficult to imagine a court concluding that it is legal – for a fiduciary - to set its software to deny all payments for new technologies. Unfortunately, state insurance regulators have not stopped this practice even though medical billing software controls the vast majority of "decisions" made today by health insurers and plan administrators.[6] Perhaps one of the problems is that regulators do not understand the systems and the adverse outcomes they generate for persons with cancer and other major diseases. Whatever the problem may be with regulators, it is plain the issues and problems will only increase because more new medical technologies are in progress, and the omnipresent CPT codes (and other similar codes) must keep evolving and expanding to address the new treatments and diagnostic tests. According to the American Medical Association, it and other groups devote much time to creating and defining new codes for new treatments.[7] As a result, insurers and plan administrators will find it mechanically easy to continue to set their computer programs to look for and deny all payments for new technologies. If an insurer actually follows that practice, then at a minimum, that fact should be made an explicit part of the health insurance contract, and should be disclosed in "check the box" tables that communicate the information to policyholders and expert advisory groups who can use the information to rank or grade insurers and/or plan administrators. Proper use of check the box tables would reveal the use of this "rigged" programming, and one would expect that expert groups would then "shame" and give failing grades to insurers that use such methods, thereby reducing the number of consumers who would purchase insurance from companies which act in that manner.

Disclosing and Comparing Objective and Subjective Factors Is Appropriate Because Health Insurers and Plan Administrators Must Act as Fiduciaries and Cannot Apply Subjective Factors to Disallow Payments for New Treatments or Diagnostics

Insurers should not be heard to complain about glossary terms that disclose and compare the use of objective factors and/or the use of subjective factors. Providing that type of comparative information is important and perfectly proper. In fact, there is no room for complaint by insurers or plan administrators because courts have time and again held that is illegal to use subjective terms to the detriment of policyholders, and that fiduciaries must make full disclosure of all relevant information, even if the policyholder does not know the questions

---

http://www.wphealthcarenews.com/appealing-medicare-denials-of-new-medical-technologies/ (last visited March 27, 2016).

[6] For a general overview of the extensive use of medical billing systems, see a report from the Inspector General of the Department of Health and Human Services. http://oig.hhs.gov/oei/reports/oei-05-99-00100.pdf.

[7] The AMA's website provides background and more specifics on its four decades of work on coding, and how the processes work. See http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq/code-becomes-cpt.page (last visited March 26, 2016).

to ask. These rulings have arisen, for example, in cases where courts were considering lawsuits arising from "experimental exclusions" of the sort presented in the cited law reviews and Table 1 above. Courts also have issued similar rulings in cases arising from interpretation of "medically necessary" clauses of health insurance contracts. The point is illustrated by the "medically necessary" clause below, which is taken verbatim from the opinion in *Diane Maddred-Exum v. Davco Restaurants, Inc*., No. 04-660 (D. Md. May 13, 2004).[8] Highlighted below in bold are subjective terms of the sort some insurers or plan administrators point to when trying to justify denial decisions based on subjective factors:

"The Plan consists of 60 pages, and is not provided in full since it is known to the parties. However, certain Plan terms bear particular mention. First, at Appendix B, the Plan defines "Medically Necessary" as follows.

Medically Necessary. Medical services, supplies or treatment:

- which are ***required*** for the diagnosis or treatment of the Sickness, Accidental injury or pregnancy;
- which are ***safe and effective*** according to ***accepted clinical evidence*** reported by ***generally recognized medical professionals or publications***; and
- provided the recommended treatment or diagnostic services meet the standard of care as outlined by Medicare, National Institute of Health (NIH) or National Comprehensive Cancer Network (NCCN).

The Plan Sponsor ***may determine, at its discretion, if such services or supplies are "Medically Necessary***" for the diagnosis or treatment of a Sickness, Accidental Injury or pregnancy. This determination, in part, is based on and is ***consistent with*** standards outlined above and approved by the Plan Sponsor. (emphasis added)

The facts of the *Maddred-Exum* case illustrate why subjective terms are important and dangerous, and why insurers and plan administrators – as fiduciaries – are not permitted to disregard objective conclusions by experts and cannot rely on subjective or discretionary language to act to the detriment of policyholders. In that case, a blood cancer known as multiple myeloma had stricken Ms. Maddred-Exum, and a stem cell transplant was to be performed as the standard of care treatment, as recommended by her doctor. The same "standard of care" conclusion also was reached by two more doctors, both working for the insurance plan administrator. Slip op. at 6-7. Through discussions among the three doctors, these facts were known to Ms. Maddred-Exum, her doctor, and the plan doctors. Id. Thus, it was plain to all of

[8] The opinion is available online at no cost at https://www.scribd.com/doc/106289028/Opinion-Sanctioning-Health-Insurer-for-Wrongful-denial-of-stem-cell-transplant-for-a-person-with-cancer-Maddred-Exum-v-Davco-Restaurants-Et-Al.

them that there was no objective reason for denial of the stem cell transplant. Nonetheless, the plan administrator did refuse to approve the stem cell transplant, and so Ms. Maddredd-Exum might well have died because of the wrongful denial. Happily, she did not die because the doctor and hospital took the risk of not being paid and went ahead to provide the needed stem cell therapy. Slip op. at 7-8 ("Rather than allowing Ms. Maddred-Exum's health to be jeopardized by further delays, Dr. Rappaport performed the bone marrow transplant at GCC, without guarantee of payment, at an approximate cost of $90,000. Ms. Maddred-Exum now argues that she should be able to recover that cost under the Plan due to Defendants' unreasonable denial of coverage.") While kudos are owed to the doctor and the hospital, the larger point here is that insureds should not be exposed to a very real risk of death if their doctor or hospital is not willing to take the financial risks of going forward despite denial of approval. Requiring full and effective disclosure of objective and subjective factors will allow policyholders to lessen their risks by declining to purchase insurance policies from plans that fail to give enough weight to objective factors, and that fail to defer to truly expert physicians with actual first hand knowledge of the medical situation of a particular patient.

The absurdities that can and do occur are further illustrated by the *Maddred-Exum* case. There, to try to justify its actions, the defendants argued that the entire procedure was rendered "experimental" because Ms. Maddred-Exum had agreed to be part of research in which she would receive – 30 days after transplant - a new form of post-transplant vaccine aimed at reducing the risk of graft versus host disease, a problem that emerges after some stem cell transplants. In a terse and pointed opinion, Senior Judge William Nickerson rejected the purported excuse, and explicitly held that the denial was in bad faith. Slip op. at 8-9. He explained that the bad faith arose from trying to elevate subjective over objective:

> Surprisingly, Defendants offer no medical opinions nor relevant case law to support their position. Instead, they offer an affidavit of a nurse case manager to clarify that the coverage decision rests with CoreSource, Inc., as the claim processor, and DavCo Restaurants, as the Plan Administrator, rather than with reviewing physicians contracted by Defendants. While Defendants argue that the opinions of their two reviewing physicians are irrelevant to the issue before this Court, they make no proffer that any other physician would agree with their harsh interpretation of the Plan, nor any other facts that would lead the Court to conclude their denial was reasoned and principled. Nevertheless, Defendants claim that whether they abused their discretion is a genuine issue of material fact that can only be resolved by a full trial. The Court cannot agree.
>
> The only evidence before the Court is that Ms. Maddred-Exum suffered from a life threatening condition for which she sought a bone marrow transplant which three physicians agree, with no dissent on the record, falls within the appropriate standard of care. Without some theoretical medical support, this

> Court will not sanction an insurer's failure to cover that treatment simply because the patient will also participate in an experimental procedure, beginning some 30 days after her transplant, that is designed to increase her chances of a successful recovery. **The Court can find no language in the Plan meriting such an exclusion of coverage and concludes that Defendants' attempted construction of one to be a bad faith abuse of their discretion.** (emphasis added).

In the end, as a sanction for bad faith conduct, Judge Wilkerson ordered the defendant to pay of all of the attorney's fees incurred to enforce the health insurance contract. See *Diane Maddred-Exum v. Davco Restaurants, Inc*., No. 04-660 (D. Md. May 13, 2004).[9] The final result was a sanction of over $40,000 for bad faith actions that could have killed Ms. Maddred-Exum if her doctor and hospital had not been willing and able to afford taking a risk.

Ultimately, the even larger point is that transparency in decision-making is key. The related point is that when all the objective factors are known and "on the table" (e.g. the three doctors all knew the situation), it becomes easier to see and overturn illegal, subjective decisions to deny payments for new and/or expensive treatments or diagnostics. Therefore, "check the box" tables are desirable because they would reveal all of the relevant objective and subjective factors an insurer will apply in decision-making, and putting those factors on the table would make it more dangerous for an insurer – or a plan administrator – to try to twist some subjective factor as a basis for acting to the detriment of the insured person. Moreover, glossary tables can and should expose and compare the subjective terms and how they compare between and among different health insurance contracts. Consumers can and should be educated to avoid insurance policies that purport to give broad discretion to administrators.

It Is Illegal to Use Subjective Factors to Create Purported Excuses to Deny Payments for New and/or Expensive Therapies

As fiduciaries, insurers and plan administrators cannot properly oppose glossary terms that would increase transparency regarding objective and subjective factors applied in decision-making. Indeed, rule number one of health insurance contracts is that health insurers and plan administrators are not just parties to ordinary contracts. Instead, they are fiduciaries required to act ***solely*** in the interest of plan participants and to exercise their duties with the "care, skill, prudence, and diligence" of an objectively prudent person. 29 U.S.C. § 1104(a)(1); Eyler v. Comm'r of Internal Revenue, 88 F.3d 445, 454 (7th Cir. 1996). Therefore, health plan fiduciaries ***must*** administer a plan ***solely*** in the interest of plan beneficiaries. *Fish v. Greatbanc Trust Co*., 749 F.3d 671, 679 (7th Cir. 2014); *Kenseth v. Dean Health Plan,* 722 F.3d 869 (7th Cir. 2013). These duties imposed by federal statutory law also exist under state law because the

[9] The opinion is available online at no cost at https://www.scribd.com/doc/106289028/Opinion-Sanctioning-Health-Insurer-for-Wrongful-denial-of-stem-cell-transplant-for-a-person-with-cancer-Maddred-Exum-v-Davco-Restaurants-Et-Al.

duties are analogous to the duties of loyalty and care that are imposed upon a trustee under the common law. *Kenseth v. Dean Health Plan*, 610 F.3d 452 (7th Cir.2010). These fiduciary rules apply to each and every benefit decision. "[A] benefit determination [is considered] to be a fiduciary act (i.e., an act in which the administrator owes a special duty of loyalty to the plan beneficiaries)." *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105, 1111(2008) (quoting *Firestone*, 489 U.S. at 111-13, additional citations omitted). Under those standards, health insurers and plan administrators obviously cannot – legally – seek to create and utilize subjective terms to the detriment of insured persons. Instead, they must act objectively and prudently, and using check the box tables to disclose and compare objective and subjective factors would make it easier to expose and stop imprudent and/or bad faith denials of new therapies or diagnostics.[10]

The same point is further illustrated by the Second Circuit's decision in *Durgin v. Blue Cross and Blue Shield ,* 610 F.3d 452 (2d Cir. 2009). There, a person with a spinal injury sought payments for a wheel chair with a special component to help him stand up out of the wheel chair. To that end, the patient's doctor supplied his own opinion and ten supporting medical journal articles. But the request was denied due to a plan administrator's subjective conclusion that plaintiff's doctor had failed to supply enough proof of controlled, clinical, or peer reviewed studies that would show that this particular man would be helped by such a wheel chair.

Through litigation, the denial was stricken. In legalistic terms, the decision was stricken because it imposed "an "atextual requirement [and] therefore "impose[d] a standard not required by the plan's provisions," *McCauley, 551 F.3d at 133* (internal quotation marks omitted), and accordingly was arbitrary and capricious."). Said in plainer words, the administrator tried to use subjective words to impose a burden of proof that was not stated in the policy. That of course was not proper under the fiduciary standard. Accordingly, the *Durgin* court explicitly ruled that under the terms of the contract, the insurers and plan administrators had not explicitly given themselves a right to use subjective terms and conclusions to disregard the opinions of treating physicians and published medical articles. As to medical articles, the court rightly rejected a frequent ploy, which is to disregard a medical article simply because it arose from a source other than a randomized or well-controlled clinical trial. As the court explained, the patient's doctor:

---

[10] Moreover, even ordinary contracts are judged by the words actually in the contract, and so courts seek "to give effect to the intention of the parties as expressed in the unequivocal language they have employed." *British Int'l. Ins. Co. Ltd. v. Seguros La Republica, S.A.,* 342 F.3d 78, 82 (2d Cir. 2003) (citation omitted). In addition, even ordinary contracts must be written and performed in good faith; [o]ne of the implicit terms in every contract is the duty of good-faith performance. *Denil v. DeBoer, Inc*., 650 F.3d 635, 639 (7th Cir. 2011);*Market Street Associates Ltd. Partnership v. Frey*, 941 F.2d 588, 593-96 (7th Cir. 1991). It requires the performing party, in this case the plan administrator, to avoid "tak[ing] deliberate advantage of an oversight by your contract partner concerning his rights under the contract." *Id.* at 594.

> "put forward ten articles from medical journals providing varying degrees of support for the medical benefits of the standing component. *Durgin v. Blue Cross and Blue Shield ,* 610 F.3d 452 (2d Cir. 2009). He also proffered his treating physician's statement that the standing component had led to "a marked decrease in spasticity, as well as an overall improvement in maintaining his skin integrity," had "very positively impacted his history of decubitus ulcers," and had "helped [him] maintain bone density and has prevented osteoporosis." J.A. 68, 74. *Durgin v. Blue Cross and Blue Shield,* 610 F.3d 452 (2d Cir. 2009).

However, the physician's opinion and the ten articles were deemed "not enough" by the plan administrator (BCBS). Specifically, in a common ploy, BCBS disregarded the medical articles as not from clinically controlled studies and then bootstrapped that conclusion to also seek to disregard the treating doctor's opinion letter as "no evidence." The Second Circuit rebuked BCBS' action as illegal; it held:

> "BCBS first stated that Durgin did not show that the standing component [of a wheelchair] was "medically necessary" because there were no "peer reviewed *clinically controlled studies"* showing "improve[d] net health outcomes." *Id.* (emphasis added). But the Plan does not contain any requirement that a service be supported by "peer reviewed clinically controlled studies" before BCBS will provide coverage, and such a requirement is impossible to square with the lower standard that the Plan establishes for "Medical and Scientific Evidence."
>
> ***
>
> While [on remand, the evidence from the patient] might ultimately be deemed inadequate to require BCBS to insure the standing component (a question we need not and do not reach), it cannot be said that *"no* evidence" showed the medical benefits that Durgin alleged. J.A. 76 (emphasis added). BCBS's second ground thus "arbitrarily refuse[d] to credit a claimant's reliable evidence," *Black & Decker, 538 U.S. at 834*, and cannot support BCBS's denial of the claim." *Durgin v. Blue Cross and Blue Shield ,* 610 F.3d 452 (2d Cir. 2009).

Under the preceding rulings, insurers and others cannot complain about glossary disclosures of objective and subjective factors, and cannot complain about regulators pushing for long-term changes to create fair and modern standardized terms regarding when payments will (or will not) be made for innovative new technologies.

Similarly, insurers are not allowed to subjectively "cherry pick" pieces of data to support denials. The point is explained well in *Holmstrom v. Metropolitan Life Ins. Co*., 615 F.3d 758, 777 (7th Cir. 2010). There, the Seventh Circuit reviewed and explained some of the hallmarks of improper denials of treatments:

> [S]elective review of and reliance on selected bits of information is a "hallmark of an arbitrary and capricious decision. *See Majeski v. Metropolitan Life Ins. Co*., 590 F.3d 478, 483-84 (7th Cir. 2009) (holding that denial decision was arbitrary where insurer selectively relied on pieces of evidence to support denial of benefits, while that evidence in context demonstrated disability); *Leger*, 557 F.3d at 832-33 (denial decision was arbitrary where insurer "cherry-picked the statements from her medical history that supported the decision to terminate her benefits, while ignoring a wealth of evidence to support her claim that she was totally disabled"); *see also Glenn v. Metropolitan Life Ins. Co.*, 461 F.3d 660, 672-74 & n.4 (6th Cir. 2006) (holding denial decision was arbitrary where plan selectively considered evidence to reach decision unsupported by the record as a whole), aff'd 554 U.S. 105, 128 S. Ct. 2343, 171 L. Ed. 2d 299 (2008) (approving Sixth Circuit's reasoning)."
>
> Courts also review health care decisions bearing in mind that grants of discretion to fiduciaries may also create economic conflict of interest situations that must be taken into account when reviewing a decision. "[A] structural conflict of interest is a relevant factor where the administrator has both the discretionary authority to determine eligibility for benefits and the obligation to pay those benefits. *Glenn*, 128 S. Ct. at 2346; *Jenkins v. Price Waterhouse Long Term Disability Plan*, 564 F.3d 856, 861 (7th Cir. 2009). "A structural conflict is one factor among many that are relevant in the abuse-of-discretion analysis . . . and will 'act as a tiebreaker when the other factors are closely balanced.' " *Raybourne v. Cigna Life Ins. Co. of New York*, 576 F.3d 444, 449 (7th Cir. 2009), quoting Glenn, 128 S. Ct. at 2351-52.

Under the preceding rules, insurers and administrators are duty bound to act in a systematic and objectively prudent manner. Therefore, they cannot complain about use of "check the box" glossary disclosures that would increase transparency and would more effectively communicate to insureds and medical experts the objective and subjective factors used in reaching outcomes on payments for new medical technologies. Indeed, opposing disclosure would violate the fiduciary duties to completely and accurately disclose material information to beneficiaries of trusts, such as ERISA plan participants. *Kenseth v. Dean Health Plan, Inc*., 610 F.3d 452, 466 (7th Cir 2010). "That duty encompasses both an obligation not to mislead the participant of an ERISA plan, and also an affirmative obligation to communicate material facts affecting the interests of plan participants." *Kenseth v. Dean Health Plan*, 722 F. 3d at 872 (following Kenseth I, 610 F.3d at 466). "We have previously held that an insurer has an affirmative obligation to provide accurate and complete information when a beneficiary inquires about her insurance coverage." *Kenseth I,* 610 F.3d at 468; *Bowerman v. Wal-Mart Stores, Inc.,* 226 F.3d 574, 590 (7th Cir. 2000). In fact, the duty goes even further because a fiduciary is under a duty "to timely identify and communicate to the beneficiary material facts affecting the interest of the beneficiary which he knows the beneficiary does not know and which the beneficiary

needs to know for his protection in dealing with a third person." (internal quotation marks omitted))." *Killian v. Concert Health Plan*, 742 F.3d 651, 668 (7th Cir. 2013).

Additional Unknown Numbers of Denials Based on Experimental Exclusions

To the best of my knowledge, it is impossible to document the complete extent of denials tied to "experimental exclusions" because insurers are not required to and do not publicly report such numbers to state or federal regulators. If insurers choose to assert the untenable claim that all is well and there is no need for better glossaries of terms, state insurance commissioners can and should demand immediate reporting on denials tied to experimental exclusions in persons with cancer and other dangerous diseases. In this computerized age, such reports could and should be generated within a few days.

There are, however, objective reasons to believe that every year brings thousands of incorrect denials of access to new medical technologies. Examples lie in the many cases reported in the articles cited above, as well as Ms. Parrish's demonstration of how some insurers set their software to target and refuse to pay claims for "new" technologies. There also are other factors to consider, such as the fact that examples some health insurance companies back down and agree to pay for therapies without the need for a lawsuit if a trial lawyer enters the picture. For example, I was personally involved in an instance in which, in 2009, BCBS of Illinois informed a 52 year old woman with stage IV cancer that it would not approve a stem cell transplant that had been recommended by the word's best cancer focused hospital (MD Anderson - Houston). The stem cell transplant had been recommended due to the woman facing a second, massive return of a previously indolent blood cancer known as DLBCL. After some chemotherapy brought some initial improvement, it later became plain that her cancer could not be fully controlled by chemotherapy, and her physicians advised that near term death was inevitable unless stem cells were transplanted.

Despite the situation, BCBS told the woman – in a casual phone call – that it would not approve the stem cell transplant. Through the serendipity of life, I became involved in the situation and made it plain to Blue Cross that a federal lawsuit would be filed to challenge the denial. Thereafter, Blue Cross soon backed down and paid for the procedure without the need for a lawsuit. Six and a half years later, that woman is thriving.

We can only guess how many other similar situations have occurred. And we also can only guess how many other wrongful denials are allowed to stand because serendipity did not link up the insured and a lawyer who understood the law and facts, and was willing to work for free. Indeed, there no doubt are additional situations that do not become lawsuits even when the denial was improper. The point is illustrated by a 2015 denial of treatment to a woman with a unique history involving breast cancer and apparent metastases. And, once again this is a

situation as to which I know the facts from personal involvement. In this instance, however, the insurer refused to back down and Mrs. Doe declined to proceed with litigation for personal reasons. Thus, the facts of her situation illustrate why it is reasonable to think that many hundreds or thousands of people are similarly mistreated every year, and simply knuckle under without filing suit.

Detailed specifics of Mrs. Doe's situation are set in Appendix 2 because they very precisely illustrate how some plan fiduciaries abuse subjective standards to assert demands for studies that can never and will never be performed because a person's medical history is so unique it cannot possibly be replicated in a randomize trial In brief, Mrs. Doe's situation is a classic illustration of an "n of 1" situation for which there can never and never will be a "randomized clinical trial" to prove that a new technology is "effective" or "medically necessary." Mrs. Doe's journey with cancer began during 2008. That year, Mrs. Doe received a diagnosis of breast cancer in both breasts. During 2008-09, Mrs. Doe went through –and her health insurance paid for –mastectomy of both breasts. Later that year, she went through surgical removal of her fallopian tube and both ovaries. The surgeries were intended to treat and suppress breast cancer and risks of recurrence. Subsequently, Mrs. Doe went through multiple chemo-therapies and other anti-cancer drug therapies. As of year-end 2009, there was no evidence of cancer in Mrs. Doe.

But, things changed in 2014. That year, biomarker tests indicated possible cancer, and her doctor ordered subsequent body scans by CT and MRI. The scans identified four possible metastases in Mrs. Doe. Two small tumors were found on her chest wall and two on her liver. The tumors on the chest wall were successfully removed by surgery in January 2015. For some persons, the two small tumors on the liver also would have been removed through surgery. But a surgical procedure for the remaining tumors would have been less wise for Mrs. Doe because the tumors were located in areas of the liver not readily accessible for surgical removal. In a March 4, 2015 letter, one of her doctor's explained the situation as follows: *For the liver lesion, we suggested liver-directed therapy. Because of the location of the tumor, surgery was not appropriate. It was decided to do other local liver-directed therapy such as cryoablation/radiofrequency ablation versus radioembolization.*

The end point of the story is that after her long journey with cancer, the entities overseeing Mrs. Doe's insurance refused to pay for the cryoablation for the liver tumors. They refused even though the cryoablation procedure is in essence simply a more complex version of destroying warts by freezing the tissue, and is well-accepted for many purposes. Payment for the procedure was denied on the grounds that there are no studies showing "long term successful outcomes in persons with histories similar to Mrs. Doe's history." To borrow a popular phrase these days: OMG! Of course there are no such studies, and there never will be: Mrs. Doe plainly is "n of 1." (Or, maybe she is "1 of 10," but those 10 will never find each other, much less become part of a randomized clinical trial.) And, any unbiased doctor knows and would admit

that Mrs. Doe is "n of 1" (or maybe 10).

Nonetheless, the insurer demanded the impossible, in bad faith. More specifically, set out below is the precise language of the denial letter regarding Mrs. Doe. However, underlining has been added to highlight the rampant use of subjective terms and demands not set out in the insurance plan at issue:

> *The cryoablation of liver metastasis from breast cancer has not been proven to be safe, effective, and standard of care based on current medical standards. There is a lack of published high grade clinical outcome evidence of cryoablation of metastatic liver metastasis from breast cancer. Published data on cryoablation of liver metastasis are mostly from uncontrolled single institutional experiences reporting on initial response. No prospective controlled study has been conducted to investigate long term outcome (local control, survival and toxicity) of cryoablation for metastatic liver lesion from breast cancer. Until long term clinical outcome evidences are available in peer reviewed literature, it is reasonable to consider cryoablation of metastatic liver lesion from breast as not medically necessary. NCCN practice guideline does not include cryoablation in the management of liver metastasis from breast cancer.*

Ultimately, the big picture point is that subjective terms are dangerous and the standards used (or not used) should be fully spelled out in policies and should be fully disclosed through glossaries with “check the box” tables and other tools for comparing objective and subjective factors.

Overall, Mrs. Doe’s case facts illustrate why systemic changes are badly needed. While it is possible to challenge particular denials, there are notable barriers to challenging denials. The barriers include the reality that most patients lack the money, time and knowledge needed to find any of the relatively few lawyers who understand the relevant policies, case law and medical facts. Time also poses very real barriers for litigation when cancers already are at stages III and IV. Treatment decisions sometimes can be delayed for days, but not months and too often cannot be delayed for even weeks. Therefore, it is critical that the Department of Labor and state regulators work with health insurers and expert groups to expand glossaries so that consumers can make better choices and avoid insurance companies with the worst policy terms.

Section II: Additional Reasons to Act, and Specific Suggestions

Policy Terms are Material For Tens of Millions of Americans With Cancer and Other Diseases

Information on the scale of cancer further illustrates the larger context and the need for prompt actions, instead of delay. Approximately 4% of Americans fall under the definition of "cancer survivor." Today, that number is around 14 million people; the number is expected to approach 19 million by 2024. Part of the reason for the increase is that cancer incidence rates escalate significantly with older age, and thus America's massive "baby boom" population is a growing cohort of persons facing materially increasing rates of cancer. At present, approximately 1.6 million Americans are diagnosed each year with cancer. In a decade, the 16 million people diagnosed with cancer will exceed number the total population of the cities (not suburbs) of New York, Los Angeles and Chicago. These and other statistics are at the American Cancer Society's most recent online compilation of cancer data.[11] And, further detailed information on the scale and pace of cancer and cancer treatments is set out in ASCO's free, 2016 publication: *State of Cancer Care in America: 2016*.[12]

14 Million Americans Survived Cancer, But Cannot Access the Information needed to Intelligently Purchase Health Insurance

For the 14 million Americans who are cancer survivors, having access to the best possible therapies and diagnostics often – not always – can make a difference between life and death. Indeed, for survivors, a real key is taking advantage of new, highly sensitive biomarker tests that can find new cancers far earlier than could be done even two or three years ago. And, more tests in the works. Indeed, a world class genetics firm (Illumina), and billionaires such as Bill Gates and Jeff Bezos, have put their science and money to work seeking to create a molecular test that could find any cancer at the earliest possible moment. They are seeking that goal through a new joint venture announced this year. The new venture is "Grail." It is headed up by the Google genius, Jeff Huber, who developed previously unheard of technologies, such as Google Maps and Google earth. And, Mr. Huber is highly motivated; his wife died in her 40s due to surprise cancer. Their goal? Start testing Grail in 2017 and bring it to market in 2019. [13]

With so much new technology in progress, that set of 14 million cancer survivors has every reason to want to shop oh so carefully for health insurance policies in order to find and purchase a policy that is reasonable (or perhaps even generous) in its definition of

---

[11] http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/.
[12] http://www.asco.org/practice-research/state-cancer-care-america-2016
[13] http://www.bloomberg.com/news/articles/2016-02-10/google-s-huber-to-lead-illumina-cancer-detecting-startup-grail

"experimental." But in view of the variations and numbers set out in Tables 1 and 2, they cannot possibly accomplish that goal. Therefore, change is imperative, so that potential buyers at high risk actually can evaluate choices themselves, and/or receive reasonably expert guidance from expert advisory groups.

Advances in Medicine Make It Even More
Imperative to Act Quickly and Knowledgeably

The imperative need for action cannot be disputed even if medicine were standing still. The evidence is plain: for many years, the terms "experimental" and "medically necessary" have been abused by some health insurance companies and plan administrators. Moreover, the data in Tables 1 and 2 show the abuse continues up through today. It is therefore plain that the health insurers have known of the issues for many, many years, but have failed to fix them. And, as shown by the cases discussed above, these are not simply matters about money. The issues instead can be absolutely critical for anyone trying to avoid death from fast moving blood cancers, breast cancers or other major diseases. And, the point goes well beyond cancer, and applies to any person suffering from a major disease of any kind, including Parkinson's, Alzheimer's, diabetes and the other 15-20 major scourges. Therefore, with so much at stake for so many, it is troubling (to say the least) that most (not all) health insurance companies have failed to take material steps towards better, more consistent, and more modern terms and policies that reflect modern medical standards. Therefore, it seems plain the Department of Labor and state insurance regulators need to make it a top priority to work with the health insurance industry to quickly expand glossaries, with many put into use for 2017 health insurance contracts. And, work should begin now with experts to adopt meaningful, cogent, and standardized terms that actually implement modern medical standards.

The need for rapid action is even more imperative because medicine and science are not standing still and rapid advances are occurring, especially as to cancer. The need for major change is accentuated by the arrival of new moonshot efforts for "precision medicine" treatments and diagnostics, which Vice-President Biden and President Obama are pushing to accelerate. Precision medicine involves new technologies that can and do save lives by looking very precisely at the genetic and other "omic" characteristics of a particular person. Unfortunately, the current "experimental" and "medical necessity" terms proven above are even less useful in the age of precision medicine. The failure of health insurers to build better terms for the present situation is especially troublesome because the current issues and problems were foreseeable and in fact were foreseen and much discussed at least 15 years ago. Specifically, in 2001, the Institute of Medicine issued a widely known study – *Crossing the Quality Chasm: A New Health*

System for the 21st Century"[14] - pointing out the need for "major restructuring" of our health care systems, including health insurance plans and treatments. Among other things, the study pointed out the need to focus on 15 or 20 chronic conditions that account for the bulk of health care problems and expenses, and the need to look for and find precision answers for particular afflicted people through genetic and other molecular testing.[15] However, that effort is being materially delayed and befuddled by payors and billing systems that place multiple barriers in the way of obtaining paid access to precision molecular diagnostics.

Many of the barriers to precision medicines and diagnostics have been identified and explained in some detail in a series of papers by Bruce Quinn, an MD/PhD with extensive experience in medicine and diagnostics in both the public and private sector.[16] In a 2008 white paper, he provided a big picture view of the then-existing barriers. Of particular note here, Dr. Quinn repeatedly pointed out that private and public payors are demanding impossible amounts of "proof of efficacy" in light of modern medical ethics and standards. In simplest terms, one of the problems is that health insurers and other payers have spent years and years insisting that a new treatment or diagnostic will deemed unproven – and will not be paid for – until it is put through a "randomized clinical trial." That is, the insurers have been insisting on proof through a process that compares the old treatment to the new one through a trial in which people are randomly assigned to receive either the old method or the new method. That familiar sounding old saw about "randomized trials" might seem comforting to some. But in fact, using that old saw is a sure way to cause large delays and untold numbers of needless deaths. Why? Because, today, it is often unethical (and thus impossible) to conduct those randomized trials because some of today's new technologies are so obviously effective that doctors and researchers cannot ethically subject people to the randomized trials demanded by insurers. Why? Because doing a randomized trial would deny many of the people in the trial access to a great new treatment. Therefore, the trial cannot be conducted. By continuing to demand the impossible, some insurers are creating a situation much worse – and more deadly - than the well-known "Catch 22."

Dr. Quinn's 2008 Diagnoses of Three Key Barriers,
Including Insurers Demanding Impossible Proof

Dr. Quinn's 2008 "white paper" presented his diagnoses of three primary barriers to faster, better implementation of precision medicine. He diagnosed health insurers, CMS/Medicare, and medical codes as key sources of the problems. Dr. Quinn's diagnoses are presented in some detail below, for two reasons. First, his diagnoses should help the Department of Labor and state regulators to more quickly see the problems, and how insurers fit in. Second, the other big

[14] IOM (Institute of Medicine) Washington, D.C: National Academy Press; 2001. Crossing the Quality Chasm: A New Health System for the 21st Century.
[15] For a broad but brief view of the history, see Janet Corrigan, Crossing the Quality Chasm, http://www.ncbi.nlm.nih.gov/books/NBK22857/
[16] http://www.faegrebdc.com/bruce-quinn

picture point is to see that the 2008 problems still have not been fixed. Specifically, as shown by Table 1, the 2008 problems still exist because many insurers continue to use inconsistent and vague terms that do not fit with the rapid and substantially important changes in the use of molecular biology.

For purposes of this comment, a key point to appreciate is that consumers and doctors should flock to relationships with health insurers who replace obsolete insurance policy terms with new, up to date terms that make sense and fit today's medical world. By adopting the recommendations in this comment, the Department of Labor and state regulators could help reward forward looking and fair-minded insurers because the new comparators would help experts and consumers see and appreciate better health insurance policies with better terms. Without such comparators, everyone remains mired in the same old, same old. Therefore, it seems critically important to encourage forward movement, and a few examples of check the box tables are discussed *infra*. But, before turning to where some progress has been made, set out below are key sections from Dr. Quinn's 2008 white paper that identified three key problems arising from private insurers, Medicare/CMS, and the various billing codes. The paper is titled: *Crossing the Three Chasms: Complex Molecular Testing and Medicare Regulations (2008).*[17]

For molecular personalized medicine, not one but three chasms must be crossed. As we describe in detail, these chasms stem from new revisions to Medicare rules for billing jurisdiction, Medicare payment rules, and dilemmas in making coverage decisions for innovative technologies. Personalized medicine – getting the right treatment to the right patient at the right time – is a pillar of efforts to bring increased effectiveness and efficiency to healthcare. Frequently, this goal will be unattainable unless physicians have precise molecular information about the disease being treated. Therefore, it is crucial that the healthcare system facilitates the adoption of new molecular technologies when they are clearly shown to be effective.

In this white paper, we demonstrate that several critical reimbursement barriers, or "chasms," have emerged to block the progress of diagnostic molecular medicine. Unlike scientific or technological barriers, the three chasms facing molecular diagnostics are regulatory conventions. If not addressed, these conventions could easily present a more severe barrier to progress than do purely scientific challenges.

Two of the chasms (billing – Medicare's specimen rules and coding – the US system of legacy code formats) are unintended consequences of certain regulations, coding conventions, and statutes. These rules are already in collision with the realities of molecular diagnostics, but the resulting problems could be solved by regulatory change or minor statutory change.[18] ***The***

[17] The paper can be found by running a web search for the title, but the Faegre website brings the paper up without producing a URL address.

[18] *Regulatory change is a rule revision which can be undertaken directly by a government agency. Statutory change describes the revision of a point of Medicare law by Congress.*

third chasm is the limitations of current approaches to evaluating the value of complex tests in molecular personalized medicine. Payers and providers do not have a standard body of tools for evaluating the effectiveness of new approaches, particularly when the results of a test substantially shift existing treatment pathways. *(emphasis added)*

* * *

Too often, good intentions – which look for large, randomized, prospective clinical trials to verify every claimed value – run afoul of practical realities. For instance, a new molecular test for prostate cancer, developed through $10M of preclinical and clinical research, confirms that for a given patient, his chance of prostate cancer recurrence is 2% or below. As a result, he will not be given radiation therapy or chemotherapy because the risks of the therapy are greater than his negligible risk of tumor recurrence. Assume that development trials assure us that the risk of recurrence is indeed 2% or less. An insurer may thus take that stance that while the data is promising, "there is many a slip twixt the cup and the lip" and therefore, the insurer cannot accept the test as "proven" valuable until after the completion of a prospective, randomized controlled trial.

Surprisingly, the insurmountable problem here is not the duration of the trial, the cost of the trial, or the time required to analyze and publicize the results. Rather, the randomized trial cannot be conducted at all, because no institution will take patients with a 2% risk of recurrence and randomize half of them to radiation and chemotherapy. That is, the trial cannot be randomized because clinical equipoise between the two treatments cannot be assumed. Many new complex tests, by their nature designed to powerfully impact clinical paradigms of decision-making, will negate clinical equipoise and thus block randomized trials before such trials can be undertaken.[19] There will be circumstances where payer coverage, withheld until after randomized trials are undertaken, will permanently block test availability. In short, there is a net loss of social benefit. *(emphasis added)*

Although important, the point we make is not new. Thought leadership in the area of evidence-based medicine recognizes that a clearly established impact on medical decision-making is the platform for coverage decisions for diagnostics.[20] The problem described here,

---

[19] The general point, that strong but not definitive data may make randomized trials unethical, has been made before, e.g., Ioannidis J et al. (2001) JAMA 286:821-30.

[20] E.g., Straus SE et al. (2005) Evidence Based Medicine, 3rd Ed., Churchill-Livingstone. Jenicek M (2003) Foundations of Evidence Based Medicine. Informa. Riegelman RK (2004) Studying a Study, Testing a Test. Williams & Wilkins. Khoury et al. (2007) The continuum of translation research in genomic medicine. Genetics in Medicine 7:665-74. Ramsey SD et al. (2007) Toward evidence-based assessment for coverage and reimbursement of laboratory-based diagnostic and genetic tests. Am J Managed Care 12:197-202. Lewin Group/Advamed (2005) The value of diagnostics innovation, adoption, and diffusion into health care.

that the accuracy and clinical validity of new tests often make prospective randomized trials unethical, is well-recognized in the evidence-based medicine literature. ***Practical experience suggests that these concepts may be very poorly recognized at the level of insurer coverage.***[21] ***New paradigms must be implemented judiciously at the level of actual coverage decisions that recognize this paradox and provide a reasoned, clinically sound approach to determining*** **when coverage is appropriate and raises the effectiveness and efficiency of treatments.** (emphasis added)

* * *

3. Ensure acceptance of appropriate frameworks for coverage decisions.

*Develop white papers and peer-reviewed publications to clearly describe the problems with current evaluation of the value of new complex molecular tests in the actual world of payer decisions, including Medicare, and provide a framework for effective decisions. Evaluation of novel molecular tests may require a distinct framework from the kinds of analysis focused on changes in clinical decision- making. (****For example, the "poster child" dilemma occurs when initial clinical data may be so clear that randomized trials are unethical, but some payers may insist that coverage follows completion of such a randomized trial.****) No formal change of existing CMS codes and laws is required. As noted in the body of this paper, these frameworks exist in the public policy, public health, evidence-based medicine literature. The need addressed here is to ensure that this thought capital is readily available to payers, including Medicare contractors. For example, creation of an explicit Medicare guidance document or inclusion of guidance in Medicare's contractor program manual would be very helpful.* (emphasis added)

A Further Problem – Insurers Refuse "N of 1" Studies and Data

A further point is to explain more explicitly a point alluded to by Dr. Quinn. The point is that the "experimental" and "medically necessary" terms quoted above fail to reflect the modern knowledge that people are highly unique and variable, and therefore "N of 1" studies are increasingly important and useful. But, despite scientists accepting "N of 1" studies in some contexts, insurers and their lawyers and plan administrators continue to policies and/or denial latters that purport to demand proof of effectiveness through journal papers from "major institutions" regarding "randomized controlled trials." A further point about "N of 1" is that some people are so unique in their medical history that there never can or will be clinical trials applicable to them because their medical history is so unique. Consider, for example, the unique medical history of Mrs. Doe, describe earlier. Yet another relevant "N of 1" point is that even massive randomized trials are in some ways illusory because many drugs deemed "effective" simply will not and do not work in many people because we are all so genetically variable. The

[21] Institute of Medicine (2008) Knowing What Works in Healthcare: A Roadmap. US must still "develop a common language and standards" for evidence assessment and decision-making.

latter points are cogently explained in a 2015 article by Nicholas J. Schork, a director of human biology at the J. Craig Venter Institute in La Jolla, California, and a professor at the University of California, San Diego, and at the Translational Genomics Research Institute (TGen) in Phoenix, Arizona, USA. He explained:

> "Every day, millions of people are taking medications that will not help them. The top ten highest-grossing drugs in the United States help between 1 in 25 and 1 in 4 of the people who take them (see 'Imprecision medicine'). For some drugs, such as statins – routinely used to lower cholesterol – as few as 1 in 50 may benefit. There are even drugs that are harmful to certain ethnic groups because of the bias towards white Western participants in classical clinical trials.
>
> Recognition that physicians need to take individual variability into account is driving huge interest in 'precision' medicine. In January, U.S. President Barack Obama announced a US $215-million national Precision Medicine Initiative. This includes, among other things, the establishment of a national database of the genetic and other data of one million people in the United States.
>
> Classical clinical trials harvest a handful of measurements from thousands of people. Precision medicine requires different ways of testing interventions. Researchers need to probe the myriad factors – genetic and environmental, among others – that shape a person's response to a particular treatment.
>
> Studies that focus on a single person – known as *N*-of-1 trials – will be a crucial part of the mix. Physicians have long done these in an ad hoc way. For instance, a doctor may prescribe one drug for hypertension and monitor its effect on a person's blood pressure before trying a different one. But few clinicians or researchers have formalized this approach into well-designed trials – usually just a handful of measurements are taken, and only during treatment.
>
> If enough data are collected over a sufficiently long time, and appropriate control interventions are used, the trial participant can be confidently identified as a responder or non-responder to a treatment. Aggregated results of many *N*-of-1 trials (all carried out in the same way) will offer information about how to better treat subsets of the population or even the population at large.
>
> Formalizing and scaling up the *N*-of-1 approach means solving various practical problems. These include exploiting the diversity of health-monitoring devices, developing new ones and identifying appropriate disease biomarkers, such as tumour DNA circulating in the bloodstream. It will also require a cultural shift on many levels – in regulatory agencies, in pharmaceutical companies and, most of

all, in the clinic."

See Nicholas J. Schork, Personalized medicine: Time for one-person trials, *Nature,* 520, 609-611 (30 April 2015) doi:10.1038/520609a.

Mr. Schork's list of needed "cultural shifts" is fine as far as it goes, but also should have included health insurers, plan administrators and state insurance regulators. The antiquated policy terms shown above in Table 1 do not explicitly provide for or account for "n of 1" situations. Therefore, new glossary check the box tables are needed to expose the insurers which are failing to accept outcomes from "n of 1" trials, or other small but informative trials of a few people with a rare disease.

Example Check the Box Tables for Health Insurance Glossaries

The following "check the box" tables are merely examples to be improved by medical experts, health insurers, others in health care, and regulators.

Again, the term "technology" is used in a generic sense and is intended to cover the range of medical care from treatments to drugs to diagnostics to early detection tests.

The first table should be a relative "no brainer" to implement. At its core, it simply would reveal whether an insurance plan will (or will not) pay for a particular molecular test that already is in the market place, usually with full FDA approval. And of course the responses could be grouped so that experts and consumers could compare and see which plans would cover which tests. Surely tables of this sort could and should be ready for use before 2017 policies are offered for sale, and surely expert medical groups would have much to say about the answers. In this vein, consider the questions when Illumina, Mr, Huber and all succeed in bringing Grail to market. Most of America's 14+ million cancer survivors will want to know: is Grail covered, yes or no? And, how often will you pay for the test to be run?

Example Check the Box Table for Existing Cancer Related Genetic/Molecular Tests

This is an example of a check the box table that will show whether an insurer will (or will not) pay for existing genetic/molecular tests when ordered for a patient with a stage II, III or IV cancer, when ordered by a board certified oncologist (Scenario A), when ordered by any licensed oncologist (Scenario B), or when ordered by a non-physician or physician certified as competent by the American Board of Genetic Counseling (Scenario C). The listed tests are examples of existing tests aimed at one or a few genes related to a particular form of cancer or multi-gene tests useable to assess a wider range of	Y or N	Y or N	Y or N

genetic and other molecular conditions involved with many forms of existing cancers (e.g., most blood cancers). Additional variables could be easily added, such as whether a patient counseling session is required before ordering a test, or variations based on the stage of cancer.				
Test Name (CPT codes could be added)	Description of Test and related web page site	A	B	C
Cologuard	"Cologuard uses advanced stool DNA technology to find elevated levels of altered DNA and/or hemoglobin in these abnormal cells, which could be associated with cancer or precancer. http://www.cologuardtest.com/"			
Foundation One Heme	"FoundationOne Heme uses comprehensive, clinical grade next-generation sequencing (NGS) to assess routine cancer specimens for all genes that are currently known to be somatically altered and unambiguous drivers of oncogenesis in hematologic malignancies and sarcomas. FoundationOne Heme simultaneously detects all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and select gene rearrangements in 405 cancer-related genes. In addition to DNA sequencing, FoundationOne Heme employs RNA sequencing across 265 genes to capture a broad range of gene fusions, a type of alteration that is a common driver of hematologic cancers and sarcomas." http://foundationone.com/learn.php			
Caris Molecular Intelligence	"Caris Molecular Intelligence uses multiple molecular testing technologies – including Immunohistochemistry, Chromogenic *in situ* Hybridization (CISH), Fluorescence *in situ*Hybridization (FISH), 46- and 592-gene Next-Generation Sequencing (NGS), Sanger Sequencing, Pyro Sequencing and Fragment Analysis – in order to detect and analyze biomarkers. Coupled with an exhaustive review of literature correlating biomarker to drug responses, Caris Molecular Intelligence provides the information oncologists need in order to personalize cancer treatment based on the biology of their patient's tumor." http://www.carislifesciences.			

	com/platforms/cmi-overview/			
Broca	"BROCA is useful for the evaluation of patients with a suspected hereditary cancer predisposition, with a focus on syndromes that include breast or ovarian cancer as one of the cancer types. Depending on the causative gene involved, these cancers may co-occur with other cancer types (such as colorectal, endometrial, pancreatic, endocrine, or melanoma). Single gene testing (next generation sequencing) can be ordered for any gene on the BROCA panel. This assay sequences all exons and flanking intronic sequences." http://tests.labmed.washington.edu/BROCA Tested genes presently include: *AKT1*, *APC*, *ATM*, *ATR*, *AXIN2*, *BAP1*, *BARD1*, *BMPR 1A*, *BRCA1*, *BRCA2*, *BRIP1*,*CDH1*, *CDK4*, *CDKN2A*, *CHEK1*, *CHEK2*, *CTNNA1*, *FAM175A* (Abraxas), *FH*, *FLCN*, *GALNT12*, *GEN1*, *GREM1*, *HOXB13*, *MEN1*, *MLH1*, *MRE11A*,*MSH2* (+*EPCAM*), *MSH6*, *MUTYH*, *NBN*, *NF1*, *PALB2*, *PALLD*, *PIK3CA*, *PMS2*, *POLD1*, *POLE*, *POT1*, *PRKAR1A*, *PRSS1*, *PTCH1*, *PTEN*, *RAD 51B*,*RAD51C*, *RAD51D*, *RB1*, *RET*, *RINT1*, *RPS20*, *SD HB*, *SDHC*, *SDHD*, *SLX4*, *SMAD4*, *SMARCA4*, *STK11*, *TP53*, *VHL*, and *XRCC2*.			
Comment: The listed tests are simply a few examples. Obviously, a list of existing genetic tests can be generated at any time and updated at any time. Additional scenarios of course could be added to address other variables. Price points also could be added, whether using list prices, numbers reflecting list price plus a % discount of X, or other appropriate variables. Some employers, such as Google, already are offering potentially life saving broad coverage of molecular cancer testing as a means to attract employees. See http://www.reuters.com/article/google-health-cancer-idUSL1N0SV3WR20141105 (last visited March 27, 2016). However, to date, the vast majority of health insurance companies have refused to pay for many of the potentially life saving molecular tests, and that objective information should be communicated to insurance purchasers. Most such tests fall under a category known as MAAA, which stands for multi-analyte algorithm-based assays. The practices of CMS for such tests have generated notable debates and arguments among test sponsors, including its fall 2015 decisions and pricing methods. *See generally* https://www.genomeweb.com/molecular-diagnostics/initial-cms-2016-lab-test-pricing-cuts-rates-several-multi-analyte-algorithm (last visited March 27, 2016).				

Example Check the Box Table for New Technologies for Cancer

The check the box table below is a bit more complex. It keys off of various actions FDA may take with respect to medical technologies, at different points in time. While the words below may not be familiar to many, the words are highly familiar to expert groups, which could easily assess the favorability (or not) of the terms of a particular health insurance contract.

Check the Box Table to Show the Impact of submission of New Cancer Technology Application, and /or FDA and/or CMS Approval, After Successful Completion of an Approved Phase III Clinical Trial for the New Technology			
Possible grading level	List of objective events that will (or will not) result in payments under a health insurance contract	Yes	No
Platinum	Will pay for a new technology beginning the day after FDA accepts a New Drug Application for the technology, for on label or off label indication, when recommended by a board certified oncologist practicing in an NNCN cancer center		
Gold	Will pay for a new technology beginning the day after FDA accepts a New Drug Application for the technology, only for indication sought in NDA, when recommended by a board certified oncologist practicing in an NNCN cancer center		
Silver	Will pay for a new technology beginning the day after FDA approval for the technology, for on label or off label indication, when recommended by a board certified oncologist practicing in an NNCN cancer center		
Bronze	Will pay for a new technology beginning the day after FDA approval for the technology, only for on label indication, when recommended by a board certified oncologist practicing in an NNCN cancer center		
Tin	Will pay for a new technology beginning six months after FDA approval for the technology, only for on label indication, when recommended by a board certified oncologist practicing in an NNCN cancer center		
Cement	Will pay for a new technology beginning the day after both (1) FDA approval and (2) AMA issuance of Category I CPT code for the technology		
Comment: These examples are based on the reality that when a new technology has successfully met the endpoints established for a Phase III clinical trial, the technology is highly likely to receive FDA approval, and is highly likely to be useful to persons with diseases. Similar check the box tables could be built for successfully meeting endpoints in "pivotal" Phase II and/or Phase IB trials, and for other FDA actions, such as granting “Breakthrough Therapy ” status to a new technology, or granting “Orphan Drug Designation” to a new technology. Check the box tables should be built for variables of that sort because new technologies and testing methods have caused FDA to increasingly approve new technologies			

after and/or during Phase II trials. Those changes are occurring in part because, to oversimplify, it is unethical to run randomized clinical trials that deprive a participant of access to a new technology that plainly is better than an old technology and that could save the life of the patient. Similar check the box tables could be built for other objective factors, such as a technology recommended by expert guidelines issued by NCCN, or recommendation by professional medical societies. Expert groups already understand the importance of these factors and terms, and so do responsible health insurance companies and/or plan administrators. Indeed, lawsuits over issues of paying for new technology have proved that the latter two groups already purport to use objective factors of this sort (e.g., FDA approval, NCCN guidelines) as part of an internal decision-making process used to decide when to pay (or not) for a new technology. Moreover, some health insurance companies have made public guidelines or policies that explicitly cite to objective factors of the sort listed here. *See, for example*, https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Genetic_Testing_HBOC_Syndrome.pdf. Less transparent health insurance companies and/or plan administrators may or may not have such policies, and may or may not stay up to date. Such insurers often do not really understand these events, and instead engage in ad hoc processes that are materially behind in applying new science and depend heavily on too often arbitrary judgments by non-expert doctors and/or computer software systems that simply refuse to pay for technologies coded as "new" in the computerized medical billing systems that predominate today. More broadly, check box tables of this sort could be used for many of the major types of diseases because more or less similar processes are utilized for most technologies for most diseases.

Some Insurers are Involved in Some New Thinking, But More is Needed, Quickly

Some insurers are making some moves to update terms and policies to adapt to modern medicine, but some efforts are much too slow and others are unwieldy. One example lies in the "Investigational (Experimental) Services" policy of Blue Cross Blue Shield of North Carolina.[22] According to the words in the policy, it was first created in November of 2009, was reviewed on March 18, 2015 and the next review has been slated for two years later, in March 2017. Those dates are important to note because they reflect an unacceptable lack of urgency. Again, every day, over 1,500 Americans die of cancer and thousands more are diagnosed with new cancers. Some of these people can and would be saved by the new technologies now in clinical trials or that already are FDA approved. What can possibly be more important than saving lives? In addition, recall the caselaw presented earlier which demonstrates that most health insurers and plan administrators are fiduciaries obligated to act solely for the benefit of their insured, and they are obligated to provide their policyholders with complete and up to date information, even if the

[22] https://www.bcbsnc.com/assets/services/public/pdfs/bluemedicare/medicalpolicy/investigational_services.pdf

policyholders do not know the right questions to ask. In view of the pace of modern medicine, an advocate for persons with major diseases might well argue that it is per se a breach of fiduciary duty for BCBS to allow two months to pass between updating its thinking and actions on "experimental practices," much less two years. And, an even more aggressive advocate might argue that criminal charges should be filed when corporate officers and directors at insurers or plan administrators endanger lives by failing to act promptly despite significant known risks of injury or death if they fail to act.[23] In that same vein, one might also consider the Yates Memorandum from the Department of Justice, and its focus on pursuing prosecution of individual corporate officers and directors.[24] In light of these and other legal rules, catalysts implemented by the Department of Labor might well help some slow moving companies and individuals avoid future civil or criminal litigation.

A different sort of some better thinking by insurers is the G-003 "Coverage Summary" by UnitedHealth for genetic and other molecular tests.[25] This 36 page document is chock full of information about when tests may (or may not) be paid for. It covers, for example, some molecular testing topics in great detail, replete with jargon and defined terms that would baffle the average consumer. It also includes lists of specific tests approved for payments by some plans (think again of Grail and the first example of a check the box table for products on the market). UnitedHealth's document is a useful step forward to adapt to modern medicine. The 36 page policy is, however, overwhelming and illustrates the need to break information down into check the box tables and/or other tools that would make it possible to effectively manage and compare information between payors.

Overall, the other good news is that are other experts out there who are working on these issues and who could bring significant expertise to the table so that at least some changes can be made quickly. Dr. Quinn, for example, recently authored a comprehensive review of various aspects of the status of precision diagnostics, and did so for a consortium of diagnostics companies working through an association known as the Personalized Medicine Coalition. The newer paper is titled The Future of Coverage and Payment for Personalized Medicine Diagnostics.[26] In addition, persons such as Mrs. Parrish obviously could add value. And, I would

---

[23] *See People v. O'Neil*, 550 N.E.2d 1090 (Ill. App. 1990)(trial resulted in conviction of a company president, plant manager, and foreman for a form of homicide following the death of workers due to unsafe conditions created by the company through the three defendants).

[24] http://www.dandodiary.com/2016/03/articles/director-and-officer-liability/the-yates-memo-and-the-responsibilities-of-corporate-directors/

[25] https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/UnitedHealthcare%20Medicare%20Coverage/Genetic_Testing_UHCMA_CS.pdf (last visited March 27, 2016).

[26] http://www.personalizedmedicinecoalition.org/Resources/The_Future_of_Coverage_and_Payment_for_Personalized_Medicine_Diagnostics (last visited March 27, 2016)0

like to think that trial lawyers such as me could add some value. And, of course the AMA, ASCO and other professional groups no doubt would get involved.

Conclusion – It Is Well Past Time for Rapid Action

Failures of health insurance companies and policies can be uniquely dangerous. Unlike most breach of contract situations, breach of health insurance and administration obligations can and do result in physical harms and deaths. Breaches also can bankrupt all but the .01% if a family is forced to pay for an expensive life saving procedure wrongly denied to a family member. It is, therefore, illogical and unwise to continue to tolerate the continuing sale of inscrutable health insurance policies with inconsistent and subjective "experimental exclusions" and other related terms. The baby boom demographics make the situation even more urgent as tens of millions of Americans are now at ages of rapidly and severely increasing incidence rates for cancer and other diseases; some of the upward curves are so steep they look like the blades of hockey sticks. Rapid changes in the glossary are needed to make insurance policy terms more comparable, manageable and understandable. As shown in this letter, use of "check the box" tables in glossaries could help both insurers and consumers, and could be implemented as requirements and/or free market "nudges."

It is well past time for material changes, and regulators should not tolerate more delay. For over 20 years, most health insurers have failed to adopt consistent and objective health insurance policy terms that reflect modern medical standards. The facts are proven by the web site survey data presented above in Tables 1 and 2, and by the previously cited law review articles and cases discussing the widespread use of inconsistent and subjective terms to define "experimental exclusions." Through manipulation of the subjective terms, some health insurers and plan administrators have sometimes denied critically ill people access to therapies and diagnostics by demanding that doctors, researchers and policy holders provide proof of successful outcomes at levels of purported certainty that are far beyond the levels of proof and certainty required by modern medicine and indeed far beyond the standards of proof routinely applied by courts to other civil law issues. These absurdly high demands for proof of medical necessity make even less sense when it is certain that even FDA approved drugs do not work in some people. While it is of course desirable to pay mainly for drugs that work well, it is folly to pretend that the medical system operates based on anything close to perfection. Thus, we know that the health insurers every day pay for opioids that now must carry "black box" warnings of materially adverse side effects and risks of harm or death warnings regarding addiction;[27] it is also plain that opiods have been harming and killing thousands of Americans every year, for over a decade. According to the CDC:

[27] http://formularyjournal.modernmedicine.com/formulary-journal/news/fda-requires-warning-opioids?cfcache=true

Overdose deaths involving prescription opioids have quadrupled since 1999, and so have sales of these prescription drugs. From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.

Opioid prescribing continues to fuel the epidemic. Today, at least half of all U.S. opioid overdose deaths involve a prescription opioid. In 2014, more than 14,000 people died from overdoses involving prescription opioids.[28]

Follow-up

Thank you for your time and attention. I'm happy to talk by telephone or otherwise communicate if there are any questions.

Very truly yours,

Kirk T. Hartley

KTH/jan
enclosure

[28] http://www.cdc.gov/drugoverdose/data/overdose.html

Appendix 1 – Methods for Survey of Insurance Company Web Sites

Methods: Internet searches were used to identify 17 websites operated by various health insurance companies. The websites were then reviewed for the presence of a "glossary." If a glossary was found, the internet address for it was pasted into the left most column of Table 2. The glossary was then reviewed to determine if the glossary defined the term "experimental." If a definition was found, its full text was pasted into the center column of Table 2.

In addition, the reviewers further investigated health insurer use of the word "experimental" by typing the word "experimental" into general search boxes located on the home page for each of the 17 websites. The number of returned search results was noted, and the number is set out in the right most column of Table 2.

The described searches and data collection were undertaken at two different times. The first review took place during the weeks of February 22 and March 3, 2015. For 1 of the websites reviewed (Anthem), the reviewers could not find a way to access the website's information without entering a policy number. Therefore, searches could not be performed at that site. For 2 of the websites reviewed (Kaiser, Centene), the investigators were unable to find a glossary. For the remaining 14 websites, a glossary was found. Some provided alphabetic listings of terms, which were reviewed. Some included a " search box" useable to search for the word "experimental." Of the 14 websites with a glossary, the alphabetic lists and/or searches for the word "experimental" did not yield a set of words or phrases for 7 of those websites. In contrast, 7 other sites did yield words or phrases explaining the term "experimental." For those 7 sites, the search result was copied and pasted into the center column of Table 2.

A second review of the same websites was performed on January 8-11, 2016, and the same process was followed. Italics were used to highlight the definitions found in 2016. With the exception of one website (HCSC) that apparently went through structural changes, the search results in 2016 were essentially identical to the 2015 results as to (1) the web address for the glossary and (2) the wording of the definition for the term "experimental" for those sites that did provide a definition. Also essentially identical were the 2015 websites that did not contain a glossary or did not contain a definition of the term "experimental." However, variations were found in the number of results returned when a search for the word "experimental was performed using a home page search box." The CIGNA site showed a dramatic increase from 191 to 430. The 2016 review also included capture and preservation of "screen shots" for the web address visited and the search results returned. The screen shots are on file with the first author, Kirk Hartley. Research and data compilation was undertaken by Kirk Hartley, Jessica Hartley (2016 identification of additional sites, site review and data analysis and compilation) and a researcher who prefers to remain anonymous at the present time (initial identification of web sites and 2015 review, analysis and data compilation).

Appendix 2 – Further Specifics Regarding Denial of Treatment to Mrs. Doe

During 2008, Mrs. Doe received a diagnosis of breast cancer in both breasts. During 2008-09, Mrs. Doe went through mastectomy of both breasts, later followed by surgical removal of her fallopian tube and both ovaries. The surgeries were intended to treat and suppress breast cancer and risks of recurrence. Subsequently, Mrs. Doe went through multiple chemotherapies and anti-cancer drug therapies. As of year-end 2009, there was no evidence of cancer in Mrs. Doe.

In 2014, biomarker tests indicated possible cancer, and her doctor ordered subsequent body scans by CT and MRI. The scans identified four possible metastases in Mrs. Doe. Two small tumors were found on her chest wall and two on her liver. The tumors on the chest wall were successfully removed by surgery in January 2015. The procedure was successful and well tolerated. Surgical removal of the chest tumors was performed knowing that it was anticipated that radio ablation would be used to destroy the tumors on the liver.

For most persons, the two small tumors on the liver also would have been removed through surgery. But a surgical procedure for the remaining tumors would have been less wise for Mrs. Doe because the tumors were located in areas of the liver that are not readily accessible for surgical removal. In a March 4, 2015, one of her doctor's explained the situation as follows:

> *For the liver lesion, we suggested liver-directed therapy. Because of the location of the tumor, surgery was not appropriate. It was decided to do other local liver-directed therapy such as cryoablation/radiofrequency ablation versus radioembolization*

The process is known as percutaneous cryoablation, and is performed with FDA approved devices. The cryoablation procedure is in essence simply a more complex version of destroying warts by freezing the tissue.

Mrs. Doe's hospital did not provide cryoablation, and so Mrs. Doe was referred to an "in network" interventional radiologist, Dr. Radiology (a generic name), at a larger, NCCN hospital. After a pre-procedure appointment, the procedure was approved and scheduled. However, on the morning of the procedure, the insurer withdrew approval.

Upon learning of her insurer's denial decision, Mrs. Doe left the hospital and made a series of telephone calls seeking to determine the basis for the reversal and denial. However, she never received a logical explanation for the reversal. Ultimately, on January 26, 2015, Mrs. Doe received a letter dated January 21, 2015. The letter was on her insurer's letterhead but the letter failed to identify the author of the letter. The letter ends as follows: "Sincerely, Medical Advisor/UR -228AB

Some form of medical review follow-up (ostensibly) took place, if one accepts as accurate the substance of the next letter sent to Mrs. Doe by her insurer. This letter was dated January 22, 2015 and received by Mrs. Doe on January 27, 2015. Mrs. Doe, however, was not privy to the conversation. According to that letter:

> *"A Peer to Peer/reconsideration/consultation was conducted on January 22, 2015 between patient's physician and a Board Certified Medical Internist and the non certification determination was upheld."*

Additional medical review follow-up ostensibly took place, if one accepts as accurate the substance of the next letter sent to Mrs. Doe by her insurer. This letter was dated February 18, 2015, and was received by Mrs. Doe on February 23, 2015. Once again, Mrs. Doe was not privy to any communication or action by her insurer. According to that letter:

> *"A request for a Standard Appeal has been completed as provided by your employer's health plan program. Based on the medical information provided, the decision not to certify cryoablation of the liver stands. This decision, rendered by a physician board-certified in RADIATION ONCOLOGY, is based on the following rationale: the treatment with cryoablation is not medically necessary for metastatic lesion to liver from recurrent infiltrating ductal breast carcinoma with ER/PR+, Her2 negative disease."*

Mrs. Doe appealed from that decision.

Her Insurer's Denial Decision dated February 18, 2015

In its February 18, 2015 denial decision, Mrs. Doe's insurer proffered the following legally and factually inadequate and unsupported rationale for the decision to deny cryoablation for the small liver tumors at a place on the liver that made surgery a less desirable choice. Specifically, the letter stated:

> *A request for a Standard Appeal has been completed as provided by your employer's health plan program. Based on the medical information provided, the decision not to certify cryoablation of the liver stands. This decision, rendered by a physician board-certified in RADIATION ONCOLOGY, is based on the following rationale: The treatment with cryoablation is not medically necessary for metastatic lesion to liver from recurrent infiltrating ductal breast carcinoma with ER/PR+, Her2 negative disease.*

The cryoablation of liver metastasis from breast cancer has not been proven to be safe, effective, and standard of care based on current medical standards. There is a lack of published high grade clinical outcome evidence of cryoablation of metastatic liver metastasis from breast cancer. Published data on cryoablation of liver metastasis are mostly from uncontrolled single institutional experiences reporting on initial response. No prospective controlled study has been conducted to investigate long term outcome (local control, survival and toxicity) of cryoablation for metastatic liver lesion from breast cancer. Until long term clinical outcome evidences are available in peer reviewed literature, it is reasonable to consider cryoablation of metastatic liver lesion from breast as not medically necessary. NCCN practice guideline does not include cryoablation in the management of liver metastasis from breast cancer. A copy of the internal guideline relied upon in making this determination, and an explanation of the scientific or clinical reason for this determination, are available free of charge upon request by writing to the Appeals Coordinator at the address on this letter.

This determination was based only on medical necessity, and did not consider eligibility, available health care benefits or claim payment guidelines. Questions about such issues should be directed to the claims payor.

If this appeal decision is not satisfactory, a second appeal may be requested within 30 days of receipt of this letter. We will respond to the second appeal within 15 days of receipt of the request. (italics and underlining added for emphasis)

The Insurer's Purported "Internal Guideline

As highlighted immediately above with underlined italics, the insurer's denial letter said that Mrs. Doe could – upon request - receive an "internal guideline" purportedly related to the denial decision. The "internal guideline" was requested by Mrs. Doe. In response, her insurer sent a March 2, 2015 letter that sets out text that purportedly was taken from some internal document. The March 2 letter, however, did not include and is **not** a copy of an internal document. Moreover, the purported "internal guideline" was not dated, signed by or identified to any particular person, or to knowledge as of any particular date. The March 2 letter from her insurer instead merely shows the sender as "Appeals Coordinator." The text of the March 2, 2015 letter simply stated the following as the purported “internal guideline”:

> The cryoablation of liver metastasis from breast cancer has not been proven to be safe, effective, and standard of care based on current medical standards as demonstrated by meeting one or more of the following criteria: established to be proven per NCCN Guidelines; or established to be proven per NCI Guidelines; or

recognized appropriate per National Medical Policy; or considered acceptable per peer reviewed medical literature.

There is a lack of published high grade clinical outcome evidence of cryoablation of metastatic liver metastasis from breast cancer. Published data on cryoablation of liver metastasis are mostly from uncontrolled single institutional experiences reporting on initial response. No prospective controlled study has been conducted to investigate long term outcome (local control, survival and toxicity) of cryoablation for metastatic liver lesion from breast cancer. Until long term clinical outcome evidences are available in peer reviewed literature, it is reasonable to consider cryoablation of metastatic liver lesion from breast as not medically necessary. NCCN practice guideline does not include cryoablation in the management of liver metastasis from breast cancer.

REFERENCES:

1. Seifert JK, et al: Technol Cancer Res Treat. 2004 Apr;3(2):1 51-63. Cryotherapy for liver tumors: current status, perspectives, clinical results, and review of literature.

2. Flanders VL, et al: Ablation of liver metastases: current status. J Vase Interv Radiol. 2010 Aug;21(8 Suppl):S214-22. doi: 10.1016/j.jvir.2010.01.046. Review.

3. http://Doe.nccn.org/professionals/physician_gls/PDF/breast.pdf

Contrary to the Interests of Mrs. Doe, Her Insurer Failed to Reveal and Communicate Recent Medical Articles Detailing Use of Cryoablation for Metastases

To be rid of her tumors, Mrs. Doe underwent three successful surgeries – 2008 mastectomy of both breasts and removal of her ovaries, plus the January 2015 surgery to remove the small tumors in her chest wall. The surgeons and related reports defined the surgeries as successful. The medical need, as explained by Dr. Radiology, therefore became to rid Mrs. Doe of the small liver tumors that are better suited for cryoablation than for surgery.

Happily, numerous medical articles and studies explicitly report that cryoablation is a safe, effective procedure for destruction of primary or metastatic tumors located on or in a wide range of organs and tissues. Contrary to the interests of Mrs. Doe, unknown employees of her insurer and/or a plan administrator failed to reveal to Mrs. Doe these or other medical articles

and related information which demonstrate that cryoablation is effective to destroy tumors and thereby stop or delay further spreading of cancer.

Her insurer's "internal guideline" also was further flawed because it imposed evidentiary burdens not specified or allowed by the Plan by demanding medical studies using terms and standards not provided in the Plan, and contrary to the defined term, Medically Necessary. Contrary to the Plan terms, and contrary to the fiduciary duty to serve solely the interests of Mrs. Doe, her insurer's "internal guideline" proffered the following four generalized assertions, all of which are contrary to the Plan terms and the interests of Mrs. Brodgon. Moreover, the assertions all suffer from use of subjective terms that can be used in bad faith to avoid objective, accurate decision making.

> *1) "There is a lack of published **high grade** clinical outcome evidence of cryoablation of metastatic liver metastasis from breast cancer."*
>
> *2)" Published data on cryoablation of liver metastasis are **mostly** from **uncontrolled** single institutional experiences reporting on **initial response**."*
>
> *3) "No prospective **controlled** study has been conducted to investigate **long term** outcome (**local control, survival and toxicity**) of cryoablation for metastatic liver lesion from breast cancer."*
>
> *4) "Until **long term** clinical outcome evidences are available in peer reviewed literature, it is **reasonable to consider** cryoablation of metastatic liver lesion from breast as not medically necessary. (bold text and underlined* text added for emphasis)."

The highlighted words are not found in the Plan, and are not found in the definition of Medically Necessary. Therefore, the terms are irrelevant and cannot be applied to the detriment of Mrs. Doe. See *Durgin v. Blue Cross and Blue Shield ,* 610 F.3d 452 (2d Cir. 2009). However, Mrs. Doe's insurer and plan administrator did wrongfully demand proof to match the terms.

Contrary to the Interests of Mrs. Doe, Her insurer Also Failed to Reveal and Communicate That Other Payors and Medicare Pay For Percutaneous Cryoablation

Her insurer's denial decision also was wrongful because the persons involved acted contrary to the interests of Mrs. Doe by failing to gather and present information that would favor Mrs. Doe by showing that other payors in fact approve and pay for cryoablation for tumor metastases. For example, through investigation by counsel, Mrs. Doe learned that CMS/Medicare in fact approves of and reimburses for cryoablation of liver tumors, with no

limitations on the source of the tumor. The specifics were set out in Exhibit A hereto, which is a medical billing code data sheet compiled by personnel at HealthTronics, a firm that manufactures and sells cryoablation equipment. CMS/Medicare cryoablation procedure codes and reimbursement rates for physicians and hospitals are set out middle section of the sheet under the heading: MEDICARE PHYSICIAN AND HOSPITAL OUTPATIENT CODING & REIMBURSEMENT. As noted in footnote 5 of the data sheet, the code for cryoablation of liver tumors was published in the Federal Register on November 13, 2014 as part of a massive notice issued that day with CMS/Medicare billing information.[29] A massive publication of that sort surely attracted the attention of virtually every health insurance entity in the United States. Nonetheless, contrary to the interests of Mrs. Doe, her insurer failed to seek out, find and communicate to Mrs. Doe the fact that CMS/Medicare has approved of and agreed to pay for cryoablation for liver tumors.

Her insurer's failure to find and communicate the cryoblation approval by CMS/Medicare is especially troubling when one looks back at the terms the Plan termfor determining when a procedure is "Medically Necessary." According to the definition:

> ***Medically Necessary***. *Medical services, supplies or treatment:*
>
> ***
>
> - *provided the recommended treatment or diagnostic services meet the standard of care as outlined by Medicare ……*

Under that Plan term, her insurer plainly should have investigated for, found and communicated to Mrs. Doe the favorable fact of cryoablation approval by CMS/Medicare.

A lawsuit and discovery would be needed to determine just how badly her insurer breached its duty to Mrs. Doe. That is, did her insurer find and suppress the information about CMS/Medicare approvals, or did it simply fail to look for and/or fail to find the information?

In a further breach of duties owed to Mrs. Brodgon, her insurer also failed to investigate, find and communicate to Mrs. Doe the favorable fact that some private payors approve of and reimburse for cryoablation for liver tumors. Thus, for example, the HealthTronics data sheet likewise reveals the existence of ICD 9 billing codes created so that physicians and hospital may issue bills for cryoblation for private payors. Those codes are set out in the top section of the data sheet that is Exhibit A hereto. Moreover, similar information could have been derived if her insurer had talked to and listed to clinicians with an open mind and a goal of helping patients instead of saying "no." Thus, Dr. Radiology told Mrs. Doe that the experience in his practice is

---

[29] *See* https://Doe.federalregister.gov/articles/2014/11/13/2014-26183/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-clinical-laboratory#Doe-26

that other health insurers have approved and paid for cryoablation to destroy small tumors in the liver and in other organs. Indeed, for a different patient of Dr. Radiology, Blue Cross/Blue Shield had recently approved and paid for cryoablation for small liver tumors in another woman who was suffering from breast cancer. Id.

Mrs. Doe's insurer also breached its duties to Mrs. Doe by failing to act solely in her interest. As a result, it issued a selective, one-sided and incomplete denial decision that imposed evidentiary burdens and standards not provided for the Plan, and that did not correspond to or even mention the Plan's definition of Medically Necessary. The denial decision also failed to communicate to Mrs. Doe an accurate, complete and up to date review of medical literature that is not known to her personally, but that is of great importance to her goal of defeating the two small liver tumors that cryoblation can destroy using an FDA approved device for a procedure widely recognized and utilized as safe and effective safe and effective "*according to accepted clinical evidence reported by generally recognized medical professionals or publications."* Under the actual terms of the Plan and the applicable legal standards arising under ERISA, the denial decision was based on procedures and actions that breached the fiduciary duties owed to Mrs. Doe, and the decision therefore was both incorrect and arbitrary and capricious.

Appendix 3 – Kirk T. Hartley - Background and Disclosures

- Licensed to practice law in Illinois in 1983, and served as a law clerk for one year for Howard C. Ryan, Chief Justice, Supreme Court of Illinois.

- Since1984, trial lawyer in private practice of law for 16 years with a large law firm, followed by two boutique firms and now my own law firm, LSP Group.

- Also a Director in a boutique national economic consulting firm (Gnarus Advisors).

- Personal investments in biotech stocks and ETFs that cover much of the biotech market, including Illumina, Foundation Medicine and other companies developing and selling precision drugs and diagnostics.

- Unpaid director of Triage Cancer (www.triagecancer.org), an IRS approved 501(c)(3) not for profit focused on educating professionals and persons with cancer regarding the legal rights of persons with cancer, as well as priorities processes for navigating through the maze of rules and laws related to cancer.

- Periodic pro bono legal work for persons with cancer when health insurers deny treatments or payments.