Inconsistent and Subjective “Experimental Exclusions” In Health Insurance Policies Are Material Barriers to Access To “Precision Medicine” for Cancer

5th Annual Arizona State University Workshop on Regulation and Reimbursement of Molecular Diagnostics
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Tempe, Arizona
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Deep Flaws and Failures “Experimental and Investigational” Diagnostics and Drugs

- This presentation focuses on state regulation and state law issues arising when real people are denied access to precision medicine treatments for cancer
- Obamacare has NOT solved the problems, and persons with cancer cannot make intelligent health insurance purchasing decisions because of lack of objective, comparable, understandable terms of health insurance contracts
  -- SEER says cancer rates under 65 are about 1/3 of over 65
- States regulate (or fail to regulate) health insurance companies
- Most states have a thinly staffed “insurance commission” that lacks scientific knowledge, and lack adequate staff
- Many states have major problems of regulatory capture
- For over 20 years, health insurers and plan administrators have commonly cited “experimental exclusions” (and related terms) when denying access to potentially life saving diagnostics and therapies for persons with cancer
Deep Flaws and Failures
“Experimental and Investigational” Diagnostics and Drugs

• For over 20 years, health insurers and plan administrators have commonly cited “experimental exclusions” (and related terms) when denying access to potentially life-saving diagnostics and therapies for persons with cancer

• To investigate current use of the term “experimental” in health insurance policies, 17 websites of health insurance companies were surveyed for information that could be found by a would-be insurance purchaser, a doctor or a person building a drug or diagnostics business

• Results show:
  – 10 failed to present information on the term experimental, and
  – 7 defined “experimental” using inconsistent and subjective terms
    • Subjective terms are often used to impose requirements and conditions never disclosed in the contracts
  – The industry has failed to change itself over 20 years, and regulators also have not acted; major catalysts and changes are needed

10 Health Insurers Failed to Provide an Accessible Definition of “Experimental”

• An initial failure

• The majority of the health insurance company websites (10/17) did not provide an accessible definition of the term “experimental

  – 1 of the 10 websites (Anthem) was impossible to access for any purpose without an insurance policy number

• Lack of information precludes intelligent decisions
7 Health Insurers Disclosed Inconsistent and Subjective Definitions of “Experimental,” and Hundreds of Uses

- 7 websites provided a glossary and definition for the term “experimental;” the 7 are materially inconsistent and subjective

- The definitional failures are made worse by unmanageably frequent uses of the term “experimental”
  - One website returned 999 search results
  - Numbers are: 2, 25, 197, 389(2x), 443, and 999
  - That many search results makes it impossible for review and understanding by even trained professionals, much less consumers and other non-expert stakeholders seeking to make intelligent decisions

Examples of Inconsistent Terms Used by Health Insurers

<p>| “Experimental – Investigational or unproven, not yet proven safe or effective.” | “Experimental Procedures Any service or supply that is in the developmental stage or is in the process of human or animal testing.” | “Experimental Procedures Procedures that are mainly limited to laboratory research.” |
| “They may not be proven as effective or safe for most people.” | Health care services, procedures, therapies, devices, or supplies that the insurance company considers medically unproven are considered experimental or investigational procedures. | “not yet accepted by insurance plans as standard treatment” |
| “not yet accepted by doctors....” | “Any ... [1] that has not received FDA approval or [2] is not yet supported by the clinical community because the scientific evidence available does not demonstrate the effectiveness of the service or technology .....” | “not in line with generally accepted standards of care.” |</p>
<table>
<thead>
<tr>
<th>Insurer and Website address for glossary, if found</th>
<th>If a glossary was present, exactly what words or phrased were found or returned as a result of searching the glossary for the term “experimental”</th>
<th># of search results returned for the term “experimental”</th>
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<tbody>
<tr>
<td>2016 Aetna <a href="https://www.aetna.com/glossary.html">https://www.aetna.com/glossary.html</a></td>
<td>“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.”</td>
<td>999</td>
</tr>
<tr>
<td>2016 Cigna <a href="http://www.cigna.com/glossary">http://www.cigna.com/glossary</a></td>
<td>“Experimental Procedures Unproven or investigational treatments that are not in line with generally accepted standards of care.”</td>
<td>389</td>
</tr>
<tr>
<td>2016 Emblem <a href="http://www.emblemhealth.com/en/Members/Resources/Glossary.aspx">http://www.emblemhealth.com/en/Members/Resources/Glossary.aspx</a></td>
<td>“Experimental Procedures Procedures that are mainly limited to laboratory research.”</td>
<td>197</td>
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</tr>
</thead>
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<tr>
<td>2015 HCSC <a href="http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=i2kcy40k&amp;corpBrand=HCSC&amp;corpEntCd=IL1">http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=i2kcy40k&amp;corpBrand=HCSC&amp;corpEntCd=IL1</a></td>
<td>“Experimental – Investigational or unproven, not yet proven safe or effective.”</td>
</tr>
<tr>
<td>2016 Carefirst Inc. <a href="https://member.carefirst.com/individuals/health-insurance-glossary/health-insurance-glossary-e.page?alphaid=glossary-e">https://member.carefirst.com/individuals/health-insurance-glossary/health-insurance-glossary-e.page?alphaid=glossary-e</a></td>
<td>“Experimental Procedures Any service or supply that is in the developmental stage or is in the process of human or animal testing.”</td>
</tr>
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Table 1 cont’d

<table>
<thead>
<tr>
<th>Company/Insurance Co.</th>
<th>Definition</th>
<th>Page</th>
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</table>
| 2016 Blue Cross Blue Shield of Michigan | “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.: | “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    |

Survey Timing

- Searches and data collection were undertaken in both 2015 and 2016.
- The first review took place during the weeks of February 22 and March 3, 2015.
- The same form of review of the same websites was performed on January 8-11, 2016.
- The 2016 results were essentially identical to 2015 as to the definition for the term “experimental” for the 7 responsive websites.
- The CIGNA site showed a dramatic increase from 191 search results for “experimental” up to 430 search results.
Examples of Subjective Terms Used

<table>
<thead>
<tr>
<th>Uncontrolled</th>
<th>Clinically controlled</th>
<th>Uncontrolled single institutional experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>No evidence</td>
<td>Published high grade clinical outcome evidence</td>
<td>Discretion</td>
</tr>
<tr>
<td>Improved net health outcomes</td>
<td>Long term outcome (local control, survival and toxicity)</td>
<td>Reasonable to consider</td>
</tr>
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Subjective Terms Are In Fact Used to Reject Perfectly Proper Treatments and Diagnostics

- Regulators apparently are not reading the caselaw and articles describing the sometimes awful abuse of insureds

- One federal judge – on his own – stopped the lawyers for plan administrators, and entered sanctions against the plan fiduciary for bad faith actions
  
  – see Maddred-Exum infra

- Plan fiduciaries are breaching fiduciary duties owed to every single insured for each coverage decision
The “Experimental” Problem Has Existed for Two Decades, and the Health Insurance Industry and Regulators Have Failed to Fix It

The Term Experimental Has Been At Issues for At Least 20 Years

- The term “experimental” has been widely used and defined in health insurance policy exclusions for at least twenty years, with definitions that are inconsistent, subjective and unmanageable.

- Thus, the various exclusions were frequently applied to deny access to stem cell transplants and other therapies for cancer. See, for example, Natalie L. Regoli, Insurance Roulette: The Experimental Treatment Exclusion & Desperate Patients, 22 Quinnipac L. Rev. 697 (2004)(review of cases and law).

- See also Lee Black, Experimental Breast Cancer Treatments and Health Insurance Coverage, Virtual Mentor, January 2007, Volume 9, Number 1: 34-37 (reviewing some cases back to 1996, and compiling specific examples of terms at issue regarding “experimental exclusions and medical necessity definitions”).
More on Experimental At Issue for At Least 20 Years

• Mr. Black reviewed cases back to 1996, and concluded:
  – “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.”

• Due to litigation, health insurers and plan fiduciaries have been made very aware of the problems, but have failed to find an industry-wide answer to the problem.

• State insurance regulators also have failed to fix the problems, despite optimism by some
  – Timothy Stoltzfus Jost, Reflections on the National Association of Insurance Commissioners and the Implementation of the Patient Protection and Affordable Care Act 159 U Pa L Rev 2043 (2011), online at http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1116&amp;context=penn_law_review

Failure of Regulatory Processes

• FDA does not oversee or regulate private insurance companies

• Federal agency intersections appear weak and burdened by process

• Insurance companies are regulated by states

• Obamacare statute gave roles to National Association of Insurance Commissioners

• NAIC has made some progress on financial issues and simple terms but not on topics and issues involving science
  – Lawyers, actuaries, legislators, and insurance companies
  – No role for physicians, diagnostics makers or persons with cancer or other diseases

• State insurance commissions – almost always completely inept as to science
Failure to Work in Meaningful Multidisciplinary Teams Way

- Health insurers and regulators are failing to use objective terms of art that matter to physicians, product makers, drug makers, and persons with cancer
- Regulators need to include:
  - Oncologists
  - Computer programmers
  - Drug makers
  - Diagnostic makers
  - Epidemiologists and researchers able to highlight speed of deaths

Examples of Terms Not Used

<table>
<thead>
<tr>
<th></th>
<th>NCCN</th>
<th>NIH or NCI</th>
<th>ASCO or AMA</th>
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<tbody>
<tr>
<td>Orphan</td>
<td>Breakthrough</td>
<td>Pivotal</td>
<td></td>
</tr>
<tr>
<td>Precision medicine</td>
<td>Multi-gene</td>
<td>Actionable</td>
<td></td>
</tr>
<tr>
<td>Complete remission</td>
<td>Partial remission, Durable remission</td>
<td>PFS (progression free survival)</td>
<td></td>
</tr>
<tr>
<td>ORR or Stable disease</td>
<td>Companion diagnostic</td>
<td>N of 1</td>
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Use of Predatory and/or Defective Software by Public and Private Health Insurance Plans and/or Administrators

Plan Administrators and/or Insurers
Use “Predatory” Software Coding

- According to at least one lawyer in a good position to know, some health insurers routinely deny approval of or payments for new treatments or diagnostics based on practices that are not disclosed in health insurance contracts, according to 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)
Some Medicare Contractors Are Involved in “Predatory” Coding

• “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.”

• 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.

Health Insurers and Plan Administrators Also Are Using Shoddy Software Coding Practices

• Automated software decision-making systems are heavily involved in the processing and payment of (or rejection of) medical bills and related information for medical therapies and/or diagnostics.

• Unfortunately, these systems inevitably can and do fail for multiple reasons. For example, incorrect decisions result when human beings miscode entries or make mistakes in coding or logic.

• Some insights into the scale of the errors can be gleaned from a lawsuit recently filed in federal court in Manhattan, known as *Anthem, Inc. v Express Scripts, Inc.*, #16 CV 2048 (S.D.N.Y.) (Judge Ramos). In a detailed complaint totaling over 125 paragraphs and 40 pages, Anthem laid out a scathing indictment of Express Scripts’ mishandling of pharmacy benefit management (PBM) services that Anthem in turn offered to health plan as part of its offers administrative services only (ASO) for other businesses.

• Anthem alleged errors involving about 100,000 insureds, and 300,000 physicians. See Supplemental Materials
Health Insurers Are Continuing to Generate Unenforceable “Policies” Filled With Jargon and Massive Jumbling of Information

#1 - Examples of Actual Terms of Policies that Change and are Not In the Insurance Contract Itself

- United Healthcare Molecular Pathology/Molecular Diagnostics/Genetic Testing
- GEN01252012RPApproved By UnitedHealthcare Medicare Reimbursement Policy Committee, Current Approval Date 1/28/2015
- 17-page policy that begins with broad caveats and disclaimers that mean a user cannot depend on its terms, as shown by the text set out on the following slide
#1 - Examples of Actual Terms of Policies that Change and are Not in the Insurance Contract Itself

- “This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation.
- Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case.
- Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees.
- Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents.
- Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however,
- UnitedHealthcare strives to minimize these variations. UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.”

#2 - Examples of Actual “Experimental” Policies That Are Not In the Insurance Contract Itself

- United Health Experimental 003.9 T2 Effective Date December 1, 2014
- Part of this policy appears relatively progressive, but other phrases continue the decades old problems.
- “Experimental and/or Investigational Treatment: Oxford recognizes that peer reviewed documents in scientific and medical literature may establish that an experimental and/or investigational treatment or procedure may be better than the standard treatments available to treat a member’s life threatening or disabling condition and/or disease.
- Oxford has determined that it will create a limited exception to the exclusion of experimental and investigational treatments and provide coverage for in-network experimental and investigational procedures that meet the criteria set forth in this policy. Such coverage is subject to the member’s other benefits and exclusions.
- Oxford’s determination of whether the criteria have been met will be based upon the opinion of an independent consultant/peer reviewer with expertise in the area of practice appropriate to treat the member’s condition or disease.”
For Their Own Purposes, Insurers Are Making Vast Use of Better Software

- Regulators or marketplace need to force insurers to implement and disclose coding and modeling, perhaps with national minimums.
- “About 28 percent of respondents said they’d use predictive modeling for fraud potential. That will jump to 70 percent in two years.
- Approximately 10 percent said they use the technology to calculate litigation potential. That jumps to 61 percent two years from now.
- While 18 percent said they rely on the tech for marketing and advertising, that number grows to 52 percent in two years.
- 42 percent said that big data helps with pricing, underwriting and risk selection, but 77 percent expect it to do so within two years.
- 60 percent said they expect big data to help inform their management decisions two years from now, up from 19 percent today.
- 58 percent said they envision big data helping their loss control and claims management within two years versus 17 percent now.”


How Big is The Problem of Denial of Access Based on “Experimental” Denials?
Data and Disclosures Lacking Regarding “Experimental” Denials

• This author has searched at length for data on the extent of all “experimental” denials, but no data found
• Efforts include:
  • review of National Association of Insurance web site
  • outreach to persons on NAIC consumer committees
  • outreach to others working in the area
  • outreach to American Cancer Society,
  • outreach to a lawyer at national association for teaching hospitals

Personal Observations Based on Experience Since 2009

• One or more daily calls for help from people with cancer to a non-profit I serve (Triage Cancer)
• Other advocacy groups report many calls
• Marcia Horne may offer her own observations
• Belief - most people accept denials
• Insurers sometimes but not always withdraw objections upon appearance of an knowledgeable lawyer - 2x in stem cell transplant cases
• Most people have no idea how to find a lawyer
• Physicians are too often zero help (fear? money?)
45 Federal Lawsuits
Since 2010 Regarding Experimental Exclusions

- Additional evidence of the current definitional deficiencies consists of 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 posted online 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.

Every Day Brings Thousands of New Cancer Diagnoses and Deaths

- Scale of the Problem: Per 2016 Cancer Facts & Figures (online at cancer.org)
- 1,685,210 million people in the US are diagnosed with cancer each year
- 595,690 persons in the US die of cancer each year
  - An average of 1,539 new cancer diagnoses during an eight hour workshop
  - An average of 544 cancer deaths during an eight hour workshop
  - Cancer death rate in the US is about 1 per minute
- For 2011-2016, there were 33,000 needless deaths if proper terms and systems would have saved 1% of 3,300,000 persons who died of cancer (550,000/year)
- Awful incidence numbers for children 0-14 years – rising about .06% /yr 1975-2012
  - 10,380 new diagnoses /year in US - average of over 9 during an eight hour workshop
  - 1,250 deaths /year in US - average of over 1 during an eight hour workshop
- Overall lifetime incidence of cancer
  - 1 in 2 men and 1-3 women
- Per ACS 2014 Cancer Survivorship Statistics – US cancer “survivor” population was about 4% of our population, or 14,483,830 million
Insurers and Administrators Demanding Impossible Levels of Proof

- As shown, there are many situations in which insurers or plan administrators “reserve discretion” and/or insist on impossible levels of proof
- Dr. Bruce Quinn has time and again presented the issues, dating back to at least 2008
- Demand for “controlled studies” that are or may be ethically impossible because of modern medical ethics rules that preclude access to better care
- Refusal to acknowledge value of “N of 1” or small groups
- Demands for studies that cannot possibly be conducted because patients are unique
  - Individual variability in genes and other “omics”
  - Individual variability in somatic mutation patterns (e.g., now many types of breast cancer)
  - Individual variability in clinical history
Dr. Quinn’s “Three Chasms” Paper

• 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).
  – 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.

Three Specific Chasms Identified by Dr. Quinn

• 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.

• The 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)
Dr. Quinn on Plan Fiduciaries
Demanding Impossible Clinical Trials

• **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.**

• **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)

More from Dr. Quinn on Ethically Impossible Trials

• **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. The problem described here, 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.** 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)

More from Dr. Quinn on Ethically Impossible Trials

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)

     US must still “develop a common language and standards” for evidence
     assessment and decision-making.

Plan Fiduciaries Must Act Solely to Benefit Insureds

• 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 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
(quoting Firestone, 489 U.S. at 111-13, additional citations omitted).
Plan Fiduciaries Must Act in Good Faith

- 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.

Plan Fiduciaries Must Fully Disclose Complete and Accurate Information

- Plan fiduciaries are obligated 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).
Health Insurers and Plan Administrators Cannot Insist on Data From “Randomized” Trials

- 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 wheelchair with a special component to help him stand up out of the wheelchair. 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.

- 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:
  - “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).”

Example of Insurer and Administrator Abuse of Subjective Words
An Example of Bad Faith Abuse of Subjective Terms

- The abuse of subjective words is illustrated the opinion in *Diane Maddred-Exum v. Davco Restaurants, Inc.*, No. 04-660 (D. Md. May 13, 2004)
- Federal judge – on his own – stopped the lawyer’s arguments and issued his ruling
- In a terse opinion, Senior Judge William Nickerson rejected the denial of stem cell transplant as “experimental,” 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.” (emphasis added)

Example of Bad Faith Abuse of Subjective Terms

- “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 [approve] 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).

- Judge Wilkerson sanctioned the defendants over $40,000, which ultimately was transferred to a cancer research fund. See Supplemental Materials for more.
Most Doctors and Lawyers are Not Able to Effectively Challenge Insurer Denials

- Most doctors were not trained in genetics
- Oncologists cannot keep up with the pace of change in precision medicine
- “Without credible guidelines to guide their decision-making, physicians are currently forced to wade on their own through a stack of conflicting studies, expert advice and recommendations on whether or not genetic testing is indicated and useful in particular circumstances and patients.” — See Physician Liability: The Next Big Thing for Personalized Medicine?, Gary E Marchant; Doug E Campos-OUTcalt; Rachel A Lindor, Personalized Medicine. 2011;8(4):457-467.
- Most lawyers know even less than the doctors about genetics and diagnostics, and so cannot effectively help patients challenge wrongful denials
- Most doctors and lawyers therefore cannot effectively argue with payors about denial of access to genetic diagnostics to better understand an existing cancer, and so front line changes are critically needed

Act Now to Avoid the Growing Storm: People with Cancer Will Be Demanding Answers and Pointing Fingers
Americans Cannot Access the Information Needed to Intelligently Purchase Health Insurance

- A storm is brewing among those most at risk
- 14+ million Americans are people who survived cancer
- Unknown numbers of people are presently “in remission”
- Some persons with inherited mutations (e.g. BRCA) are at extreme risks for cancer
- 1.6 million new cancers per year, and incidence rates rise steeply after age 50
- 16 million in a decade > cities of Chicago, Los Angeles, and New York (excluding burbs)
- Most cancers kill through metastases
- For all of those people, a real key is taking advantage of emerging highly sensitive biomarker tests that can find new cancers far earlier than could be done even two or three years ago.

More Science and More Diagnostics Will Lead Americans to Demand Timely Answers to Material Questions

- More early cancer diagnostic tests are in the works
- A new grand scale diagnostic effort is underway by people who may well get it done
- The project is known as “Grail”
- The project has a dream team; it is led by the world leader in genetic diagnostics (Illumina)
- The financial backers include longtime biotech investors and billionaires Bill Gates and Jeff Bezos
- The project leader is Jeff Huber, a senior Google person with an enviable record of success
  - Huber previously created unheard of technologies, including Google Maps and Google Earth.
  - Mr. Huber is highly motivated; his wife died in her 40s due to “no warning” cancer
  - Their goal? Start testing Grail in 2017, and bring it to market in 2019.
Suggestions for Improvements

Create Comparative Data to Promote Intelligent Choices

• Better insurance has value

• Some employers, such as Google, already are offering potentially life saving broad coverage of molecular cancer testing as a means to attract employees, such as the Foundation Medicine multi-gene tests. See http://www.reuters.com/article/google-health-cancer-idUSL1N0SV3WR20141105 (last visited March 27, 2016).

• Create chances for comparison shopping
Suggestions for Improvements

• Short term triage efforts for seriously ill persons – millions are at risk and some are dying needlessly during regulatory delay
• Reject one size fits all “experimental” terms – they do not work
• Develop laws and regulations that are disease specific
• New insurance policy terms and formulary laws drafted by multi-disciplinary groups which include
  – medical specialists (genetics, oncology, pathology)
  – medical groups (AACR, ASCO, AMA)
  – “big data” managers and coders
  – forensic computer specialists
  – federal judges
  – state supreme court judges
  – develop centers of knowledge in courts and professional associations

More Suggestions for Improvements

• Require or “nudge” extensive comparative disclosures
• Need use of objective factors instead of subjective words
•Require up to date, real time deadlines for decisions on new products as they progress through regulatory process (suggestion of Lee Black)
• Mandate disclosure of software coding to a neutral source that can compare criteria and find “predatory” software
• Encourage health insurance evaluations and grades by medical specialty groups
• Require insurer deference to board certified experts with treatment plans approved by medical review boards; force insurance plans to prove decision was grossly unreasonable
• Require use of check the box tables in health insurance glossaries
Examples of Check the Box Tables

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

<table>
<thead>
<tr>
<th>Test Name (CPT codes could be added)</th>
<th>Description of Test and related web page site</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cologuard</td>
<td>&quot;Cologuard uses advanced stool DNA technology to . . .&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FoundationOne Heme</td>
<td>&quot;FoundationOne Heme uses comprehensive, clinical grade next-generation sequencing (NGS) to assess routine cancer specimens for all genes that are . . .&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caris Molecular Intelligence</td>
<td>&quot;Caris Molecular Intelligence uses multiple molecular testing technologies – including . . .&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broca</td>
<td>&quot;BRCA 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.&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Comments on Check the Box Use

- 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.

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Example Check the Box Table for New Technologies for Cancer

The check the box table below keys off of various actions FDA may take with respect to medical technologies, at different points in time.

<table>
<thead>
<tr>
<th>Possible grading level</th>
<th>List of objective events that will (or will not) result in payments under a health insurance contract</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platinum</td>
<td>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</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Gold</td>
<td>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</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Silver</td>
<td>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</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Bronze</td>
<td>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</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
Comments on Check the Box Table

• 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

• 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 merely is better than an old technology and that could save the life of the patient. See papers by Bruce Quinn.
Comments on Check the Box Table cont’d

- 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.

Ethical Considerations Are Essentially Irrelevant for Most Persons With Aggressive Cancers

- Lengthy ethical debates are adverse to the interests of virtually all persons with fast moving solid cancers or blood cancers prone to recurrence

- Regulators and insurers need to use a triage approach to create solutions quickly for persons with advanced disease

- Most debates about efficacy usually fail to account for costs and agony avoided, such as agony and costs of treatments that might not be pursued after seeing dismal results from the analysis of the somatic mutation pattern of a tumor
  - Avoiding cost and agony matters when roughly 1,500 people die of cancer every day in the US, and much expense arrives at end of life

- Most persons with stage III or IV cancer are not worried about arcane debates about dissemination of genetic information

- Non-US alternatives will emerge – Abstract debates about ethics and fears of disseminating genetic information ultimately will be mooted by non-US diagnostics businesses providing genetic data for those who want to know the facts.
Conclusion: Rapid and Radical Changes Are Needed

• Theoretic debaters often assume free flow of information and immediate learning of information
• Theory often assumes prompt, sensible decision-making by market actors without financial biases and conflicts of interests
• Those assumptions are demonstrably false as to precision diagnostics and drugs for cancer treatments
• Abstract debates about pricing and marketing are interesting and useful in some settings, but delay and extended debates are counter-productive and possibly fatal for persons with aggressive cancers
• Due to past failures to find meaningful answers for the many different diseases we call “cancer,” radical and rapid changes are occurring in approaches to applying molecular cancer science in clinical trials
• Equally radical changes are needed in the pace of decision-making by regulators and private payors, along with radical changes to laws and insurance policies

• The same lesson should be applied to thinking about both free markets and regulators with respect to precision medicine, cancer and other major diseases
• Failures arise at the intersections between science and law, including:
  – failure to rapidly inter-relate advances in science to legal rules and insurance policy terms, and
  – failure to embrace new approaches, such as:
    • disease-specific standardization of terms for insurance contracts
    • At least, banding along the lines of “gold, silver and bronze.”
    • increased deference by payors to truly expert physicians (e.g. board certified oncologist practicing at a major medical center)
• Multi-disciplinary teams – with all stakeholders - are needed to rapidly accomplish changes to increase access to precision drugs and diagnostics for persons with cancer, and persons with other diseases
Questions or follow-up?

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GlobalTort Blog

- GlobalTort blog is located at www.GlobalTort.com
- Focus is on intersections between science, law, and other disciplines
- Numerous articles on asbestos and other toxic tort litigation
- Updated 3-5 times per week, most weeks
Background and Conflicts Disclosure

- Since 1984, trial lawyer in private practice of law with large and now boutique law firm; also a principal in a boutique national economic consulting firm.

- Over 20 years of involvement in paid corporate litigation against commercial insurance claims against insurance companies, and.

- Over 6 years in pro bono claims and complaints for persons with cancer.

- 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.

- Pro bono 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.

Supplemental Materials
Links for Department of Labor Glossary Materials

DOL Guidelines on Summary Descriptions

• The U.S. Department of Labor (DOL) issued an updated template Summary of Benefits and Coverage (SBC), Glossary of Coverage and Medical Terms, and related materials

• Revised materials would replace December 2014 glossary and would be approved for three years for plans beginning after April 1, 2017

• The SBC is a “precisely formatted document that group health plans and health insurers are required to provide in connection with enrollment and re-enrollment periods.”
• Proposed revision says nothing about “experimental” or other related terms
DOL Guidelines on Summary Descriptions

Links for relevant documents and background

http://www.dol.gov/ebsa/healthreform/regulations/summaryofbenefits.html#proposed


http://www.jdsupra.com/legalnews/dol-issues-proposed-updates-for-12776/

Supplemental Information Regarding:
The “Experimental” Problem Has Existed for Two Decades, and the Health Insurance Industry and Regulators Did Not Fix It
Historic References

• 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)

Examples from Lee Black on “Experimental Terms”

• 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)].
More Examples of “Experimental Terms”

- "...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 [types of treatments]: especially in the 1990s, these medical procedures were given inconsistent treatment by judicial circuits.”

Supplemental Materials on Shoddy Software Coding Practices
More Shoddy Software Practices

- Anthem’s complaint describes in detail myriad errors in the work of Express Scripts, and the software that Express Scripts created to accept or reject claims. According to Anthem, ESI’s system and processes have flaws in a wide range of areas. For the medical data forms known as PDE records. Anthem alleged that the systems devised by Express Scripts “are riddled with errors.” (Complaint, ¶63).
- Overall, a few sections of the Complaint describe in detail errors affecting not less than 97,000 persons insured under the plans. The Complaint also alleges miscoding errors for over 300,000 prescribers.
- On a percentage basis, Anthem alleged that 23% of the decisions contained denial errors in a random subset of 150 claims. On the other side of the coin, 15% of approvals were incorrect, for the same set of 150 randomly drawn claims.
- Moreover, the complaint does not claim to describe every mistake by Express Scripts in processing claims, and indeed the Complaint appears to only present significant examples of mistakes. The following assertions are all taken verbatim from the federal court complaint; the original paragraph numbers have been retained. Some portions of the Complaint were redacted by Anthem, and the redactions are included below. Some footnotes have been added to some phrases through use of italics, underlining and use of red text.

Anthem’s Allegations Against Express Scripts

- Allegations below are taken verbatim from Anthem, Inc. v. Express Scripts, Inc., #16 CV 2048 (S.D.N.Y.) (Judge Ramos)(filed March 21, 2015).
  55. ESI’s failures are largely due to its implementation of an inadequately-tested new computer software program known as “C360,” as part of a larger new system known as “Foundation 14.” ESI implemented C360 on September 1, 2013 for a portion of Anthem’s business, and on January 1, 2014 for the remainder. ESI acknowledged that the migration to C360 created a host of problems, but ESI falsely claimed that it remedied its failures to accurately and timely apply the Defined Criteria within the cure period.
  56. Anthem reviewed ESI’s application of Defined Criteria in 150 cases, selected on a random basis, during the period of April 1, 2015 through April 14, 2015, and found that ESI applied the wrong Defined Criteria in an astounding 23% of cases (35 of 150). Further, ESI incorrectly approved the request in 15% of the cases (23 of 150). Anthem also found other highly significant, recurring errors in ESI’s application of Defined Criteria. For example, ESI representatives repeatedly answered key questions incorrectly, such as stating that alternative drugs have been tried by the member when there was no evidence of the drug having been tried and failed, or stating that the member had been on the drug for 6 months when there were no paid claims.
More Anthem Allegations

• 57. Subsequently, Anthem reviewed an additional 232 cases processed by ESI during this April 1-14, 2015 period. This expanded review confirmed the findings from the previous review. Specifically, for the entire set of 382 cases reviewed:
  - Anthem identified 95 errors by ESI, including some cases involving multiple errors.
  - One case was built for the wrong drug.
  - In 10% of cases (39 of 382), ESI applied the wrong Defined Criteria for the given request, and ESI incorrectly approved the request in 13% of the cases (50 of 382).
    - 20 out of the 39 did not meet criteria and should have been sent to Anthem for review.

• Since January 2014, ESI has acknowledged the need to correct the "APS" (Auto-Product Select) functionality in C360, so that ESI’s computer system could correctly identify the Defined Criteria for the ESI employee reviewing the request, as required -functionality that had existed before ESI’s defective implementation of C360. Despite having had some 26 months to correct these defects amid repeated requests from Anthem, ESI has failed to do so. Instead, ESI has repeatedly missed various target dates for implementing necessary fixes. ESI has continued to delay the necessary system corrections, and has not provided any date by which it will complete the required work.

More Anthem Allegations

• 59. ESI’s failures go to the heart of what ESI is required to do in "managing " pharmacy benefits for Anthem under the Agreement in a "prudent and expert manner" and have resulted in member/customer abrasion.

• Among other errors caused by ESI's systems and inadequately trained personnel, ESI has incorrectly approved many high-cost drugs at alarming rates, resulting in substantial damages to Anthem exceeding $100 million.
More Anthem Allegations

• On January 27, 2016, ESI advised Anthem that approximately 299,000 prescribers were end-dated in its internal databases, resulting in erroneous rejections for members at the point of sale. The erroneous rejections were the result of two prescriber data jobs running concurrently in ESI’s systems. The batch jobs were required to run in a scheduled sequence to prevent disruption of data availability. The schedule was not followed, resulting in concurrent loads that end-dated the referenced prescriber records.
• This error impacted 5,849 claims, representing 3,956 members. Anthem notified CMS of this error on February 2, 2016.
• On February 3, 2016, ESI advised Anthem an additional 5,287 prescribers were end-dated in its internal databases, resulting in erroneous rejections for members at the point of sale. The erroneous rejections were the result of a sorting issue during file processing for prescribers with taxonomies with multiple timelines on the CMS file. Updates for these records were subsequently applied out of sequence in ESI’s system, and ultimately caused the prescribers to be end-dated in error.
• This error impacted 675 claims, representing 622 unique members. Anthem notified CMS of this error on February 8, 2016.

Supplemental Materials Regarding:
Legal Standards Applicable to Health Insurers and Plan Administrators
### Examples of Abuse of Subjective Terms

- Failure to utilize up to date information in making decision
- Failure to communicate complete and up-to-date information to patients and doctors
- Demanding impossible levels of evidence
  - Ethical rules preclude some clinical trial possibilities
  - “N of 1” Situations preclude some clinical trials

### Plan Fiduciaries Must Act Solely to Benefit Insureds

- 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 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).
Plan Fiduciaries Must Act in Good Faith

• 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 “take[ing] deliberate advantage of an oversight by your contract partner concerning his rights under the contract.” Id. at 594.

Health Insurers and Plan Administrators Cannot Insist on Data From “Randomized” Trials

• 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.

• 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:

  “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).”
Examples of Abuse of Subjective Terms

• 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).

Plan Fiduciaries Cannot Cherry Pick Data

• Plan Fiduciaries 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 Majoeksi 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.
Plan Fiduciaries Must Fully Disclose Complete and Accurate Information

- Plan fiduciaries are obligated 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 Examples of Actions by Some Health Insurers
Blue Cross “Investigational Policy”

• Some insurers are making some moves to update terms and policies to adapt to modern medicine

• Some efforts are much too slow

• Some efforts are much to unwieldy.

Blue Cross “Investigational Policy”

• One example lies in the “Investigational (Experimental) Services” policy of Blue Cross Blue Shield of North Carolina. 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.
More Delays Create Risks for Entities, Officers and Directors

• 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.

• 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.

• 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.

  – 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).


UnitedHealth’s 36 Page “Coverage Summary”

• A different problem is shown by the G-003 “Coverage Summary” by UnitedHealth for genetic and other molecular tests.

• This 36 page document is a positive development in the sense that it 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, but the descriptions are 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.
Supplemental Materials Regarding the N of 1 Problem

“N of 1 Barriers” in General
Dr. Schork on N of 1 Problems

• Some N of 1 situations 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.

More from Dr. Schork on N of 1 Problems

• 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.
More N of 1 Problems

- 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.”

The N of 1 Problem – The Example of Mrs. Doe

- Mrs. Doe’s situation very precisely illustrates 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 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 N of 1 Problem

- Nonetheless, the plan fiduciary demanded the impossible, in bad faith. More specifically, set out below is the precise language of the denial letter regarding Mrs. Doe, with underlining 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.

Plan Fiduciaries Wrongfully Demand Randomized Trials Instead of "N of 1" Studies and Data

- "Experimental" and "medically necessary" terms 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 Insurer’s Out of Date, Abusive “Internal Guideline”

- “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.”

• 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.”

In 2015, The Plan Fiduciaries Relied on Out of Date Citations for its “Internal Guideline”

• The insurer’s policy stated the following “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:
Breach of Duty by Mrs. Doe’s Plan Fiduciaries

- Mrs. Doe’s 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. Doe. 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 specifically 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.

Supplemental Materials on Failures Related to Multi-Gene Tests
Examples of Multi-gene Tests

• “BROCA” test developed and in use at the University of Washington
  – Test can analyze any or all of a panel of genes associated with breast and ovarian cancers
  – University of Washington team is said to include Mary-Claire Williams, of BRCA fame

• Foundation Medicine
  – Publicly traded Boston biotech spinoff from Harvard, Broad and more; brought multi-gene tests to market in 2012 and 2014 for solid tumors and blood cancers
  – Dozens of peer reviewed papers by FMI and collaborators demonstrate successful uses of its diagnostics for persons with solid tumors and blood cancers
  – Test results include a road map telling doctors which drugs and clinical trials are available, with online updates available

• Caris
  – Much the same as Foundation Medicine but privately held

Payors are Major Barriers to Private Developers of Precision Diagnostics for Cancers – The Example of Foundation Medicine

• An example of the barriers - Foundation Medicine, a publicly-traded company (FMI)
• “FoundationOne is a test that interrogates the coding sequences of 315 cancer-relevant genes and a number of introns from 28 genes that are known to be altered in solid tumors.”
• FoundationHeme is a test to find gene mutations and chromosomal translocations common in blood cancers.
• Foundation Medicine began selling tests in 2012 and went public in 2013
• No one will find questions about the accuracy of the tests; they are as good as it gets
• Novartis, Celgene, AstraZeneca, Sanofi, and other signed service deals with Foundation in order to use its “diagnostics to help find the patients most likely to respond to their experimental drugs.”
• Roche bought over 50% of the shares of Foundation Medicine after it failed to buy Illumina (the world leader in genomic sequencing).
More of the Foundation Medicine Example

• Foundation Medicine has a backlog of thousands of unreimbursed tests or tests paid in only a limited way, with few payments by CMS/Medicare and very, very modest, payments by “for profit” private payors, generally based on code-stacking.

• Less than 5 “for profit” private payors have committed to pay for FoundationOne solid tumor multi-gene test offered by FMI

• For further specifics, see:

More of the Foundation Medicine Example

• Lack of off-label reimbursement approval impairs physician interest

• Lack of reimbursement can discourage use by oncologists, which in turn leaves patients without often important information

• FMI recently stated: “In the third quarter [of 2015], the company already saw a 10 percent sequential decrease in test orders from oncologists, which officials attributed to a lack of reorders, saying that community oncologists in particular are unwilling to order tests if they are not reimbursed by insurance.”

Supplemental Materials Regarding Methods for and Results of Survey of 17 Health Insurers

Survey Timing

- Searches and data collection were undertaken in both 2015 and 2016.
- The first review took place during the weeks of February 22 and March 3, 2015.
- The same form of review of the same websites was again performed on January 8-11, 2016.
- The 2016 results were essentially identical to 2015 as to the definition for the term “experimental” for the 7 responsive websites.
- The CIGNA site showed a dramatic increase from 191 search results for “experimental” up to 430 search results.
Methods for Survey of Insurer Websites

- 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.

More Methods and Outcomes for Survey of Insurer Websites, cont’d

- A glossary was found for the remaining 14 websites.

- 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 in the glossary 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.”
More Methods and Outcomes for Survey of Insurer Websites, cont’d

- Some 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).