

## CRITERIA FOR HEALTH CARE INSURANCE COVERAGE

Keynote Speaker Dr. Hugh Hill

### **Prof. Baram:**

Our keynote speaker has one of the heaviest schedules imaginable. We are delighted that he is able to join us here today, despite aircraft delays. It is my pleasure to introduce Dr. Hugh Hill, Acting Director of the Coverage and Analysis Group in the Office of Clinical Standards and Quality at the federal Health Care Financing Administration in Washington (“HCFA”). Dr. Hill’s group at HCFA determines Medicare coverage policies and makes coverage decisions that are applied nationally. In other words, the Coverage and Analysis group serves a tremendous gate-keeping function. Dr. Hill is on assignment to HCFA from his position on the faculty at Johns Hopkins School of Medicine. It should be noted that in addition to holding a medical degree from Medical College of Virginia, he also holds a law degree from the University of Virginia Law School.

### **Dr. Hugh Hill:**

I am very grateful to have the opportunity to speak. The weather is getting bad out there, so thank you all for staying. Professor Baram had the sequence exactly right, because what I am going to talk about is a little more general than what the other speakers had to say. At the end, I will try to take questions as long as you are interested.

There is another way in which the sequence in today’s symposium is appropriate. Manufacturers and other people are promoting devices. We are finding now that most of the time it is promoters coming forward with devices, although we are beginning to get some special interest groups and sufferers of diseases as well. Maybe these interest groups are fronts for the manufacturers. We do not know, but some group is always coming forward asking us to cover this, that, or the other thing for their particular medical problem. A device manufacturer would have to go through the FDA first, so it was a positive that you heard that talk first.<sup>[1]</sup> I had to give a chat at the NIH, and I talked about pathways to reimbursement because, of course, what the promoters want to know are what mistakes they can make, and when the money will start coming in. We use the analogy of Ulysses’s journey. One of the first stops is the Cyclops; that is the Federal Food and Drug Administration (“FDA”). Everything else is easy after that starting point.

I want to point out something about our reorganization within HCFA. This is an agency of Health and Human Services, like the Centers for Disease Control, the FDA, and the National Institutes of Health. About three years ago, after much labor and lots of consultation, the Administrator, Bruce Vladick, reorganized HCFA into different offices. A partial motivation for the reorganization was this Jeffersonian notion: a little revolution is good every now and then. The reorganization has forced us to reexamine things.

I have only been at the HCFA for a few months. What I have learned is that the thinking behind moving and separating the Center for Health Plans & Providers (“CHPP”), and the Office of Clinical Standards & Quality (“OCSQ”), the office in which Coverage is located, has to do with the notion of separating costs from coverage. Coverage is in the quality office. The people that determine the codes under which health care providers can bill are over in the payment office, the CHPP. Other functions that we perform in our OCSQ are quality reporting or the hospital’s condition of participation. For example, our principal look at single use devices and hospitals currently comes not as much from the Coverage office, and whether or not we are going to cover the re-used single use device, but from the people that determine the rules or conditions of participation at the hospitals. If you want to learn more about our organization and

that structure, I encourage you to visit our website, [www.hcfa.gov](http://www.hcfa.gov).<sup>[2]</sup>

You may ask, “Where do we get off saying what is going to be covered?” The program is interestingly stated in the statute, which states that we will pay for medical care and hospitalization, but we are forbidden to pay for anything that is not “reasonable and

necessary.”<sup>[3]</sup> It is the conjunction of these negatives that actually creates some interesting issues. Ever since the beginning of the program, we have been trying to get at what is meant by “reasonable and necessary.” If you are interested, I will talk a little more about our most recent attempts to create a coverage regulation.

Let me try to explain what we think the statute means. It is kind of like rule-making, and I say “kind of” because it is only a bit like rulemaking. First, let me talk a little bit about the Medicare program. You thought all those taxes you were paying meant that Medicare was a defined *contribution* program. Well, Medicare is actually more like a defined *benefit* program, because we cannot pay for something unless its within a statutory benefit category. For example, we would not pay for preventative services unless Congress has passed a preventative service clause for a mammography, screening for prostate cancer, or whatever other service.

Thus, the first question you ask when you apply to HCFA and ask for coverage after you have gotten FDA approval is whether the device fits into a suitable category, before we determine whether or not it is “reasonable and necessary.”

There are two general categories of coverage decision-making. One is local and one is national. Most of the coverage decisions are still made and have historically been made locally. For those of you who may not have been around then, let me explain that when the Medicare program was first enacted, organized medicine and health-care providers generally insisted on local contractors rather than a big nationalized contractor. Instead of a centrally planned system, the providers wanted to have a bunch, or a plethora in fact, of local contractors through which HCFA would work. So we would have, for example, Aetna operate the program at the local level and we would just write the checks. The providers, then, would determine what was to be paid and what was not. You can probably tell from my tone that we are being driven by a lot of different forces, including the same people in organized medicine that originally wanted local variations, to achieve national consistency in coverage. Thus, lately we are getting more coverage decisions made on a national level. The local contractors are still supposed to be deciding whether or not to cover something on the basis of medical effectiveness. However, we have a more formal process for reviewing coverage decisions.

How does HCFA determine what is reasonable and necessary? We have changed the process slightly and I am going to talk about that. Our notice last April outlined our new

processes.<sup>[4]</sup> It happened for a number of different reasons. I find it interesting that part of the reason was the advisory committee “process” that we were using. There were complaints that we were implementing decision-making in a black box and somebody figured out that our advisory committees might be violating a long-standing rule, the Federal Advisory Committee

Act (“FACA”).<sup>[5]</sup> Thus, we opened up that process for review and created a whole new process.

We continue to base our coverage decisions on medical evidence, where there is adequate medical evidence, and the best evidence we can get when there is not great medical evidence. We need to ask several questions, similar to those a doctor would ask when he or she is trying to decide whether an intervention is appropriate for a patient: What is the balance of risks and benefits, and what are the chances of improved health outcomes? Our first threshold is that we cannot approve anything that has not been approved by the FDA. It is hard to identify good evidence except in the extreme, because we are fairly clear only about what constitutes bad

evidence: apocryphal stories, testimonials, and those sorts of things. This “evidence” is not very reliable.

What is the essence of evidence in science? In my opinion, the essence is reproducibility. What suggests reproducibility? A double-blind randomized controlled prospective trial that is duplicated in three places, each of which has an adequate power and involves at least a hundred patients. This is a standard we would like to have, but as you can understand, tests like those are expensive for a manufacturer and represent a significant hurdle. I was glad to hear the previous panel because when I meet with manufacturers, it seems like *we* are the ones that are holding up the engine of progress in preventing patients from getting all these wonderful new products. It is nice to hear that the FDA comes up for a little complaint, too. If there is interest, we can talk about the coordination between the two agencies and the flow of applications. As attorneys, you will understand that I sometimes get a little frustrated when there arrives on my desk the same application package that arrived the same day at the FDA and the desk of the people who decide whether or not to issue a new code for a product.

Today, I can come to Boston and take revenge. For years, I have sat in lecture halls and had experts from Boston put up too dense slides with too much information. I just want to ask you to follow me through the entire algorithm. Let me just point out that we have this trifurcated point on the decision tree. Once we have gotten the information that we need in order to make a decision about whether or not something should be covered, we can decide it internally in-house. We can refer it outside for a technology assessment. Technology assessment has developed enough in the last ten years that there are commercial houses doing this and there are people, like those at Blue Cross and Blue Shield’s national organization, doing technology assessments and literature analysis. We have some budget to purchase that information. Also, we can look at those results and decide whether or not that is sufficient to give us the answer as to whether something should be covered or not. Finally, we have a very new Medicare Coverage Advisory Committee Process that has been hotly covered in the trade press recently. I would be glad to talk with you about this if you are interested. Fortunately, there has not been litigation over this yet.

Out of this entire process comes a final decision that is announced in the nature of a rule. We do have to be compliant with some, but not all aspects of the Administrative Procedure Act.

[6] For example, our rules have to be forward-looking. If you have been putting your device in people, hoping that we would pay for it down the road, we cannot issue a retroactive coverage rule.

I want to talk very briefly about the input side, or what triggers or causes our review. When the system was set up last April, it was characterized as being subject to inconsistent local coverage policies. When I became the Acting Director of the Coverage & Analysis Group, I recognized this situation as similar to a Circuit split. When the various contractors that work for HCFA have perhaps a balanced misinterpretation, or when maybe one local contractor is aberrant and does not want to cover something that everybody else does, those issues are for the enforcement side and the contract relations side of HCFA to address. However, when there really is a lot of inconsistency that is causing confusion, it is a concern for the coverage side. For example, we pay on the basis of site of service, not of where you live. If you have people moving, or driving themselves from one jurisdiction to another to get care that might not be covered in their own jurisdiction, that does not seem very right and fair. We should have something a little more consistent. If it is a good idea to cover it in one place it ought to be covered in all, unless there is some local factor. Recently, we had a particular circumstance in one city where a specific hospital had a particular ability to do a procedure that nobody else seemed to do so well. There is some evidence that maybe they are very good at that procedure

and we should cover it for this specific facility.

The other things that can trigger us to make a decision are listed on the screen.<sup>8</sup> The services are now considered obsolete. There is by the nature of our national coverage process a downside that I do not think many people have stumbled upon yet. Anybody can send us a request to consider. Any of you tomorrow can send us a package of medical data or information that you have researched, and request that we make a national coverage decision. You could ask us to make a national coverage decision about one of your competitors. Thus far, most of the formal actions that we have taken in the short time that we have had this new process have been through a formal request. Program integrity is our codeword for our version of the “cops.” That is the section of HCFA that takes care of fraud or abuse and tries to reduce the cheating on the program.

The external requests come in. We are getting lots of informal requests. I will explain why this is so in a minute. I get a lot of requests crossing my desk from manufacturers for informal reviews for coverage, and then wanting to have us tell the carriers. They want us to tell the contractors, “We’re not going to issue a national coverage decision, but we want you to cover this, or not cover that.” The request has to be in writing, accompanied by supporting documentation, and we have set for ourselves a time limit of ninety days for review. We hope we have written this thing so that you can not sue if we have mistakenly violated that ninety-day review period. We have put in enough weasel words in the language of our rule-making process to make sure that ninety days is simply a guiding timeframe. Our hope is that when compared with the process in the past, where a request came in and manufacturers would wait years to find out what was going on, without a clue, this new process represents an improvement, even if the process is not exact. Our theory is that industry and the market can compensate for the difficulties that are involved and react in an efficient way if they can estimate how long it is going to take and how much it is going to cost. Those sorts of variables can be factored into an estimate.

So what do you have to send in when you make a request? We expect you to supply these things,<sup>[7]</sup> although we have said that if a request comes in from a group of sufferers who do not have quite the access to the medical information that the manufacturers do, that we will look more kindly and do a little more of the research ourselves. We are not limited to the package of information that you send in. We will look for adverse research and literature ourselves. We want to know about the current clinical trials and the status of the FDA approval. Let me just give you an example of how the interplay between FDA and HCFA coverage plays out.

If you are a device manufacturer who has a product that is similar to what is out there on the market already, you want to be in Class II of the FDA’s three classes: dangerous, not dangerous, and in-between. “Not dangerous” devices include things like bedpans. You are not going to get a lot of reimbursement for a bedpan. However, if you can get that Class II category, you can get a 510K permission to market your product on the basis that you are substantially similar to what is out there already.<sup>[8]</sup> So you argue to the FDA that you are very similar and therefore, that you do not need new trials. You would argue that you should not have to perform a pre-marketing analysis and research plan, and spend the billions of dollars. You would argue that you should just be permitted to enter the market because you are similar to what the FDA has already decided is safe and effective.

Then you would come to HCFA. You want to be paid more than what is already out there because you think it is a superior product, and it costs more to manufacture. You must argue to us that the product is highly superior, has substantial differences, and an increased

medical benefit in order to get a different code, and thus a different price. The only way I can figure out how one can argue to HCFA that a product is substantially different from another product, and to the FDA that it is substantially similar to the same product is to hire two different lawyers.

Now, HCFA needs to find out first if there is a statutory benefit. Internally and structurally, we punt that decision over to the payment folks. They will tell Coverage whether or not there is a benefit category. Then we ask if there are statutory exclusions to the coverage, for example, the preventative exclusion I mentioned earlier. Second, we ask if there is sufficient evidence for us to be able to make a review.

One of the things that I like about this job, this wonderful job I am now performing, is that nearly everything we are looking at and reviewing is a case of first impression. Imagine bringing your law training into a situation like this in the government, where you are having to think theoretically. You will be extremely glad you went to a national law school, and not a “black letter” school where you learned the answers to the questions. For example, somebody will say, “Well, we’ve had this request in to you, and you’ve promised to make a decision, now we want to withdraw our request.” We cannot just research the law on withdrawal of requests like we could in another situation. However, we have the option of deciding what to do with that request, and we’re very conscious that whatever we do, the process needs consistency for the next person who asks the same question.

We can look at it ourselves, we can send it out, and we can use the advisory committee. Let me talk very briefly about the advisory committee, the new FACA-compliant committee. The FDA uses committees, too. We used to use a technological assessment committee in Coverage. We have incredible, nationally-known experts, people of whom I am in awe, sitting on our panels who look at evidence and give us their opinions.

This committee was initially structured cleverly. We were given permission for one FACA-compliant committee. One of the things that FACA does is limit the number of committees.<sup>[9]</sup> Now, there is still a tea-tasting advisory committee that sits for the FDA but the limitation on the number of committees meant that we could only have one. However, we anticipate an enormous number of different issues requiring different special interests, knowledge, skills. My predecessor came up with, and guided through our general counsel’s office and through the Office of Management and Budget, what I thought was the rather clever plan of having a committee with an executive committee through which all the decisions of the various subcommittees or panels would pass, with each meeting of both the subcommittees and the executive committee being FACA-compliant; i.e., open, inviting the public, posting notice in the Federal Register, etc.

Thus, we had two meetings to discuss stem-cell transplant for multiple myeloma, and whether or not we should cover tests for human tissue sensitivity, or tumor tissue sensitivity to different cancer chemotherapeutics. Both panels told us after they met that they thought we should cover the cost, while one was more enthusiastic than the other. We tried to stress the importance of their decision in the early stages, and told them not to invade the province of the jury, or tell HCFA that they thought we should cover it or not. We wanted to have them review the scientific evidence. They basically tried to tell us there was enough evidence to support our covering both of these two procedures. Then we had the Executive Committee meeting on December 8. In its charter, the Executive Committee’s job is to ratify the results of the subcommittees. The charter actually read, “ratify and pass on to HCFA the results of those subcommittees,” but the Executive Committee refused to ratify these results. The Executive Committee said the cases had not been properly processed and needed to be examined further. They wanted to know more about what the literature was in each case, and refused to ratify the

sub-committees' decisions.

Their refusal caused some concern and uproar. The process was written in such a way that most observers believed that the Executive Committee would just be an administrative pass-through. Yet these well-intentioned, but hard-nosed, high-quality people said, "No, this isn't right," and now we are scheduled on March 1 to have another Executive Committee meeting where they are going to suggest to us: 1) what they think is a proper hierarchy of evidence; 2) how they want information presented to those panels; and 3) how we should be judging scientific evidence.

So these are the various panels of the Executive Committee. We are going to be taking those two decisions back. What can we do at the end of this pipeline? What decisions can we come to? We can decide we do not want to cover something. That decision is binding on Administrative Law Judges ("ALJs"), and there is basically no appeal process for our decision.

[10] The Local Medical Review Policies decisions (remember I told you that ninety percent of decisions are still made at the local level) are appealable to ALJs. The hearings tend to be ex parte. The provider goes in with the patient, or the patient herself will appear before the ALJ and state that the provider had a thing-a-ma-bob put in her, and now they want it paid for because it helped her. What is an ALJ to do? HCFA does not have counsel, and the other side is arguing for coverage. Generally, the other side wins those cases. For a young attorney, these are good ones for you to start with because you can amass a healthy won-loss record initially.

National coverage decisions are not reviewable through the ALJ process. HCFA could say that we are not going to make a decision, and HCFA is going to leave it to local carrier discretion. This is why Coverage gets so many informal requests. Manufacturers want us to simply direct the carriers, so that if the carriers do not take our direction, or the form in which it is done does not suit them, they still can go to the ALJs and get coverage in a lot of cases. Although it is a tool that we still would like to be able to use when the information is not right or the technology is still developing, we try not to direct the carriers. You can imagine some situations in which it would be advantageous to leave that sort of thing up to carrier discretion.

We can make a decision with limitations. How can we do that? If we are purists, as I say we are, and we are trying to decide coverage without concerns about costs and without worrying about what the other side of the house at HCFA does in terms of deciding how much to pay, how can we make limitations? Well, the way we can limit coverage is by looking at the evidence and talking about sub-groups of populations. There may be enough evidence to cover Brand X whiz-bang device for people under fifty-five. And so we will cover it for our disability-eligible and end-stage, disease-eligible people, but maybe not for our age-eligible Medicare beneficiaries. We might leave that to local discretion or we might say there is no coverage. Then we can of course say, "It's covered."

What happens when, say, the device is covered? Does that mean if you are the sole source-provider of something that we think should be covered you can name your own price? Sort of implies that, doesn't it? There is some concern about that within the HCFA. However, if we are going to try to be true to our decision to separate cost and coverage decisions, we have to take that risk. Right now, people on the cost side of HCFA try to guess the manufacturer's cost, look at what the local carriers are already paying on average out in the nation, gather data from a bunch of different places, and set a price on that basis. Coverage is not completely a blank check. However, that concern remains.

Then what happens? We make a decision, we announce what we are going to, and then there is a pretty long delay. Our announcement in the Federal Register refers to time to give the public and industry an opportunity to react. Most complaints we have about the duration of the pipeline that I have received are from those at the other end of it. That is because of our

processing system. How much does it cost a commercial carrier for health insurance to run their system? What is the percentage of premium that they pay? It is at least double digits. We are running this program on between one and two percent of the premium. We are paying the carriers a buck a claim to process these claims. Then when the carrier does something special for us, like a policing function or finds a code variation, we will pay them extra on a job-by-job basis. We are incredibly efficient. What that efficiency means is that we cannot react rapidly. The contractor systems and their computer systems do not allow us to plug in a new code, issue a new price, and start payment right away. We have, in the short time that we have been operating under our new system, beat these deadlines. We are doing better than our own deadlines. That is our goal and this is an outside estimate.

While there is no appeal, if you have information that we have not considered already or you can tell us how we misinterpreted the information that was already out there, we will have to look at it again. For example, there are members of the imaging community that do not have any new evidence for their particular form of diagnostic imaging, but they have taken their data and they have turned it into something that looks like a meta-analysis. They have asked us to re-examine it and so we have to review it.

Our plan, the fourth part of our plan to redo quality related coverage, is to issue sector-specific guidance documents. As you can imagine, it is hard to do a double-blind randomized control trial when you are talking about a surgically implantable device. A surgeon closes his eyes while he puts the thing in. You can do sham operations, all kinds of things you can do to try to get good quality evidence, and the testing is different in different areas and different sectors of the market. Our intention is not to give sector specific guidance until we issue at least our proposed regulation interpreting what we mean by “reasonable and necessary” in the Notice for Public Rulemaking form.

It might be worth your while if you are interested in this field to pay attention to the news in the next few months. In 1989, and I am told ten years before that, and a couple of years ago as well, there were attempts made to suggest an interpretive regulation where HCFA tried to say what “reasonable and necessary” means. These attempts caused a great deal of dismay and concern, and sometimes outrage throughout the industry and the public. For some, the concern is based on a fear that if we pay attention to cost concerns at all (and there was some mention of “value” in one of these previous iterations of that regulation), Medicare beneficiaries will be denied something they need. This may be something they think they are entitled to. I’m told when I attend briefings at the Secretary’s level, “Medicare is not an insurance program. It’s an entitlement program.” We are working on the program. We hope to be able to issue that Notice in some form and start taking the comments. We would like a debate to start focusing on a document that will explain what we think “reasonable and necessary” means.

We build on the FDA’s first two blocks. We do not want to cover anything that is not safe and effective, which is already presumed after FDA approval. Then we look at the benefits versus risk. We look for outcome. Here is a big difference between us and the FDA. What you are hearing from them is that they want to know if something is safe and effective. At core, “effective” to them means it does what it says it does. Remember how they focus on the label they get for advertising purposes? For example, the implantable whiz-bang improves blood flow to the lower extremities. We want to know whether these people with improved blood flow to the lower extremities actually do better in the long-run. Maybe the side effects of this whiz-bang cause a problem. Maybe down the road there is less survival. We want to know future outcomes, the medical effectiveness and the medical benefits before we approve something for coverage. It is not enough, although some manufacturers would like for it to be, to simply get the FDA approval and then have HCFA coverage. Then we are talking about how to figure in

some concept of added value for the program and for the beneficiaries.

I do not have to say this to my medical audiences, but I probably sound to you like somebody who believes in science almost fanatically. But remember my earlier point about reproducibility. That point is important. We ask whether the study, the evidence, means the same thing in a group of patients across the board in a population, how often will the good outcomes happen, and how often will bad things happen. It is the reproducibility that is important. Einstein is often quoted as having said, “God doesn’t play dice.” We are reminded by Stephen Hawking that maybe there’s a different interpretation: “God not only plays dice, He also sometimes throws the dice where they cannot be seen.”

HCFA has made a commitment for an open process. We want to be transparent. We have got on our website a list of the coverage decisions that we are making.<sup>[11]</sup> We make our statements of coverage and our justifications for it available on our website. We are posting it there. One agency, Agriculture, I think, has moved to rule-making on the Web and taking in comments on that basis.

Thank you all very much. I will be pleased to take any questions.

**Prof. Baram:**

Thank you for talking to us today. We appreciate your time. While the Symposium is officially over, anyone who would like to stay to ask questions of Dr. Hill for about fifteen to twenty minutes, we can certainly continue for a while.

**Audience Member:**

When you are dealing with added value and improved outcomes, are you including quality of life?

**Dr. Hill:**

Yes, but duration of life trumps that. Right now, what we are looking at first is duration. Let me give you one example. If you look on our website, there is a rather strange device that we have approved coverage for in limited situations called external counterpulsation, which involve these pressure cuffs that squeeze in association with and in counterpoise to the rhythm of the heart,<sup>[12]</sup> the thought being that if you can squeeze at the right moment, you do not put increased pressure against which the heart has to pump, but you do get increased coronary artery filling, which happens right at the end of the systolic part of the cycle.

This has become popular enough that we were sent a grocery or K-Mart bag from somewhere in the Midwest that said, “Bypass the bypass—Jump on the pump.” There is little evidence that it helps and the only evidence that we could find that it helped at all was in cases of terminal unendurable angina (chest pain, occurring with even minimal exercise) that could not be repaired in any other way. So, for that segment of patients, the minimal little bit of evidence that it improved quality of life, we accepted and agreed to cover it for those folks. But, right now, and I hope for the foreseeable future, if it extends life we are paying for it. How much does it extend life? If you believe the study on mammography that came out in *Lancet*,<sup>[13]</sup> mammography does not help at all. The NIH and NCI doesn’t believe this, but there are some researchers that have suggested that screening mammographies may add a total of one and a half days on average to the lives of women. Those of us who are clinicians who have seen otherwise just do not believe that study.

**Audience Member:**

First, you said that a decision to deny coverage is not appealable within the Agency. Is it appealable in courts, and if so, have there been any cases? And then secondly, I guess you don't have any record under your new science advisory committee, but under the previous one, at least, does the department ever disagree with its Advisory Committee's recommendation or is it pretty much a done deal if they approve or disapprove something?

**Dr. Hill:**

Let me answer the first question as best I can, because I am new enough at this that I do not have the citations. I would refer you to *Heckler v. Ringer*, a 1984 Supreme Court case, as it contains a couple of cites that I think tend to answer that question.<sup>[14]</sup> It is, of course, appealable, but you have really got to jump through a lot of hoops and hurdles, exhaust your administrative remedies, and unless it is a major issue, it is going to be very difficult. We are talking about whether or not there should be an appeal process. But you could easily see how the exception would quickly become the rule. If you have any suggestions from a theoretical basis, we would love to hear them because we are in the discussion stages with this. As to your second question, the MCACs, no, we most certainly are not simply taking their recommendations and accepting them, *carte blanche*.

The intention is to have them give us advice on evidence. We will not abrogate our responsibility to make the ultimate decision. We will ask them what is behind their advice. This is why the process that they are going through now (which has been somewhat controversial in the trade press, and for which we hope to find some answers at our March 1 meeting) is very valuable to us because we would like to know what is behind their thinking. We would like them to state some guidelines and some rules that the sub-panels will use. Maybe not everybody is going to like that, but we all can take that into account. So that, for example, if they think that we should not pay attention to evidence of this particular category, and we think we should, but maybe at a different level, then we ask them what is behind their thinking and how they rated the evidence. We can take that into account and re-balance it ourselves. For example, there is a lot of stuff in the medical literature now about how recommendations of societies, or what is being done in the medical community, maybe is not such hot evidence. Witness the Institute of Medicine's report on medical errors.<sup>[15]</sup> But what is the difference between new, emerging technology and extant technology? We have some experience with the extant ones. Maybe the value of those recommendations is different in the new versus the old technologies.

**Audience Member:**

I have a question about how your organization has dealt with advances in genetics. Have any significant cases come before you? Have you formulated any significant policies? Does your advisory committee have a significant bunch of people in this area?

**Dr. Hill:**

Nothing yet. Insofar as our interaction with the FDA is concerned, I am having at least monthly, if not more often meetings with the FDA, and the people on my staff are, too, as part of our mission to try to be ahead of the curve and aware of what they are doing and what is coming down the pike at us. Ninety days is not going to give us enough time really to evaluate something brand new and out of the blue like a new genetic test, if FDA covers it. So, not yet. You are right, we need to be paying attention to it and we are working on it.

**Audience Member:**

I would like to follow up on the last question. You said that there is no coverage, no reimbursement for prophylactic procedures.

**Dr. Hill:**

Preventative.

**Audience Member:**

Preventative procedures.

**Dr. Hugh Hill:**

Yes, so when you go to get your yearly physical, we do not pay for it. That is why your doctor says, "Please tell me you've got a symptom," so he can justify it that way.

**Audience Member:**

Does that include, for example, a woman who has a BRCA-1 test, comes from a positive family, has a very high risk and wants bilateral radical mastectomy? Would that not receive coverage because that would not be considered until after-the-fact, and you would have to wait for her to get sick?

**Dr. Hill:**

We have not hit that issue yet – familial risk, high predisposition. If there have been no manifestations, no lumps, no multiple biopsies, no psychological distress that we can specifically point to that is disabling because of cancer-phobia or fear, right now that would be tough. It would be tough. And that is the kind of thing that I am looking forward to getting our teeth into.

**Prof. Baram:**

That is the end of our program. Professor Steve Bauer and I are very happy with the day's events and hope you enjoyed it very much. We would love to get feedback from you on the program and look forward to next time.

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[1] Ellen Flannery et al., *Regulatory and Liability Considerations*, 6 B.U. J. SCI. & TECH. L. 5 (2000).

[2] HCFA - *The Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Agency* (visited May 8, 2000) <<http://www.hcfa.gov/>>.

[3] Social Security Act §§ 1861, 1872, 42 U.S.C. §§ 1395y, 1395hh (1994).

[4] *See* Medical Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,619 (1999). The new process "will streamline [HCFA's] decision-making process and will increase the opportunities for public participation in making national coverage decisions." *Id.*

[5] Federal Advisory Committee Act, 5 U.S.C. app. §§ 1-15 (1994).

[6] *See* Administrative Procedure Act, 5 U.S.C. §§ 500-596 (1994). Dr Hill notes that HCFA's coverage decision making process is exempt from ordinary notice and comment procedures because the APA exempts "rules of agency organization, procedure, or practice." *Id.* § 553(b)(3)(A).

[8] See 21 U.S.C. § 360c(f)(1)(A) (1994) (“Any device intended for human use . . . is classified in class III unless the device is within a type of device . . . which was not so introduced or delivered before such date and has been classified in class I or II, and is substantially equivalent to another device within such type . . .”).

[9] See Federal Advisory Committee Act, 5 U.S.C. app. § 2(b)(2), (5) (1994).

[10] See 42 C.F.R. §§ 405.732(b), 405.860(b) (1999).

[11] See HCFA, *Medicare Coverage Process* (last modified May 2, 2000) <<http://www.hcfa.gov/quality/8b.htm>>.

[12] See HCFA, *Medicare Coverage of External Counterpulsation Therapy* (last modified May 1, 2000) <<http://www.hcfa.gov/quality/8b3-b.htm>>.

[13] Peter C. Gotzsche & Ole Olsen, *Is Screening for Breast Cancer with Mammography Justifiable?*, 355 LANCET 129 (2000).

[14] 466 U.S. 602 (1984).

[15] COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 1999).