Patient Empowerment and Patient-Centered Care

A Clinical Conversation with Mary Hardy, MD, and Robert Rountree, MD

Mary Hardy, MD, board certified in internal medicine and a specialist in botanical and integrative medicine, has actively combined complementary and alternative therapies with traditional Western medicine for over 30 years in both her clinical practice and research projects. In 1998, Dr. Hardy founded the Integrative Medicine Clinic at Cedars-Sinai and participated in an NCCAM-funded research project that evaluated the barriers and facilitators of integrative medicine practice based on her clinic. Dr. Hardy is currently teaching in the Integrative Medicine Fellowship Program of the Academy of Integrative and Holistic Medicine focusing on efficacy and safety of herbal and dietary supplements as well as clinical management of complex patients. She has previously served as faculty for the Georgetown University Masters Program in Integrative Medicine, the Associate Director of the UCLA Botanical Research Center, the Medical Director of the Simms/Mann-UCLA Center for Integrative Oncology, board member of the Society for Integrative Oncology, co-leader of the Oncology Interest Group in the Consortium of Academic Health Centers of Integrative Medicine, a member of the Stiles Integrative Oncology Center at UCLA, co-director of a fourth year elective in Integrative Oncology, and co-director of the Integrative Medicine Health and Wellness Program at the Venice Family Clinic, the largest free clinic in the United States. She has served on and chaired several United States Pharmacopeia (USP) expert committees examining the safety of selected dietary supplements and chaired the USP committee, Dietary Supplements Safety Modeling Expert Panel. She has also served on the External Advisory Council for the Natural Product Directorate for the Canadian Ministry of Health assessing scientific issues pertinent to regulatory issues and serving as an expert in natural products risk assessment and clinical trial design. Dr. Hardy is the 2020 recipient of the ABC Fredi Kronenberg Excellence in Research and Education in Botanicals for Women's Health Award given by the American Botanical Council. Dr. Hardy's current research interests include reviewing the evidence for the safety and efficacy of natural therapies, especially botanicals as well as conducting clinical trials of dietary supplements and lifestyle choices to reduce toxicity and to improve outcomes of conventional cancer treatment.

Robert Rountree: There have been three American Botanical Council Fredi Kronenberg Excellence in Research and Education in Botanicals for Women's Health Award winners. I have interviewed the first two for this column, and now you are the third! I think the topic of women in medicine is a natural segue for any discussion on botanicals because women were traditionally the keepers of the flame for medicines made from plants.

Mary Hardy: Yes, and they also cared for each other too. For many, many thousands of years, women's medicine was practiced by women for women. This is an aspect of the award that makes this such an honor—that it brings together so many threads that are meaningful to me as a woman in medicine. Being in a sisterhood and having the sisterhood be acknowledged is a huge part of that honor. And especially nice for me because I am a fifth-generation physician. When I graduated from medical school, my dad gave me my great-great grandfather's diploma of graduation from medical school 115 years before I graduated. So when people say to me, "How did you get into alternative medicine? That is so weird." I am like, "Are you kidding? Being a woman in the Deep South, in New Orleans, going to medical school? That was weird. This is easy."

Dr. Rountree: What inspired you to be a doctor?

Dr. Hardy: It was specifically my grandfather. My dad was a radiologist, which is a much more visual kind of a step away from patients. But for me, it has always been about the patients, and it was my grandfather who was in that style of practice at that time where you did general medicine, so you did everything. You did surgery, obstetrics, everything. He had the most amazing rapport with his patients. One of my favorite things was to be able to go visit at the office. Everybody liked seeing his grandkids and he used to take me on rounds with him, in the hospital too sometimes.

I really saw what it was like to be a doctor from that perspective. So I have always had sort of an old-fashioned view about the covenant between doctor and patient. It really is a promise, and it is a sacred piece of work. It is not a punch-a-clock 9-to-5. It is really, truly sacred work. It was seeing that covenant in action, and the love and joy of that from both sides that really convinced me how to practice medicine.

And we have lost sight of that, of the sacred part of our function as physicians. Certainly the trust that someone places in you, that you then accept responsibility for their care, is a very deep and meaningful transaction. It is ignored at our peril. It is a big part of how I have always practiced. Who is the patient? Who is this person in front of me? How does that manifest in the concern they have brought to me? And then how does that affect what kind of therapies they will empower? For me, the best definition of good medicine is the most effective least toxic therapy that the patient will empower.

The kind of connection between my grandfather and his patients was what I observed, and what I saw was really the right way to do things, and how much joy that engendered on both sides. That was where I saw what the covenant of medicine looks like, from watching him practice. So I kind of came into medicine with an old-fashioned notion of what medicine was, and I think that has stood me in good stead, to have that kind of an example so that I could always know that the person was at the center of care. It was not a big revelation to me. When patient-centered care has recently been seen as a “discovery,” for me, it was like, “No, this was the way it has been done.”

Dr. Rountree: The way that has been at the core of medicine from the beginning.

Dr. Hardy: Right, and especially in the times when we did not have a lot of technically effective management, then our presence was what we had to offer, and still have to offer. It underlies all the technical medicine, and it is what remains when the person comes to the end of the benefit of technical medicine. Even if you cannot quote-unquote “fix them,” you can still attend them. You can still heal them. You can still be a consistent presence, a loving presence who says, “I cannot make this back to normal, but I can stand with you while you go through this.”

Dr. Rountree: Tell me about what your medical school experience was like. Did you already have this perspective of the importance of being present from the beginning? If so, how did you soldier through?

Dr. Hardy: I had that perspective, and I am determined enough that I kind of went about things my own way. The thing is, it does not matter what anybody else says, because the patients confirm and affirm that attitude, because they are like, “Oh, my God, you are talking to me. I feel so much better. I feel like I have been heard. I feel like now if you make the recommendation, you are making it out of an appreciation for all of me, not just you checking a box on your checklist.”

I taught in an introduction to clinical medicine class at USC for 14 or 15 years, and so I saw hundreds of new medical students come to their first clinical class, basically. One of the first questions I asked them was, “Well, why are you here? What brought you to this?” And most of them said, “Look, I am really good in science, but I want to help people.” Their basic communication skills of general politeness were pretty good. It

is an indictment of our medical system that by the time they have left medical school most medical students were worse communicators than they were before they started. Because that gets worked out of them, right? You are supposed to always just get your job done, et cetera, and that is true. You have a technical responsibility, but you still have to be compassionate even if you are a bit stepped back. You really have to be. And people who enter this career absolutely come in with that as their intention.

Dr. Rountree: When you were in medical school, were you already interested in herbal medicine, or did that come later?

Dr. Hardy: I did have some interest in this. It just was too confusing to try to pick up two different systems at the same time. There was a fair amount of folk medicine even in Louisiana still when I was there. But I just had to do my medicine first, and I promised I would pick it back up. And sure enough, opportunities kept presenting themselves to me to investigate this other aspect of medicine and be reminded that even with the most technical sophistication, you cannot always explain everything.

Being available for the mystery and the wonder of things is just a delight. How do you have congestive heart failure? What is your family social structure like? How does that impede you or support you, and how can we facilitate that? You know? There are just a zillion interesting questions and it enlivens the technical aspects for me.

Dr. Rountree: Have you found that this path of botanical medicines along with a patient-comes-first philosophy has been a challenge to integrate into the academic system? I know you have worked in large hospital systems for many years, so I am wondering what that has been like for you.

Dr. Hardy: Well, I will say, when I first started when I would present material, I remember people would just come up to the front and be distraught and say, “You are ruining medicine.” And I had to figure out what to do with that kind of input. I finally decided just to say, “Thank you. I am grateful that you feel so strongly about this. If you would like to participate with us and tell me where I am going wrong, by all means, join our board. I really would like you to be around to tell me what you think I am doing wrong.” And they would just mostly go away after that. People had been really upset about this—“There is no evidence base for this.” And I would just quietly hand them the 150 references that supported the material I was presenting. You do not fight with people like that. It creates more resistance. You just acknowledge it and basically try to see if you can incorporate it into your daily living.

Dr. Rountree: What do you think is the main source of resistance among mainstream doctors to botanical medicine?

Dr. Hardy: I think there is a kind version, a respectful version, a giving-them-their-due version. And then there is the,

“Wow, you are just not picking up on the clues here.” I spent 15 years of my practice in integrative oncology. And I have to say, I respect those oncologists, because what they are giving for medicines are incredibly potent and incredibly toxic. They are really committed to not have their medicine interfered with. In other words, if you made a deal where you are going to give somebody something that is very toxic, you want to make sure that you have the full benefit of that intervention. Right? So they would be very resistant to anything they thought might interfere with the effectiveness of their medicine. So I think that is the good version: “We really want to make sure our therapy is effective, and you are making us nervous.”

So, okay, I can accept that, and I can talk with you, and I can work around it, and I can keep presenting data to you and hope that eventually you will come around. I have found that after about six months at the academic center I was working at, one of the best oncologists called me up and said, “Look, I do not know what you do. The patients love it. I do not know what you do, and I do not want to learn what you do. I do not want to do it. I want you to do it.”

I am seeing everybody, because patients do better. They do not have to stop therapy. They are in much better spirits. They just go through things really much more straightforwardly. That was when that little Rubicon was crossed, when people’s own experience convinced them that it was not harmful, it was helpful, and the patients were proselytizing for me. I did not have to do it. They did it for me. That is kind of how that went in academics.

Then after a while, even the most resistant would say “Well, I am not 100% in favor of what you do, but I have to say at least you are inside the tent.” They would often send me the patients who had refused conventional therapy when it could have been very beneficial, because, “Let the witch doctor talk to them.” If I tell them to do it, I am telling them out of a context of, “Look, I understand the full spectrum of what is available, and I still think this would be a good choice for you, but I can make it less toxic for you.”

Dr. Rountree: I wonder if you think the old mindset that herbalists are witch doctors—or witches—is really hard to die.

Dr. Hardy: There is still an advancement discrepancy for women in medicine now, today. To this day, women are not paid what men are paid. So it is a very difficult trope. It is a very resistant difficult trope.

I think that is going to change. Already medical schools are now 50/50 men and women, and that is a big change from when I was a student. So I think it is just painful about how long it takes. I guess if you spend enough time there and you get enough perspective, you can step back and say, “Yes, things are changing more and better and more frequently.”

I studied ethics at one point for a semester at the Harvard Divinity School and I went to a special program and got an ethics certificate because I was firmly convinced that there is a way to figure out what is the right thing to do, and it is not just your own personal opinion—there are guidelines for this.

Ethics helped me analyze if there is a conflict here, what values are in conflict? Which means that you can always take a look and say, “If everyone is trying to work toward the good, how can I clarify this so that we can find a compromise that we can all live with, that we still honor the most important value, which is the patient’s values.”

Even evidence-based medicine, if you look back at what David Sackett and Archie Cochrane were doing, they said it is a combination of three things, the best clinical evidence available, your best clinical judgment and then what the patient wants—their values.¹ That was included in the original concept of evidence-based medicine.

Dr. Rountree: What was your experience at the RAND Corporation? How does that fit with this whole notion of including the patient?

Dr. Hardy: I think RAND is an incredible institution. It is just astonishing. There is a giant health section, and it is everything from health economics to looking at application of policy to looking at actual interventions. Ian Coulter, who has been a fellow at RAND for a long time, got a grant to analyze complementary and alternative medicine and brought it to RAND. RAND has evidence-based practice centers, and they have been used for everything like, is aspirin really useful to be used after heart attack? Do we have to give everybody XYZ? So it has been used for some very, very basic medical questions. This was kind of one of the first applications of this into this new field, and they needed a content expert. So I was their content expert and we evaluated several different practices.

The first one I did while I was the lead was Ayurveda for diabetes. That turned out to be incredibly fascinating because Ayurveda is obviously a really ancient practice. It is still a part of the world where herbal-based medicine is still used for millions of people and a lot of what they did was written down. Now, on top of that, a lot of the herbs that can be useful for controlling blood sugar have been written about in the regular medical literature, as well for a long time. So we had a lot of data to look at.

And we did something novel. We sent one of the researchers to India and we collected data from Indian studies. These studies are not on PubMed. Half of our data came from that foray into India and really enriched this experience. I also went back and did some research about what Ayurveda said about diabetes, and found out that it was relatively sophisticated for traditional healing. They were able to isolate two versions of diabetes, one that they called karmic diabetes, which happened to younger patients and that you were just born in with, and then a second diabetes that they said came because you over-indulged in eating, and something like that. It was very closely aligned with our type 1 and type 2 diabetes, which is just great, you know? Just seeing how tradition can bridge across the ages. It was a really fascinating project.

Dr. Rountree: How many years ago did they make that distinction? How old is that?

Dr. Hardy: Oh, it is thousands and thousands of years old.

Dr. Rountree: So over 1000 years ago they knew the difference between type 1 and type 2 diabetes? Wow.

Dr. Hardy: Yes, probably more than 1000 years ago. They attributed the causality differently than we do, but empirically they were able to observe this difference and treat it differently.

You had asked what empowered me. My residency was in a hospital in Boston on the edge of Chinatown. So we treated an unassimilated Chinese population, which was very cool. I went with my college roommate, who was Chinese-American, together to China, 35 years ago, when it was still really early. China was still not a westernized country in a lot of ways. So we saw surgeries done under acupuncture anesthesia only. We saw a person having a cerebellopontine angle tumor taken out with just acupuncture in the ear, and they were awake and talking and in no pain.

My roommate spoke Chinese, so we talked to the woman ourselves, and she was awake and blinking her eyes. “Are you okay?” “Yeah, it is fine.” You know, it was not like a Western theater for operating—there were not 62 different machines, and it was not all crammed up with stuff. They were just doing their work with a patient who was awake and very calm. She was not sedated to the point of catatonia. She was just basically chatting away. She was not even intubated or anything.

Then we saw two thyroid surgeries. You are standing at the head of the patient, and the field is up, the curtain is up. As you look over, you are sort of looking over the curtain, looking to the field for the thyroid, and the patient opens their eyes and looks at you, and you are like, “Oh, wow. The person is looking at me.” It was a real revelation.

You have experiences like that, and you say, “You know what? I do not know everything.” And there is a real value in that. There is tremendous value in that. Just to proceed with an open curious mind, you will observe things that you cannot explain, and you always, of course value first safety, *primum non nocere*.

But if you leave it open for possibilities, you sometimes will get extraordinary results. And if anything, you usually reduce suffering. I would often say to cancer patients, “Look, I cannot guarantee your outcome. We know it is a tough fight. You are geared up for it. You are doing everything you are supposed to do. But let us just say that we do not know the answer yet, and you are going to show me how well you are going to do.” And frequently they would.

Dr. Rountree: Tell me about your experience in integrative oncology. I think one of the earlier lectures I ever heard you give was a survey of all the different non-mainstream options that were available for cancer patients and the surprising amount of evidence behind them.

Dr. Hardy: Yes, so again, like many things in my life, I will find that if I look back, my patients are often leading me where I am supposed to go. When I got out of medical school and residency, my dad was really sick. I was supposed to do an academic endocrine fellowship, and I postponed for a year because he was basically dying of pancreatic cancer.

I wanted to be able to be free to go back and forth to see him, so I worked in a walk-in medical center in Cambridge, Massachusetts. This was one of the most liberal parts of Boston and my patients were coming in talking about all these things they were doing. They really educated me and got me thinking about ways that there were things that could be done, and challenged me. For instance, “I have bad PMS. Why do I have to only take a birth control pill? Is there not something else you could do for me?” So they really challenged me to learn a different kind of medicine. That was the first change that happened, largely through them.

Then reflecting back on these visits to China, and the unassimilated Chinese population, et cetera, I kept running up against all these opportunities, and decided, “I have to understand this better.” Then programs and teaching started to become available. And then when I was in practice at Cedars-Sinai in that first integrative clinic, we had a lot of musculoskeletal pain, which I expected from an integrative practice. Looking at the data, that was what you would expect.

I also had a ton of women’s issues coming to me then. I have always had a very robustly female practice. But then, after about a year or two into it, they started saying, “Look, you know, you did such a great job with my menopause, but now I have breast cancer, and I want the same treatment you gave me for my menopause. I want you thinking about how to do my cancer better.” They pushed, led, dragged, and challenged.

So that was really how I started doing integrative oncology, because the patients I had been caring for all along started getting sick this way. Then once I started doing it, the patient demand started to really invest me in this. It is very good work and it can make a real difference. So at that time I started doing it. I was in private practice, and I then got recruited to the Cedars-Sinai program, and then from Cedars I got recruited to go to UCLA as the Associate Director of the Botanical Research Center there.

The other half of my time I was working for the Venice Family Clinic—the largest free clinic—helping to initiate, with Myles Spar, a wellness program, which is, again, a very novel application. People did not think that poor people wanted integrative medicine. You know, you had to be the typical white, upper-middle-class, disposable-income person. It turns out everybody wants to be treated this way.

Dr. Rountree: One of the criticisms of integrative medicine that I have talked to other interviewees about is that it is only for wealthy people. But, you know, the irony is, integrative medicine came out of folk medicine practices—so the “non-elite” has used integrative medicine since the very beginning.

Dr. Hardy: Right, the indigenous and the female, disadvantaged populations, et cetera. But also, if you look back, this kind of medicine truly is Hippocratic medicine. The *Hippocratic Corpus* talked about food, your mental attitude, et cetera, as well as herbal therapies, which you could consider sort of technical therapies of their day.

I do think it is a problem, because when integrative medicine first started, you had to have an available population that was willing to implement it and could afford to implement it, because this was not, and probably still is not, completely embraced by the mainstream. So the mainstream did not want to pay for therapies they thought were experimental at best and mumbo-jumbo at worst. And you have seen the waterfront here in our “integrative/alternative” world, and some things are really bizarre and probably not effective, may or may not be harmful, but probably are not effective, and some of them are cuckoo, just really cuckoo. Other things are very rational or empirically effective.

One thing I did that was so useful in integrative oncology was to empower the patient, so say to the patient, “You are not on the worst rollercoaster ride of your life. You are not a passive person being dragged all over the place. You are the captain of your ship. There are things you can do that will help you, and at any stage along this, it is your will and your consent and your engagement that makes this a functional intervention for you. And if you cannot get behind yourself, it does not matter what they do to you, because they are not doing it with you.” I have had interesting discussions with students about how we used to be healer-priests, and we do not do that anymore, but there is still a sacred function to our work. I think that is a fascinating discussion.

Dr. Rountree: There is a great book called *Braiding Sweetgrass* by Robin Wall Kimmerer, PhD. She is trained in botany and is a professor of environmental and forest biology at SUNY in Syracuse. She is also Native American—a member of the Potawatomi Nation. In the book she talks a lot about the indigenous way of thinking and how we need to incorporate those traditional values into our modern society.

Dr. Hardy: Right. And I think one of the most transformative aspects of quote-unquote “alternative medicine,” which we now at least have moved it into the integrative category, is that many traditional systems have a very holistic view. In other words, it is all of the person in context. So it is always a person in the context of their world, the season, their beliefs, and their spirit.

In integrative oncology, it was about standing in a very technical powerful place and saying, “Do not forget about nature. Do not forget about the patient’s empowerment.” Leave them in positive uncertainty, you know? They know things are bad. But do not tell them, “You have two months to live.” Tell them, “We are going to set you up for the best shot you can take, and then you will show me how well you will do.” Let them show you, let them create something that you could not anticipate.

Dr. Rountree: We can learn so much from our patients! People think it is a one-way thing, that they are kind of coming in to get this great wisdom from the healer, but they do not realize that there is this whole other side to the relationship.

Dr. Hardy: If you stop and listen, they are teaching you as well. They are teaching you about resilience, hope, laughter

and joy, and about the mutability of possibility. It is really enlivening for me, as well as for the patient. It is a much better way to practice.

Dr. Rountree: Speaking of teaching people a different way to practice, I know that you are really involved in the Academy of Integrative Health and Medicine (AIHM). Tell me about what that organization is doing. How are they different than for instance the American Board of Holistic Medicine?

Dr. Hardy: I teach with the AIHM. They have a postdoctoral fellowship, which is a distant fellowship, and they get together two or three times a year. The model is very similar to the one at University of Arizona. Arizona is the first one and this is another one. What I find particularly interesting about this fellowship is it is incredibly multidisciplinary. I will have physicians, but I will also have nurses, social workers, physical therapists, and nutritionists—a whole different diversity of people. It allows physicians to see other practitioners in action and learn about their work from them, which is incredibly useful, and it automatically means that there is going to be multiple perspective-taking when you discuss a case, because there are all kinds of different people in the mix.

I teach some of the early classes. I like this because you get to sort of inoculate people against what is going to come, like, “Keep talking to people like this, even though they tell you not to.” And you can also set their expectation. You can help them structure how to think about a patient or a problem, and think in terms of systems, like, “This is the inflammation system. This is the physiology for this. This is the social stress for this.” So it is not just, “I learn that when you see someone with frequent urinary tract infections, you give them cranberry.” It is more like let us expand this out a little bit, and let us just not practice heroic alternative medicine. Let us practice truly integrative medicine, integrating as many parts of the person as you can hold in your hand while you are seeing them.

So I really like being in that position, where I can share with people, “Well, have you thought about it this way, or have you thought about that way?” Or you are talking, and then, “Here is the person who has developed this and done a research paper on this, or here another way to think about this.” I find that to be incredibly rich, incredibly useful and incredibly enlivening for me. You know, you can say, “Oh, it is such an unselfish practice.” No, are you kidding me? I feel great when I practice this way, and when I teach. I am doing it because I think it is the right thing to do, but I am also doing it because it feels good. You know? I really enjoy connecting with the students.

Dr. Rountree: Yes, it feels good. Is your impression that more and more docs are kind of going into this either right after they come out of training, early on?

Dr. Hardy: Yes. Well, let me tell you all the places I have taught, and then I can tell you my perspective. I have taught introduction to clinical medicine at USC for 14 years. That was just, “Jeez, at the most basic level, the most alternative thing

you can do is listen and talk to your patients differently.” So that was the piece I was teaching there. Then I have obviously had medical residents and people round with me, and I have always just practiced the way I practice. I have just broadened out the armamentarium I know about to offer, but it has always been kind of the same. So I did that both in private practice and then when I got into academia, very much did that there.

Then when I was at the integrative oncology program at UCLA, there was an elective that the senior students could take to come and spend two weeks with me while I saw patients. And what was astonishing was that most of them did not know how to take a diet history, had never talked to patients this way before. So they thought they were going to come and learn like useless herbs. It is like really, “No, let us get back to basics. What is your stress level like? How are you exercising? Let us look at this, what you have reported to me for your diet. How can I analyze that so I can make specific suggestions for modifying it, not just eat a good diet, but really, you could make this choice differently.” So, again, even when you are teaching integrative medicine, you go back to basics.

I also taught for a while at George Washington with Andy Heyman, MD. That was in a master’s program. Then I have been exposed to the program at University of Arizona and am also now teaching in the program at AIHM with Mimi Guarneri, MD.

From all those different perspectives, I think there is a unifying message, which is, go back to basics, make sure you see who the person is in front of you, encompass as much of them as you can, and offer them, again, the most effective, least toxic therapies that you can help them empower.

I do think that there are more people going into integrative medicine. It is not so much an oddity as it used to be anymore. I think that is really terrific. I see a lot of men as well as women doing this. I see a lot of psychiatrists really interested in this, and that is an interesting application of these therapies. I have seen surgeons. I have seen lots of primary care docs, but all kinds of docs are doing this. And they want to go back even to their highly technical medicine and practice it in a more mindful way, or practice it with more of a wellness attitude.

Mimi’s program at the AIHM has developed a scholarship program, and they fund health care workers who are currently working in social safety net clinics to come and be trained. And these folks are committed to putting that back into practice in their social safety net clinics, usually treating a socio-economically disadvantaged population. I think training a practitioner to then go back into those communities is one thing. Getting funding for some of these things is another thing. And having care networks like HMOs or larger health systems start to think about ways that they could provide for all patients—for instance, paying for a vitamin or herbs that have applications that are validated by research—that would be not only more appropriate, but would probably be less expensive. So focusing on funding research that will validate some of these therapies and reduce resistance and make you realize that these therapies are largely nontoxic. A huge part of my research career has been investigating the safety of these thera-

pies. But these are largely nontoxic. With very important caveats, they are largely nontoxic, that it is worth a try. And you could then try it and see how it goes, and if it goes well, do more of it. You know?

My program at UCLA was a success not because I was a brilliant practitioner, but because my co-practitioners respected me, knew that I would stay out of their way, knew that I knew what the issues were. And they said, “Well, if she thinks it is okay, we trust her. We can leave it to her.”

The more people we have who can go into the conventional system and can do that, I think that is going to be our next-generation transition. Continue to write, continue to research, and educate practitioners and patients. That is why I am spending my time on educating practitioners mostly, because I think that is what is going to absolutely drive this field forward.

Dr. Rountree: The article you wrote in the *Journal of Dietary Supplements*² assessed risk from multivitamins. I think that was in the military, correct?

Dr. Hardy: This is the USP panel sponsored by Patty Deutsch and her Department of Defense safety assessment. She said that when we go into the PX and we want to see if something is safe for our people to take, very few things have just one particular herb. They are mostly combinations. Of course, the military users would often be focused on agents that enhance physical performance. And those are supplements that have had problems with safety in the past involving inappropriate ingredients or inappropriate use or adulteration, contamination, et cetera. So she challenged us to think of a way to analyze the safety of these products. I was chair of the panel. It was Patty, Hellen Oketch, and I who led this process, and we had a brilliant group of interdisciplinary workers trying to outline a theoretical way that we could assess risk for multi-ingredient products. We looked at adverse event reports, took out the data and then put them into a matrix and analyzed them. I think it would be really great if we could get some funding so that we could test the model. That has been a big technical part of my research for a while now.

Dr. Rountree: Unfortunately, it seems like if a person shows up in a doctor’s office, and they have got, say, elevated transaminases, then the doctor asks them what they are taking, and they are taking 20 different things, and if one of those things is an herb, let us say it is kava, then they say, “It has got to be the kava.” The assumption is that they gravitate toward the supplement as being the problem. And I have seen that in my clinical practice, too, where another doctor blames an herb for some side effect the client had. The supplement automatically gets blamed.

Dr. Hardy: Right. They may be right, but they may not be right. And it is a preconfirmation bias, right? If you have an untoward event, you look for the things that you do not know about as the cause of that because “Here is something I cannot explain. Here is a product I do not know. Here is a bad outcome that I did not expect. So those two unknown things must go

together.” That is a confirmation bias, right? And I will say for one thing, assigning causality in liver toxicity is probably the most difficult case assessment of all because there are so many things that affect liver function that are part of our everyday life—alcohol, Tylenol, etc. Many drugs have an effect on the liver. So it is really difficult to isolate a single agent. Those are particularly challenging case studies.

But you are right. It is not uncommon that people will look at a bunch of toxic stuff and then say, “Oh, it is this other thing that really has done the whole deal.” For example, I was going to do a research study looking at a soluble fiber for helping diabetics by slowing stomach emptying, and maybe then decreasing their postprandial peaks of glucose. I was waiting in the Institutional Review Board meeting while they were talking about other studies. The person before me was looking at a cancer drug, which just had horrendous side effects. It was a phase 1/2 study. You could ablate your bone marrow, you could do this, you could do that, and death was very high on the list of possibilities. And then they come to mine, and they are saying, “Well, we do not know this stuff is not toxic,” and I am like, “Are you kidding me? Were you awake in the last presentation? This is fiber. This is just fiber. It is food.” They did not know what the toxicity of my fiber was. There is a real confirmation bias, which is better, but still there for sure.

Dr. Rountree: Yes. One herb that is another example of this—one that you know a lot about—is black cohosh. Can you mention some of that research? I recently had a conflict with a local academic oncologist who was on my case because I had recommended black cohosh to a woman with hot flashes after she got chemotherapy for her breast cancer. The oncologist told my client that the black cohosh had been shown to accelerate breast cancer and should be avoided.

Dr. Hardy: Absolutely. Well, first of all, I do agree that you made a rational choice that was useful for her. This goes back to a study doing bench research looking at black cohosh and several other agents, including some soy isoflavones, looking for their estrogenicity.³ I think the research was cross-contaminated because the researcher found estrogenic effects in black cohosh, which no one has been able to duplicate. That was an early study that got into the literature and never got out again. Then some of the German researchers kept saying over and over and over again for years that black cohosh was a phytoestrogen, when it is not.

Next there was excellent work that Norm Farnsworth and his team did at his botanical research center at the University of Chicago in Illinois, and they proved that black cohosh was serotonergic—it bound to the serotonergic neurons in the hypothalamus and controlled temperature that way. It was not estrogenic. Fredi Kronenberg again proved this by looking at binding and other studies. Black cohosh was non-estrogenic. But it has been incredibly challenging to get that word out. The only time there was an estrogenic effect proven was in the 1950s with a very crude extract in mice, who

do not metabolize estrogen like humans, so that is off the table as useful research for effects in human women.

A long carefully assessed safety study conducted by Bionorica from Germany with 400 women given black cohosh for a year looked at uterine lining, the maturation of cells in the vagina, and no estrogenic effect was found anywhere.⁴ They also did safety data by collecting labs. They collected white blood cell counts, liver function tests, et cetera. So we have a year’s worth of data on 400 people. When I looked at the individual person-level data, there were some LFT elevations, but they were small, and they were not sustained. So if your liver enzymes were elevated on the first draw, by the second draw they were not. So there was no place where any two levels were elevated, and no person had two elevations out of the three times tested. There was a big review done at the National Institutes of Health as well that came to the same conclusion—there was no evidence of an estrogenic effect of black cohosh and, therefore, there was not a particular risk.⁵ There was a group of researchers in Spain who gave breast cancer patients the Bionorica black cohosh extract, and they did not show any evidence of increased risk of developing breast cancer.⁶ Now, a year may not be a long time for that, but it was still much longer than we usually have.

So the evidence chain does not hold up. Black cohosh does not affect breast cancer cells in vitro via the estrogen receptor. It does not have estrogenic binding capacities. It does not act estrogenically in the body, so it does not affect the maturation of cells in the vagina. It was not hepatotoxic in these studies. And that is really robust data, rather than a few messy case reports where all the variables have not been controlled for. When you look at a case report, you are evaluating that to assess causality, you are supposed to rule out all other potential causality, like is there another explanation? You are supposed to apply Occam’s Razor. What is the simplest explanation for this, or what is the most likely explanation for this? Do you have another likely explanation? It does not mean that the thing that you are worried about could not be the cause, but it is not the only potential cause, and it may not even be the most likely cause. I think that is how literature gets distorted, and it is really hard to clean it back up.

Dr. Rountree: This is a huge point that you are making there. Once the myth gets out there, it is hard to change.

Dr. Hardy: Right. And this guy, the original bench researcher, was not malicious. He just made a mistake. The Germans knew that this material affected people’s menopause symptoms. They knew it from the early ’50s, ’60s, and ’70s. And they did not have any other mechanism to explain how you could affect a woman’s hot flashes if it was not estrogenic, so they just called it a phytoestrogen. They did not know about serotonergic neurons in the hypothalamus in the 1950s, I do not think. So this just means that if there are advances, we have to be prepared to modify our language and our understanding.

I think black cohosh is a fantastic herb, and it comes to us from a native tradition of our own Native Americans, although

it got developed commercially in Europe before it was widely used here as a modern phytomedicine. It is a very beautiful very interesting herb.

Dr. Rountree: I was just thinking of that herb as an example of how there are so many different ways we could look at botanical medicine now that we can study their mechanisms of action in detail. This is kind of a huge sweeping question, but what do you see as kind of the future of botanical medicine as it can be integrated into more of a mainstream clinical practice? Put differently, what do you think needs to happen before your average internist or family physician or pediatrician will be more comfortable prescribing an herb alongside a hypertensive drug or antibiotic or SSRI for hot flashes?

Dr. Hardy: I see this as a multistep process. I do not think you can expect that some fairy godmother is going to come by and bonk everybody on the head with a magic wand, and pretty soon we are all going to be in acting in a different way.

Right now—and it is not necessarily a disadvantage—this kind of medicine that you and I believe in with all of our hearts and souls is a specialty, and it is being recognized as this now, which I think is good, because it is a special kind of use. Now, does that mean that we could not teach enough practitioners, pharmacists, physicians, and nurses about phytomedicine so that they could maybe have a handful of things that they can use in their practice, or so that they will be more permissive rather than dismissive if someone is using these therapies, or so that they, the Western practitioner, will be able to evaluate risk? I think that is why we are in a position now where integrative medicine is a specialty. We should make our knowledge as well known as possible. But then the average practitioner is not going to end up knowing what I know about black cohosh. They just will not. I have spent years in this field, and I ran a botanical research center with my chief, David Heber, MD, and I have been in integrative oncology for 15 years, and I was in practice 10 years before all that.

Now, I have a prejudice in this area. I have a confirmation bias of my own. I really started getting a grip on botanical medicine when I learned about phytochemicals. I basically did the pharmacology of herbal medicine to wrap my head around this field, to give myself a structure so I could learn this new information in a way that made sense to me as a Western trained medical doctor. Then I could go back to the more folk tradition or the more traditional type of herbal medicine that will have multiple indications. Like, for example, black cohosh in the 19th century had a very strong indication for pain management, and there are lots of reasons why that might be. But if you are first trying to learn herbal medicine, that makes you kind of crazy. I am a doctor, and I am not going to abandon that and it is a very useful place to start from. I am going to be interested, as a doctor, in phytomedicines, really, really interested in medicines that have been regulated, standardized, are consistent, so that when I put them into this

very sophisticated system, I can be pretty clear about the actions and the effects of what I am going to see.

Now, I have some other friends who are traditional herbalists. Amanda McQuade Crawford and Tieraona Low Dog, for example. When Amanda and I sit down together, we are able to really completely share. She is trained to professional standards. That is a very different kind of herbalist than someone who casually picks some things up.

David Hoffman is another really great colleague of mine. He is a wonderful practitioner. He knows more about adaptogens than anybody I have ever met before. I would yield my training to his in a second. If he says, “Oh, this is the right adaptogen,” I would be like, “Aye-aye, sir. Will do.” You know? Because he has had years of training.

So I do not want to throw the baby out with the bathwater. If we integrate herbal medicine into conventional medicine, I think the first step is the step I am talking about, doing phytomedicines especially for medically trained practitioners. Phytomedicine has a practice in Europe. But I do not want to disadvantage and diminish our practitioners in the other realm of herbal medicine who are highly skilled, very well trained, very sophisticated practitioners, and I want us to honor them, learn from them, and maybe eventually we will find a way where a large enough primary care practice will have a visiting herbalist who can practice the way Amanda does or the way David does and be offering people, “Well, if you do not really want to take XYZ, if you are willing to do this and this and this, we can manage you in this part of the clinic,” and that would be great, too.

Dr. Rountree: What does the future hold for you? You said maybe start seeing a few more patients, more books, academics. What do you see as your main path? Teaching?

Dr. Hardy: I am very much committed to teaching and mentoring right now. I just had a really fun experience in the AIHM program where, because people cannot come follow you around anymore because of COVID, people are not practicing the same way. So for example, instead of one of my students coming and following me around because I am not in a big clinical practice right now, we agreed that we would do sort of a mentoring where he would bring cases to me and we would discuss them, and I would expose him to the literature in this area and help him develop, “How do I actually start doing this?” He is a psychiatrist. And after just a very short intervention, maybe four, five, six weeks, he is up and running on his own. He has got four or five things he is using. They are really working well. He is picking out the right patients. That young man is launched. He is going to be a very effective integrative practitioner.

And I said, “Look, do you want to be helpful if someone says to you, ‘I do not want what you have to offer’? Do you want to not listen to, not validate them, or do you want to say, ‘I respect your concern. These are strong medicines. Let us try another way first. If that does not work, we can come back and revisit this.’”

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Does that not leave you in a flexible therapeutic stance with people? Does that not create trust and accommodation so that if someone really is in trouble you say, “Look, I hate to have to say this, but you need to go in the hospital. This is not safe for you right now.” And over the course of practicing with them and being accommodating and working with them and not ever doing an inappropriate thing with them, but just trying to always find what medicine will they empower, if you say that to them, then they really have a whole history to fall back on of, “S/he has always listened to me. S/he has always taken my perspective into account. I guess I can yield this time, because I know s/he believes that, and would tell me if it was not true.”

I think that is an example of how teaching can be powerful. And if I can do that a hundred more times before I am done with my career, I will have created a future for the patients I will not be there to see.

Dr. Rountree: That’s great. If people want to follow your work, do you have a website or someplace where they can check in on what you are doing?

Dr. Hardy: I realize I am hard to find now. I am developing a website that will be patient-focused, and everything will be there together. I think I might call it Wellness Works. That is what I call that part of my practice where I do consulting and

teaching, because I really think no matter where you are on your medical journey, you can always try to be as well as you can possibly be at any point in time. ■

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