History

of the

U.S. Food and Drug Administration

Interviewee: **Sara Goldkind, MD**

Interviewer: **Suzanne W. Junod, Ph.D.**

Date: **July 29, 2014**

Place: **Silver Spring, MD**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Oral History Interview

Sara Goldkind

July 29, 2014

SJ: Today is July 29, 2014 and we are in the FDA History Office at White Oak interviewing Dr. Sara F. Goldkind, who has just left the agency after almost eleven years as the agency's bioethics expert. The interviewer is Suzanne Junod. Sara, I am really glad you agreed to come.

SG: I am happy to be here with you, Suzanne.

SJ: These interviews contribute a great deal to our ongoing efforts to preserve and enhance FDA's institutional memory. We believe it will also be meaningful to you as you are looking back and reflecting on your FDA career.

I'll start by asking you about your early life, including where and what you studied in school, and then we'll move on to discuss your emerging interests in medical ethics.

SG: I was born in Nashville, Tennessee. My father was a student at Vanderbilt University and then we relocated to Washington, D.C. when he accepted a position at George Washington University. I was raised in the city of Washington. I would say that I decided very early on to go into medicine. I was about eleven years old; I really remember that very vividly.

It took me a long time to be able to articulate that intuition, what was it on an intellectual level that I could say defined my thinking at such a young age to go into medicine. Part of it is that I have a very strong nurturing instinct and I think that caring for other people was something that was very attractive to me about medicine.

Also I went to a fairly small religious day school and many of the teachers in that school were survivors of the Holocaust. It wasn't really talked about very much -what they had gone through- but you could sort of see on their faces and feel the sadness within them.

On a very subliminal level, and this is something that I have just recently reflected on, and come to understand, the idea of making people whole again is something that also affected me and influenced my thoughts about medicine. And I liked science very much.

I went to George Washington (GW) University and majored in chemistry and had a minor concentration in art history. You can see that I was drawn to both hard sciences and humanities . . . this ying and yang. Then I went to the University of Maryland School of Medicine in Baltimore and I did my residency at Boston City Hospital (BCH).

The faculty at BCH was very good; they were very sensitive and caring and practiced a very high level of medicine and teaching. And the residents, my co-workers, had a lot of commitment to our patients and to each other. We took care of a lot of indigent patients under difficult conditions. The fact that we supported one another was especially important.

SJ: What years are we talking about?

SG: I went through my residency from 1983 to 1986. When I went through medical school, we were allowed an elective in bioethics. Bioethics was something that was not routinely taught as part of the curriculum. Our course was taught by a famous bioethicist who was not a physician.

SJ: And who was that?

SG: His name is Tristan Engelhardt from Baylor University, I believe. He taught bioethics as a philosopher, on a more theoretical level. And, it was very interesting to me.

At the time, since this was my first foray into bioethics, it was a little difficult to fully see how this instruction informed and applied to the practical aspects of medicine. But it must have lingered in my mind because, when I went through my internal medicine residency, I certainly did notice issues that came up in medical care, particularly around the end-of-life, that were ethically challenging and that created some moral concerns. And again, even though I felt like my faculty at BCH was very sensitive, very committed to patient welfare, patient well-being, we really did not talk a lot about ethical issues at that point.

SJ: Did you talk a lot about end of life issues?

SG: We did discuss patient care at the end of life but not –as I recall- patient values and how they inform end-of-life care. Attention to end-of-life issues and other biomedical ethics issues have become much more central to discussions of clinical care, appropriately so, over the past two decades or so.

SJ: Did any specific cases resonate and stick in your mind?

SG: One patient, in particular, is front and center for me. I remember her very clearly; her name, her location in the hospital ward, her medical problems.

I was working as an internist at that point and decided that I would want to explore medical ethics in a more formal manner and in more detail. We were living in Florida at the time; my husband was in private practice.

We were living in Florida where he was in private practice. And so I needed to stay within the city that we were in, Tampa, and I started thinking about how I could become more

educated in this field. Luckily, the University of South Florida School of Medicine (USF) had a small division of medical ethics and humanities that was part of the Department of Internal Medicine, which was willing to sponsor a clinical bioethics fellow. This was about 1993. We constructed a program at USF that mirrored the clinical fellowship at the University of Chicago where my mentor, the director of the Division of Medical Ethics and Humanities, did his clinical ethics fellowship. My fellowship proved to be a very, very interesting and rewarding experience, in part because of the vast and diverse clinical exposure available through USF. It had three affiliated major teaching hospitals; a cancer hospital, a VA facility, and a large municipal hospital with many types of intensive care units (for example, a burn unit, a surgical intensive care unit, a medical intensive care unit, a pediatric intensive care unit, a neonatal intensive care unit).

SJ: So the scope was really quite remarkable.

SG: Yes. And, USF also had a well-integrated bioethics program in its medical school curriculum, so I was able to participate as faculty in that program. Additionally, USF had an active ethics committee that provided ethics consults on individual patient care. This is where I was able to learn how to do ethics consults at the bedside and draft hospital policy on ethical issues.

SJ: Now were these guidelines on specific issues or more general discussions? Give me an example.

SG: The consultations were on individual patients, that is, ethical issues arising in their clinical care. Generally, we were invited to provide a consult by someone on the medical team,

although it could be the patient, the patient's family, or the hospital chaplain who asked for the input of the ethics committee. Usually, the consults related to end-of-life care or right to refuse medical care for a patient who was not terminally ill., for example a right to refuse a medically indicated limb amputation.

The development of hospital ethics policies was related to clinical ethics issues, for example, do not resuscitate decisions, evaluation of brain death, or again, right to refuse medical care for children or adults.

To provide thoughtful and comprehensive clinical ethics consultations or to effectively develop hospital ethics policies, one needs to be cognizant of the law, federal as well as state law, the hospital policies and practices to date, in addition to medical ethics literature and the medical literature for the diseases or conditions at hand.

SJ: And what years were you were in the fellowship?

SG: I did my fellowship from 1993-1994. As part of my clinical ethics fellowship, I spent about a month at the University of Chicago's MacLean Center for Clinical Medical Ethics. I also did an intensive program in bioethics at Georgetown University's Kennedy Institute of Ethics.

During my fellowship I realized that I also wanted to study bioethics from a more theoretical perspective. So, simultaneous with my fellowship, I began a master's degree program in religious studies focusing on comparative religious ethics and religion and public policy.

SJ: Wasn't that somewhat unique?

SG: It was. Again, what I did was model my course of study –to some extent -- after the program at the Kennedy Institute of Ethics, recognizing that it focuses on ethics through a philosophical lens.

I started to think about courses that I thought were important for me to study and I shopped my proposal to the Department of Philosophy and the Department of Religious Studies at the University of South Florida. Luckily for me, the Department of Religious Studies Chair understood what I was trying to accomplish and was very flexible as long as I took their core of requirements and had any independent study program pre-approved.

The Department of Philosophy's graduate program was more rigidly laid out. I wouldn't have been able to concentrate on my area of interest until writing my dissertation. It turned out to be an easy choice for me to go with the Religious Studies program, which was a great fit for me and a stellar program overall.

The faculty in my graduate department was enthusiastic, supportive, and creative in their efforts to help me learn about bioethics. I was able to be an independent student, which fit well with my personality. Some of the areas I studied as part of my degree, in addition to comparative ethics and the role of religion in informing public policy were narrative ethics and feminist ethics.

After finishing my fellowship, I worked part-time doing clinical ethics consultations (for example, helping hospitals initiate ethics committees), taught bioethics at USF's School of Medicine (where I was an adjunct faculty member), taught a course on religion, law, and bioethics at the graduate level in the Department of Religious Studies, and served as an institutional review board member. I was also busy completing my master's degree and raising my four children.

We then relocated back to this area. My husband decided after eleven years in private practice that he wanted to try something different in medicine and he came to work at the Food and Drug Administration.

SJ: What is his name and what is his specialty at FDA?

SG: His name is Larry Goldkind and he is a gastroenterologist and nutrition specialist. He came here to work in the Division of Gastroenterology at the Center for Drug Evaluation and Research (CDER). Eventually, he became the deputy director of what was then CDER's Division of Anti-inflammatory, Analgesic and Ophthalmic Drug Products.

Larry was really enthusiastic about the work he was doing at FDA. He would come home and tell me how interesting the work was . . . that it was just so exciting and cutting edge. At that point, given his endorsement of FDA and the proximity of the National Institutes of Health (NIH), I started to think about shifting from clinical ethics to research ethics.

Fortunately, and I always joke but it is absolutely true -- that it took an act of Congress for me to get my job at FDA. Not that long after I started looking for work at FDA, Congress issued the Best Pharmaceuticals for Children Act (BPCA), which gave market exclusivity to companies that conducted studies of certain drugs in the pediatric population. That piece of legislation also established the Office of Pediatric Therapeutics (OPT) and the requirement that OPT have someone on staff who is able to opine on the ethical and scientific soundness of pediatric research to ensure that children are included in research in an ethically acceptable manner.

BPCA was a result of the recognition that about 80 percent of drugs used in children were never studied in children. Children were "therapeutic orphans," and it was inadequate to simply scale back the dose according to weight. BPCA also reflected the scientific/medical understanding that children are not small adults. Rather, there are unique aspects to pediatric medicine. Moreover, the complexity and heterogeneity within the population designated as

"children" (age 0 to approximately 18), merits rigorous evidence-based therapeutics, preventions, and diagnostics.

SJ: That was part of the law?

SG: And it has been reauthorized and it is still in the law. So that is how I came to be hired at FDA.

In 2003 I started at the FDA. I worked at FDA in the Office of the Commissioner for over a decade, although I did not stay in OPT my entire tenure. Since I was the only bioethicist at FDA for my first few years, and because I have a background in internal medicine, I was asked to be involved in a broad array of pediatric and adult issues. From the day I started at FDA until my final day, the work remained fascinating, compelling, and intellectually challenging.

SJ: I want to get a feel for, say, what your typical day was like as well as some of the issues that you confronted as the fields of ethics moved forward with case studies. I wouldn't say it is universally applicable, but it is generally the case studies that challenge people to think about some of the bioethics issues they may or may not have considered before.

(00:20:00)

SG: That's true. I will come back around to my typical day – but probably it is best to understand the organization of my work, which generally fell into three categories. It had a teaching component, protocol-specific consultative function, and policy development related to ethical issues, to protection of people enrolled in research, and Good Clinical Practice. In a way,

my work at FDA was very much like my clinical work in which I did education, patient-specific consultations, and hospital policy development.

By and large, similar to my clinical consultations, I would be asked to offer an ethical analysis by the review division (that is, the FDA entity with primary regulatory responsibility) that received the IND submission from the research sponsor. Many of the consultations I received related to clinical development strategies for novel therapies. Or, they may have involved clinical development strategies for products for vulnerable populations (for example, unconscious patients who could not provide consent for themselves, pregnant women, children). My input to the FDA review division would usually take the form of letter-ready recommendations (required or suggested) to the clinical development plan, protocol, informed consent form, or other supporting documents.

If there were recurrent issues in the ethics consultations that were amenable to FDA guidance, then I would take this back to my office and to others at FDA to discuss the need for policy development in the area of concern.

Another outcome of an ethics consultation might be to take a product-specific issue to an FDA advisory committee, supplemented by outside experts including bioethicists.

SJ: And did you sit on the agency's institutional review board (IRB)?

SG: Yes, I was on FDA's IRB called RIHSC (Research Involving Human Subjects Committee) for about six and a half years. I found this to be a very interesting and important activity.

SJ: The RIHSC establishes policies related to internally sponsored research. The thing that fascinates me is that we always think about these standards primarily in association with the drug

approval process. But can you talk a little bit about your experiences with devices and the issues that might be slightly different? Devices have a different life cycle process than that for drugs. Can you tell me a little bit about what kind of problems you might see with devices that might or might not be different from those observed with drugs?

SG: That is interesting. One of the things that I really enjoyed about my position here was the cross-product comparison that I was exposed to working with the three medical product centers – drugs, devices, and biologics. And now, the Center for Tobacco Products.

One of the issues with devices that you would not typically see with drugs is the possibility of permanent and irreversible implantation of an investigational device, for example.

So if you are thinking about a device that is going to be permanently implanted, let's say in someone's brain or in someone's heart, the level of evidence that you might want to have before that surgery or procedure is undertaken would rise to a high level. For drugs, although one would also be cautious before embarking on a study with an investigational drug, in most scenarios, avoidance of future adverse consequences of the drug could be accomplished by discontinuing administration of the drug, although not always, of course.

Another distinction between devices and drugs is the nature of a trial that involves blinding. Ethical issues arising in placebo-controlled trials usually relate to the risks associated with lack of treatment or withholding treatment for a period of time. For devices, the risk assessment for sham surgeries or procedures is more complex than that, and involves risk assessment of the intervention as well.

These are a couple of differences that come to mind right off the bat.

SJ: Can you describe your typical day?

SG: On a "typical day," I would come to the office, open my emails and find – early in the morning -- that what I thought would be my work agenda for the day would not at all be what I would need to prioritize that day. I would come in and there would be a new crisis or concern that reorganized my day. There was no boredom in my work. And, that was good.

My typical day would definitely involve getting a lot of emails, informal telephone calls from both within the FDA asking for curbside input or formal consultations and/or calls from people outside of the agency. My role at FDA involved a lot of external teaching and outreach.

My typical day would involve meetings with divisions, with product sponsors, with other components of Health and Human Services (HHS), such as NIH or the Office for Human Research Protections (OHRP).

Frequently, my days involved deliberating over an issue or issues with others at FDA, other Federal agencies, or with external stakeholders. I found the "group think" to be very invigorating, edifying, and ultimately beneficial in informing the best outcome possible. Decision-making is greatly enriched by having a group of diverse individuals with diverse backgrounds bringing to bear their specialties and expertise on a particular dilemma.

SJ: I want to get some details on some of the decisions and things that you worked through while you were here that were either novel or that challenged your thinking about issues, and who you worked with. I know at one point you published an article with Dr. Robert Temple?

SG: Yes, I published a book chapter with Bob Temple. He and I worked together quite regularly on a wide array of issues. And I have published articles on clinical research in pregnant women together with individuals from FDA's Office of Women's Health and also separately with folks on CDER's Maternal Health Team.

SJ: I've got a list of your articles, I think I have most of them, but you should check my list. We would like to include them in the appendix if you don't have any objections.

SG: That's fine, no problem. I also wrote a book chapter on pediatric research ethics with Diane Murphy, the Director of OPT [the Office of Pediatric Therapeutics].

Some of the ethical issues that I addressed relate to cutting edge development strategies for diagnostic, preventive, and therapeutic products for vulnerable populations (for example, decisionally-impaired subjects). A subset of this is emergency research, particularly emergency research excepted from informed consent.

I've also been very involved in research on rare diseases and ethical issues that come up in that context. Some other ethical issues that have come up during my course of work at FDA relate to efficiency of trial design (for example, quality–by-design, risk-based monitoring, and adaptive designs) choice of a control group, and whether or not a placebo controlled trial is ethically appropriate, particularly as you are thinking about research in resource-poor countries.

SJ: Well, certainly Bob Temple was interested in data manipulation.

SG: I wouldn't call it data manipulation. Rather Bob is interested in data integrity, data credibility, that is, the robustness of the data used for evidentiary purposes. Bob and I, together with others at FDA, have discussed and worked on how quality and efficiency can be designed or built into clinical research. An example of this would be focusing in on and measuring the endpoints needed to meet the objectives of the research, but not acquiring, checking, and cleaning data unrelated to the primary and secondary endpoints, as this would create unnecessary resource burdens without benefits.

SJ: And perhaps unnecessary risks to patients?

SG: Perhaps. This approach also helps in evaluating whether the research was done well. You are looking at and monitoring safety and participants.

Bob and I were involved with thinking about large clinical trials, for example large cardiovascular trials. How can we simplify them so that we can get the answers we need and enroll the large number of patients we need, but do it in a smart, thoughtful way without compromising human subjects' protections and without collecting data elements that are non-contributory?

SJ: FDA had already published emergency provisions governing informed consent in research trials. That had already been put into the regulations. Were you tweaking that or applying it more broadly?

SG: When I got to the FDA I really wanted to understand the scope of clinical research that was being done under those emergency provisions and how the decisions were being made about what was ethical and what was not acceptable from an ethical or regulatory standpoint under those provisions. This research is regulated across three medical product centers -- CDER, the Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER).

My first task was to pull together information on what trials were being submitted to FDA for review under these provisions that permit the exception from informed consent for emergency research, which trials FDA let go forward, and which FDA put on clinical hold or stopped. In other words, I wanted how FDA approaches this type of research from an ethical, regulatory, and policy perspective

This led me to the realization that it would be optimal if cross-Center dialogue could be enhanced regarding the unique, scientifically complex, and potentially controverted research. While there are notable differences in the types of studies that might be submitted to CDRH, CBER, and CDER under these regulatory provisions, there are similarities, too.

I decided to form a cross-center working group comprised of diverse FDA experts from the three medical product centers and the Office of the Commissioner who had experience with emergency research and the pertinent regulatory provisions. Immediately after the adoption of 21 CFR 50.24, that is, the exception from informed consent for emergency research, FDA did not have a large body of experience with either the regulations or with designing and reviewing clinical trials in this setting, as there were relatively few investigational new drug and/or investigational device exemptions under 21 CFR 50.24. Bonnie Lee, Bob Temple, Diane Maloney, and Catherine Lorraine were a few of the individuals who served on this working group. In addition to considering how FDA should interpret these regulatory provisions, one of the efforts of this working group was to plan and hold a Part 15 hearing to obtain public input on how acceptable the regulations are, how well they are being implemented, what are areas of difficulty, do the regulations need to be modified, can we address concerns through guidance?

And that culminated in -- after many years of effort -- a comprehensive, long, detailed guidance in the format of frequently asked questions, which extended two earlier draft guidances. I was the chair of that working group and turned over the reins when I left FDA. The working group has been successful in centralizing and coordinating FDA thinking and experience with emergency research conducted under the exception of informed consent.

SJ: And what was the level of interest? I mean, did you have public advisory committee meetings? What was the level of interest there?

SG: The Part 15 hearing and comments on two draft guidance documents and one final guidance was the agency's avenue for public input. There was a lot of interest in this area as you can imagine for many reasons. I'll just describe two of them. For one, it's the only research that is allowed to go forward under FDA's regulations without informed consent, which makes this type of research ethically challenging. Secondly, how to give a family member at the scene of the event an opportunity to opt out when there is little time and much to do in the care of the physically compromised individual is also challenging. We generally encourage the emergency responders to say something like "we're about to enroll your family member in clinical research that possibly involves receiving an investigational product. If you are aware of any reason that the individual should not be enrolled in the research you don't want your family member enrolled, tell us." This provides an opportunity for opting out but it is difficult if not impossible to have an informed discussion in these contexts. So it's a particularly troubling and uncomfortable situation from an ethical perspective.

SJ: But again, it is an emergency situation.

SG: It's an emergency situation and, it's confined to circumstances where there are no available proven or satisfactory therapies for the life-threatening diseases or conditions and there is no other way to get the safety and efficacy data needed to develop new therapies for these emergency conditions.

SJ: The tPA research was conducted under the emergency provision, was it not?

SG: Tissue Plasminogen Activator (tPA) and Streptokinase. You're probably thinking about the GISSI Trials done on thrombolytic therapies in acute myocardial infarction. Some of those studies were done prior to FDA's implementation of 21 CFR 50.24.

(Interruption)

SJ: We are resuming our discussion after a short break. Sara, one of the things that I would like to find out about is how, once you came into the agency, how did your work, which was unique and very sophisticated, change the world that you were operating within FDA? As you are leaving, are there things that seem unfinished to you?

SG: As I mentioned, when I first came to the FDA, being the first bioethicist at FDA, I felt like I essentially needed to market what I bring to the agency, that is, to explain how involving a bioethicist in decision-making pertaining to complex issues would be value-added. In particular, I really wanted people to understand that I am not functioning as the "ethics police," so to speak, but in collaboration with them, not to say that I'd always agree with them, but that I'd always discuss my concerns with them, as we sorted through the scientific and the ethical issues related to whatever the matter of discussion was.

I went to FDA senior management, Division directors, and others explaining what unique skill sets and knowledge a bioethicist has, describing my background in detail, and encouraging them to spread the word to other members of their Centers or Divisions. I also wanted folks to understand that ethics doesn't exist in a vacuum; it's integrally related to good science, good medicine, good patient care and Good Clinical Practice. Understanding the scientific aspects of the consult is essential. As I mentioned earlier, I had the experience of being the first bioethics

consultant at the hospital where I did my fellowship and the first physician in the religious studies master's program at USF. So being "the new kid on the block" was not foreign to me.

SJ: In other words, when you are looking at in the development of a project or a process related to a drug or device approval, you need to understand what is known and what is not known?

SG: Correct, and what the alternatives are to being in the research, whether the research could be done in a different way -- why or why not. As part of my introductions, I explained to the Division and Center directors how I would approach sorting through a submission and what my contribution would be. I believe this helped them feel comfortable contacting me.

Moreover, having the endorsement of FDA senior management helped. But part of it was just building a reputation; building experiences with colleagues and having them refer me to others, mostly through word of mouth. There was no mandate that they needed to involve me; they did at will.

So some of it was my development of personal connections and a shared experience. But another part of it was a changing mindset. Before I came to FDA, the idea was, for example, that we don't deal with the ethical issues here at the FDA; it's the IRBs' role to address them. Or, it may be the academic bioethicists who might deal with them. That said, FDA reviewers, review teams, and others addressed many ethical issues, without perhaps necessarily identifying them as ethical concerns.

Helping FDA colleagues understand that ethical imperatives are already incorporated into FDA's regulations, even the Parts 312 and 812 that deal with investigational new drugs and investigational device exemptions was also important. That is, these regulatory provisions have aspects to them that relate to bioethics and the protection of research participants. It's not just our

regulations Parts 50 and 56 that deal with informed consent and IRBs that focus and attend to ethics and human subject protections. This helped FDA staff recognize that they were already implicitly attending to ethical issues and the protection of individuals enrolled in research. I'm not trying to imply that ethics weren't attended to prior to my coming. I think they were, but probably on a more implicit level than explicit level. Fundamentally, I believe that my presence at FDA facilitated the explicit consideration of ethical issues.

My feeling is that FDA developed regulatory science. Bob Temple, a "national treasure," is one of the grandfathers of regulatory science, together with Bob O'Neill. We know our regulations better than anyone else; we know the history of. . .

SJ: Because we invented them.

SG: Because we authored, issued, and implement them. FDA, therefore, has a mandate to assure that the research it requires is ethical.

SG: There's more consideration given now to whether bioethics input and expertise is needed for internal deliberations but on advisory committees.

I take it as a sign of personal success that when I decided to leave FDA at the end of May, a lot of people were saying – "Well, what are we going to do without you?" And this is my feather in the cap: Bob Temple said "This is really bad."

SJ: And he was the ones that had to be sold on hiring a bioethicist in the beginning, I think.

SG: Given that there are individuals who, both formally and informally, attend to ethical issues, I think the agency is in a good position to go on without me here.

SJ: They will be recruiting a successor?

SG: They recruited someone who has a background in human subject protections. And there are two people at FDA who address pediatric research ethics.

SJ: Well, I jotted down a few other questions as we were talking. I think part of your influence stemmed from proximity - people could stop in to see you and they didn't have to get an outside consultant every time they had an issue or question. At that point only the top questions create a compelling need to employ an expert. But did you find, and maybe there was a mixture of motives, that people were coming to you more to interpret the regulations and policies that were already in place or were they bringing you ethical problems and concerns and asking for your input assuming that they already knew the regulations?

SG: I think it was a combination. Remember, the regulations that we classically think of as "Human subject protections", on informed consent and IRBs, were adopted in 1981. Since then there have been a lot of changes in medical research. For example, future use of biospecimens, data mining and analyses, cluster randomized trials -- all sorts of things that weren't really part of the research paradigm at that time. At the time these regulations were written and issued, research was conducted by a single investigator, at a single institution, reviewed and overseen by a single IRB.

Research has become much more complex and there are a lot more partnerships in research, a lot more layers in the conduct of research. The regulations don't necessarily speak to some of these modern and new paradigms. Given these new structures in clinical research, some

questions that I've been asked about relate to how we should interpret and apply the regulations.in the era of modern trial designs.

Other questions relate to ethical issues that had not previously been considered but are imposed by new informational technologies, new scientific capabilities, and innovative therapies.

So it was a real combination.

SJ: And you are really setting boundaries that are perhaps more fluid and conducted across the table with a less formal assignment of roles.

SG: One of the things that I felt strongly about is the value of dialogue across different Centers, across different Offices, so that we could really cross-fertilize each other's thinking. As you say, with less formal assignment of roles and fewer boundaries, so that – put simply-- we could learn from one another.

SJ: That summary sounds like a good place to end. You will certainly have the opportunity to add things or correct them. By the way, did you keep detailed records? Where would the documentation for your tenure lie?

SG: My input is captured in my work products, that is, working group meeting minutes or archived with individual protocol submissions or reflected in guidance documents, for example. Hopefully, my input is now also reflected in how individuals at FDA identify and analyze ethical issues. I would not say that I have that same type of archival materials. And some of my active projects are passed on to others in the office that I left.

END OF INTERVIEW

SARA FAY GOLDKIND, M.D., M.A.
Research & Clinical Bioethics Consultant
[redacted]

Profile

- Nationally recognized authority in clinical research ethics
- Over 10 years experience at the Food and Drug Administration as the first FDA bioethicist, departing as Senior Bioethicist
- Expert in innovative clinical trial design, product development for vulnerable populations and challenging settings
- Expert in a broad range of cutting-edge bioethical issues
- Expert in human subjects protections, Good Clinical Practice, research integrity and research compliance
- Expert in designing ethics programs (FDA ethics consultative services, and hospital-based ethics consultative services)
- Experienced educator (undergraduate and graduate levels, medical school, novice and experienced professionals, content experts)

FDA Senior Bioethicist, 2003-2014:

- Served as the FDA expert for biomedical research ethics that are highly visible, controversial, and/or precedent-setting
    - Advised
        - The Commissioner of the FDA
        - Senior management of the Centers within the FDA including the Center for Drug Evaluation & Research, the Center for Biologics Evaluation & Research Center for Devices & Radiological Health, the Center for Tobacco Products
    - Participated in the planning, management and implementation of bioethics activities and policies across the Agency
    - Developed scientific, ethical, and regulatory consensus for optimal solution to specific and general matters
- Provided issue-specific ethics consultations to the various Centers within the Agency
    - In the design, review and monitoring of research protocols (specific applications)
    - On general ethics concerns, including human subject protection and clinical trial oversight
- Developed policies and procedures relevant to bioethics for FDA programs and initiatives

- Developed guidelines (FDA guidances) for FDA stakeholders (including, but not limited to industry, academic communities, advocacy groups, institutional review boards and institutional officials)
- Liaised with other agencies within the Department of Health and Human Services and the federal system as well as external groups (including, but not limited to Congressional staff and members of the press) to develop innovative solutions to complex scientific, regulatory and ethical issues
- Developed educational programs
    - For FDA staff on bioethical issues central to FDA's mission
    - For outside groups on contemporary issues in bioethics arising in clinical research

PROFESSIONAL EXPERIENCE AND POSTDOCTORAL TRAINING

--Special Government Expert, The Food and Drug Administration, November 30, 2014-

--Bioethicist, National, Heart, Lung and Blood Institute trial-specific data safety monitoring board, August 2014-

--Adjunct Assistant Professor, George Washington University, School of Medicine and Health Sciences, Department of Clinical Research and Leadership, July 2014-

--Medical Faculty, Fellowship at Auschwitz for the Study of Professional Ethics (FASPE), June 16-26, 2014

- A set of innovative programs for students in professional schools designed to address contemporary ethical issues through a unique historical context
- An intensive two week fellowship program providing medical, seminary, law, and journalism students a structured examination of the role of their chosen professions in Nazi Germany and the Holocaust in an effort to positively affect current professional ethics

--Member, Walter Reed National Military Medical Center Ethics Committee, January 2013-present

--Internist, Volunteer with Pan American Medical Society, Chincha, Peru, July 2012

--Member, Research Involving Human Subject Committee (RIHSC, FDA's institutional review board), Fall 2003-Summer 2009

--Member, Institutional Review Board, Jaeb Center for Health Research (coordinating center for multi-center clinical trials and epidemiologic research)
Tampa, FL, 1993-1999

--Clinical Assistant Professor, Department of Internal Medicine, Division of Medical Ethics and Humanities, University of South Florida, College of Medicine

Tampa, FL, 1996-1998

--Ethics Consultant, Transitional Care Hospital
Tampa, FL, 1995-1996

--Ethics Fellow, University of South Florida, School of Medicine, Department of Internal Medicine, Division of Medical Ethics & Humanities
Tampa, FL, 1993-4

-- Fellow, University of Chicago, School of Medicine, Center for Clinical Ethics
Chicago, IL, July 1993

--Internist, AMI Family Health Care Center
Tampa, FL, 1988

--Intern, Junior Assistant Resident, Senior Assistant Resident, Internal Medicine
Boston City Hospital, Boston, MA, 1983-1986

--Environmental Chemist, Biospherics Inc.
Rockville, MD, 1978-1979

EDUCATION

University of South Florida, M.A., Religious Studies, 1998

- Concentration in Comparative Religious Ethics
- Concentration in Religion and Public Policy

Georgetown University, Kennedy Institute of Ethics, Intensive Bioethics
Course XVII, 1991 (Certificate Program)

University of Maryland School of Medicine, M.D., 1983

George Washington University, B.S. Chemistry, with minor concentration in Art History, 1978

- Overall GPA 3.85/4.0
- #1 Chemistry student in the graduating class
- Phi Beta Kappa

LICENSURE AND CERTIFICATION

1999 Maryland Medical License (current)

1999 District of Columbia Medical License (current)

1986 Florida Medical License

1984 Diplomat, National Board of Medical Examiners

1983 Massachusetts Medical License

HONORS AND AWARDS

2014 FDA Special Recognition Award for outstanding leadership in revising the CDER MAPP 6030.2, Review of Informed Consent Documents

2014 FDA Distinguished Career Service Award for outstanding performance and expertise in designing FDA's ethics programs

2013 FDA Group Recognition Award for the Final Rule, 21 CFR 50 Subpart D, Additional Safeguards for Children in Clinical Investigations

2011 FDA Group Recognition Award for drafting and publication of the Guidance for Industry and Researchers by the Radioactive Drug Research Committee: Human Research without an Investigational New Drug Application

2011 FDA Office of the Commissioner Award for outstanding organization of the public workshop, Severe Bleeding due to Trauma and Other Causes

2010 FDA Office of Regulatory Affairs Certificate of Appreciation for outstanding contribution to Basic Clinical Bioresearch Monitoring

2009 FDA Office of Regulatory Affairs Certificate of Appreciation for outstanding contribution to Basic Clinical Bioresearch Monitoring

2009 FDA Group Recognition Award for Hemoglobin-Based Oxygen Carriers: Current Status and Future Directions

2007 FDA Group Recognition Award for Emergency Use Authorization Final Guidance

2006 HHS Secretary's Award for Distinguished Service for Pediatric Ethics Subpart D Team

2006 Certificate of Appreciation, Center for Drug Evaluation and Research, Division of Training and Development, "Pediatric Medicine Update"

2006 FDA Office of the Commissioner Group Recognition Award for

Emergency Use Authorization Guidance Team

2006 FDA Office of the Commissioner Group Recognition Award for collaborative effort to advance the understanding of Pediatric Obesity Devices

2005 FDA Award of Excellence, Work on Hyperbilirubinemia Product Development

2005 FDA Award of Excellence, Radioactive Drug Research Committee

2004 FDA Award of Excellence, Pediatric Emergency Research

1978 Phi Beta Kappa

1978 American Institute of Chemist's Award-Award for the outstanding Chemistry student at George Washington University

1974-1978 Alpha Epsilon Delta, Pre-Medical Honor Society

1974-1978 Dean's List

MAJOR FEDERAL COMMITTEE APPOINTMENTS

--Member, Informed Consent Working Group, Clinical Trials Transformation Initiative, 2013-present

Pending Deliverables: Publication(s) describing current landscape of informed consent processes, recommendations for best practices, proposal for pilot testing recommendations and expert meeting summary, and: recruitment and consent procedures in intensive care unit research

--Member, Center for Drug Development and Research (CDER) Working Group on Informed Consent, 2011-present

Deliverables: Seven unit electronic learning modules on informed consent for use by all clinical reviewers in CDER to guide them in their responsibilities in reviewing informed consent documents, how to review them, and when to seek additional input, and; Revision of CDER's internal policies and procedures on informed consent

--FDA representative to the Office of the Secretary of the Department of Health and Human Services in coordination with the Office of Science and Technology Policy Working Group on revisions to human subjects research protections, 2009-August 2011.

Deliverable: Advanced Notice of Proposed Rulemaking, "Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators," Issued July 2011

--Veterans Health Administration Working Group on Post Traumatic Stress disorder and Vulnerable Populations in Research, August-November, 2008

Deliverable: Working Group Report's assessment of ethical dimensions of research in veterans with Post-Traumatic Stress-Applying Guidelines for the Protection of Human Subjects in Research

-- Department of Health and Human Services Representative to World Medical Association on revisions to the Declaration of Helsinki, March 2008

--FDA ex officio to Secretary's Advisory Committee on Human Research Protection (SACHRP), Fall 2006-present

--FDA ex officio, Subcommittee on Research Involving Children

--FDA ex officio, Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research

--FDA ex officio, Subcommittee on Harmonization

--FDA ex officio, Subpart A Subcommittee

Deliverables: Ongoing advice and recommendations to SACHRP on issues and topics pertaining to the protection of human research subjects, for parent committee consideration and transmission to the Secretary of the Department of Health and Human Services for implementation. Topics included, research involving children and individuals with impaired decision-making capacity; informed consent and the use of biospecimens; harmonization of human subjects regulations and guidance, and; the reduction of regulatory burden with the preservation of appropriate protections for human research subjects

--Co-chair, IRB Working Group, April 2006-2012

Deliverables: Guidance publication, IRB Continuing Review after Clinical Investigation Approval, December 2012

--Chair, 50.24 Consultative Board on the conduct of emergency research with an exception from informed consent (under 21 CFR 50.24), June 2005-present

Deliverables: Formation of a consultative review board comprised of cross-agency experts to conduct prospective consultations and periodic retrospective reviews to assist senior management in evaluating the implementation of the

regulation and any needed modifications; Revision of CDER's internal policies and procedures on submissions involving exception from informed consent for emergency research, and; Guidance publication, Exception from Informed Consent Requirements for Emergency Research, March 2011

--Member, Human subject Protection and Bioresearch Monitoring (HSP/BIMO) Council, January 2005-present

Deliverables: Ongoing coordination and development of cross-cutting policies on modernizing and strengthening FDA's oversight and protection of subjects in clinical trials and integrity of resulting data

--Chair, Subpart D Ethics Working Group, May 2004-October 2006 and Chair, Pediatric Ethics Working Group, April 2004-April 2006

Deliverables: Establishment of pediatric ethics consultative service, and; guidance publication, Process for Handling Referrals to FDA under 21 CFR 50.54, December 2006

PUBLICATIONS (oldest to most recent)

1) Rogers, E.L., Goldkind, L., **Goldkind, S.F**., *Increasing Frequency of Esophageal Cancer among Black Male Veterans*, CANCER, 1982;49:610-7.

2) Rogers, E.L., **Goldkind, S.F**., Goldkind, L., et. al., *Adenocarcinoma of the Lower Esophagus*, Journal of Clinical Gastroenterology, 1986;8:613-8.

3) Rogers, E.L., Iseri, O., Bustin, M., **Goldkind, S.F**., Goldkind, L., *Adenocarcinoma of the Esophago-gastric Junction: A Distinct Entity*, Abstract, American Association for the Study of Liver Disease, Gastroenterology Research Group, May, 1981.

4) M. Dianne Murphy and **Sara F. Goldkind**, "Regulatory and Ethical Challenges of Pediatric Research," The Grand Bargain: Ethics and the Pharmaceutical Industry in the 21st Century. Cambridge: Cambridge University Press, 2005.

5) **Sara F. Goldkind**. *A Review of: Book Reviews Eric Kodish, Ethics and Research With Children,* American Journal of Bioethics, 2006;6(6):71-2.

6) Robert Temple and **Sara F. Goldkind**, "FDA and Drug Development," The Oxford Textbook of Clinical Research Ethics, Oxford: Oxford University Press, 2008.

7) Katherine L. Wisner, Paul S. Applebaum, Kathleen Uhl, **Sara F. Goldkind**, *Pharmacotherapy for depressed pregnant women: Overcoming obstacles to gathering essential data*, Clinical Pharmacology and Therapeutics, October 2009;86(4):362-5.

8) **Sara F. Goldkind**, Leyla Sahin, Beverly Gallauresi, *Enrolling Pregnant Women in Research-Lessons from the H1N1 Influenza Pandemic*, New England Journal of Medicine, June 17, 2010;362(24):2241-3.

9) P.I. Dickson, A.R. Pariser, S.C. Groft, R.W. Ishihara, D.E. McNeil, D. Tagle, D.J. Griebel, S.G. Kaler, J.W. Mink, E.G. Shapiro, K.J. Bjoraker, L. Krivitzky, J.M. Provenzale, A. Gropman, P. Orchard, G. Raymond, B.H. Cohen, R.D. Steiner, **S.F. Goldkind,** R.M. Nelson, E. Kakkis, and M.C. Patterson, *Research challenges in Central Nervous System Manifestations of Inborn Errors of Metabolism*, Molecular Genetics and Metabolism, 2011;102(3):326-38.

10) Mary C. Blehar, Catherine Spong, Christine Grady, **Sara F. Goldkind**, Leyla Sahin, Janine A. Clayton, *Enrolling Pregnant Women: Issues in Clinical Research*, Women's Health Issues, January 2013;23(1):39-45.

11) Richard H. Beigi, **Sara F. Goldkind**, Indira Jevaji*, Research on Vaccines and Antimicrobials during Pregnancy: Challenges and Opportunities*, Vaccine (2013);31: 4261-3.

12) **Sara F. Goldkind**, Laura Ruse Brosch, Michelle Biros, Robert Silbergleit, George Sopko, *Centralized IRB Models for Emergency Care Research*, IRB: Ethics & Human Research*,* 2014;36(2):1-9.

GUIDANCE DEVELOPMENT

- Natural History Studies for Rare Disease Drug Development-Draft Guidance pending publication
- Use of Electronic Informed Consent in Investigational Studies-Draft Guidance pending publication
- A Guide to Informed Consent-Draft Guidance
- Product Development under Animal Rule-Final Guidance pending publication
- Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials-Draft Guidance pending
- Pharmacokinetics During Pregnancy and the Postpartum Period: Study Design, Data Analysis, and Impact on Dosing and Labeling-Final Guidance pending
- Clinical Lactation Studies: Study Design, Data Analysis, and Recommendations for Labeling-Final Guidance pending publication
- Exculpatory Language in Informed Consent, Draft Guidance, August 2011
- IRB Continuing Review after Clinical Investigation Approval, December 2012
- Exception from Informed Consent for Emergency Research, March 2011
- Adverse Event Reporting to IRBs-Improving Human Subject Protections, January 2009
- Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials, October 2008
- Process for Handling Referrals to FDA under 21 CFR 50.54, December 2006

PRESENTATIONS/INSTRUCTION (oldest to most recent)

- Guest Lecturer, *Religion, Ethics and Society*-Undergraduate Course, University of South Florida, Fall 1991
- Speaker*, An Overview of Cross Cultural Spiritual Practices,* Tampa General Hospital, November 1993
- Speaker, *The Ethics of Fetal-Newborn Rights,* Tampa General Hospital, December 1993
- Instructor, *Ethical Policies and Ethical Issues*, Nursing Units and Management Forum, Tampa General Hospital, Fall 1993-Summer 1994
- Instructor, *Medical Ethics and Humanities*, University of South Florida-School of Medicine, 1994-1998
- Speaker, *Truth-telling in Medicine,* Bone Marrow Transplant Program-Didactic Conference, Moffitt Cancer Center, February 1994
- Speaker, *Ethical Issues in Nursing,* Tampa General Hospital Nurse In- Transition Workshop, February 1994
- Speaker, *Hot Topics in Ethics*, Tampa General Healthcare Senior Health Care Series, Sun City Center, February 1994
- Speaker, *Medical Futility: An Ethical Dilemma*, Controversies in Medicine, Boston University School of Medicine, March 1994
- Speaker, *Advance Directives*, Critical Care Transition Course, Tampa General Hospital, April 1994
- Develop and facilitate, *Fiction and Medical Ethics-Reading Group*, Tampa General Hospital, Spring 1994
- Develop and instruct, *Law and Medicine-Intensive Course*, Tampa General Hospital, Spring 1994
- Speaker, *Ethical Considerations in the NICU,* Tampa General Hospital, May 1994
- Speaker, *Ethical Issues in Critical Care*, Tampa General Hospital-Didactic Conference, July 1994
- Panelist, *Medical Futility: When is Enough Enough?* Inter-hospital Ethics Consortium, "Ethical Dilemmas in Healthcare: Shared Concerns," March 1995
- Speaker, *Medical Futility: What It Is and Is Not,* sponsored by The Tampa Bay Ethics Consortium, February 1995
- Panelist, *Does Medical Futility Exist, Medical Management of Futile Inappropriate Care Requests,* and *The Courts Approach to Medical Futility Issues,* sponsored by The Tampa Bay Ethics Consortium, February 1995
- Speaker, *Truth-telling and Confidentiality Issues in Medicine,* Tampa General Hospital, May 1995
- Guest Lecturer, *Comparative Religious Medical Ethics: Catholic and Jewish Views on Beginning of Life and End of Life Issues*, Berger High School, Spring 1996
- Panelist, *Hospital Policies on Futility: Should We Have Them?* Florida Bioethics Network Fifth Annual Conference, September 1995

Guest Lecturer, Med IV Elective in Medical Ethics and Humanities,

Spring 1996

- Develop and instruct, *Religion, Law, and Medical Ethics* Graduate Level Course #6938, University of South Florida, Department of Religion, Fall 1996
- Speaker and Panelist, *Assisted Suicide-What Are The Issues?* Public Forum, St. Petersburg, FL, sponsored by Menorah Manor, March 6, 1997
- Guest Lecturer, *Jewish Medical Ethics: Jewish Views on Beginning of Life, and End of life Issues* (including Physician-Assisted Suicide), Berger High School, Spring 1997
- Guest Speaker, "Advance Directives," annual Medical Staff meeting, Columbia Newport Richey Hospital, November 24, 1997
- Speaker and Panelist, *Patient Autonomy in Hospitals and Hospices: The Religious Response,* National Conference on Catholic & Jewish Perspectives on Bio-Ethics, Co-sponsored by Saint Leo College and The American Jewish Committee, February 9-10, 1998
- Lecturer, *Ethical Issues in Randomized Control Trials*, Division of Anti-Viral Drug Products, CDER, FDA, January 2004
- Lecturer, *Ethical Issues in Randomized Control Trials*, Division of Pediatric Drug Development, CDER, FDA, February 2004
- Instructor, *IRB Referrals and Human Subjects Protection*, Division of Counter Terrorism, CDER, FDA, February 2004
- Speaker, *Special Ethical Considerations for Protection of Pediatric Research Subjects,* Conference: Quality Improvement for Patient Protection, Jointly supported by University of Pennsylvania, Temple University & OHRP, May 6-7, 2004
- Panelist, "Central Versus Local IRBs," Conference: Quality Improvement for Patient Protection, Jointly supported by University of Pennsylvania, Temple University & OHRP, May 6-7, 2004
- Instructor, *IRB Referrals and Human Subjects Protection,* Division of Pediatric Drug Development, CDER, FDA, June 2004
- Instructor, *Research Misconduct and the Ethics of Data Use and Publication*, Research In Human Subjects Committee, FDA, June 2004
- Lecturer, *Assent and Subpart D Regulatory Issues in Pediatric Research*, Pediatric Advisory Board (Pedicomm), FDA, June 2004
- Speaker, *Special Ethical Considerations for Protection of Pediatric Research Subjects,* Conference: Pediatric Drug Development-Evolving Clinical & Regulatory Framework in US and Europe, Drug Information Association Annual Meeting, June 16, 2004
- Speaker, *Special Ethical and Regulatory Protections for Pediatric Research Subjects: Subpart D and Assent,* Joint Grand Rounds with Children's National Medical Center and George Washington University, June 30, 2004
- Lecturer, *Assent and Subpart D Regulatory Issues in Pediatric Research*, Pediatric Implementation Committee (PdIT), FDA, August 2004
- Speaker, *Introduction to Bioethics and Ethical Principles,* CDRH, FDA, September 21, 2004
- Panelist and Presenter, *Radioactive Drugs for Certain Research Uses,* Open Public Hearing, FDA, November 16, 2004

- Lecturer, *Ethical Issues in Randomized Clinical Trials with a Focus on International Research*, Division of Pulmonary Drug Products, CDER, FDA, December 21, 2004
- Lecturer, *Subpart D and Assent: What does an IRB Need to Know?* RIHSC (FDA-IRB), June 8, 2005
- Panelist, *Adverse Event Reporting to Institutional Review Boards*, Part 15 Hearing, FDA Cross Agency Initiative Task Force, March 21, 2005
- Presenter, *Update on Subpart D Process*, SACHRP, November 2, 2005
- Panelist, *Medical Ethics in the Regulatory Process,* CDER Clinical Reviewers' Retreat, FDA, November 3, 2005
- Presenter, *Ethical Issues at the FDA,* International Exchange between Japanese and US Representatives: Pediatric Research, FDA, November 10, 2005
- Presenter, *Bioethics Seminar: Informed Consent and Case Analyses*, CDRH, FDA, November 28, 2005
- Presenter, *Ethical Issues in Pediatric Research,* President's Council on Bioethics, December 8, 2005
- Panelist, *Consortium to Examine Clinical Research Ethics: Policy Forum, December* 14, 2005
- Presenter, *FDA Perspective Regarding Ethics, Regulation, and Research Involving Children,* Children's Oncology Group, March 24, 2006
- Presenter, *Ethics in Counter-terrorism Trials*, CDER Pediatric Medicine Update, June 1, 2006
- Presenter, *FDA's Role in Human Subjects Protection,* "Human Subjects Protection, Bioresearch Monitoring, Critical Path Update," DIA, June 21, 2006
- Presenter, *Pediatric Subjects in clinical Investigation: Subpart D, Assent, and Inspections,"* Advanced BIMO Course, June 30, 2006
- Instructor, Division Directors for CDER, Pediatric Trial Review and Inspection: Review Pediatric Protocol Review Guide, July 7, 2006
- Speaker and Panelist, *Emergency Research Update,* "Strategies for Research in HIPAA Environment and other Regulatory Issue," NINDS sponsored, July 26, 2006
- Speaker and Panelist, *Emergency Research and Human Subject Protections: Challenges and Solutions*, Part 15 Hearing, FDA Bioresearch Monitoring Initiative, October 11, 2006
- Speaker and Panelist, *When and How to Seek an Emergency Exception to Informed Consent,* PRIM&R, 2005 Annual HRPP Conference: A Commitment to Ethical Research, December 16, 2006
- Speaker and Panelist, *IRB's Experience with FDA's Emergency Research Waiver of Informed Consent Rule,* PRIM&R, 2005 Annual HRPP Conference: A Commitment to Ethical Research, December 17, 2006
- Panelist, *Development of Guidance for the Application of The Exception from Informed consent for Emergency Research,* National Association of EMS Physicians, February 7-8, 2007
- Develop and Moderate, *Defining and Implementing Quality in Clinical Investigations: From Design to Completion,* DIA Workshop, May 10-11, 2007

- Speaker, *Ethics in Clinical Investigations with a Focus on Emergency Research,* Medical Policy Coordination Committee, CBER, April 24, 2007
- Instructor, Trans NIH Bioethics Committee, *Supervisory Responsibilities of Investigators,* June 19, 2007
- Speaker and Panelist, *Can the Prospect of Direct Benefit Be Based on Animal Studies Alone?* American Society for Bioethics & Humanities, October 19, 2007
- Speaker, *FDA Perspectives on "Adverse Events,"* Data and Safety Monitoring: An Educational Program for the NIMH DSMBs, November 19, 2007
- Speaker and Panelist, *Can the Prospect of Direct Benefit Be Based on Animal Studies Alone?* PRIM&R Annual HRPP Conference: Human Research Protection Programs in Evolving Research Landscape, December 1-4, 2007
- Speaker and Panelist: *A Guide to the Perplexed: Navigating OHRPs and FDAs and NIH's Expectations for Reporting Adverse Events and Unanticipated Problems,* PRIM&R Annual HRPP Conference: Human Research Protection Programs in Evolving Research Landscape, December 1-4, 2007
- Speaker and Panelist, *Emergency Exception to Informed consent: When and How?* PRIM&R Annual HRPP Conference: Human Research Protection Programs in Evolving Research Landscape, December 1-4, 2007
- Speaker & Moderator, *Ethical Issues in International Research*, CDER (& CBER) Scientific Rounds, January 15, 2008
- Speaker, *Genotoxicity: Should we be checking for it?* CDER Pharmacology-Toxicology Scientific Rounds, January 30, 2008
- Speaker, *FDA Perspectives on "Adverse Events,"* Addressing the Challenges of Human Subject Research in 2008, Sacramento Regional Conference Forum for OHRP, February 8, 2008
- Speaker and Panelist, *Conduct of Emergency Research Trials*, Clinical Hold/RTF Committee Meeting, CDER, March 14, 2008
- Develop and Moderate, C*linical Investigations as a Quality System: From Design to Completion,* CDER Workshop, Office of Critical Path Programs, March 18, 2008
- Speaker, *Ethical Perspective on Drug-Induced Liver Injury: Premarketing Clinical Evaluation,* Drug-Induced Liver Injury Workshop, FDA, March 26, 2008
- Speaker, *Ethical Considerations for Trials in Community Acquired Pneumonia,* Anti-infective Drugs Advisory Committee, FDA, April 1, 2008
- Speaker, *Risk-Benefit Considerations in the Context of §50.24 and §312,* Hemoglobin Oxygen Carrier Workshop, FDA-NIH, April 29, 2008
- Panelist, *Developing Guidance on Conducting Scientifically Sound Pharmacoepidemiologic Safety Studies Using Large Electronic Healthcare Data Sets*, FDA Public Workshop, May 7, 2008
- Lecturer, *IRB Considerations Regarding Protection of Vulnerable Subjects with a Focus on Decisionally Impaired Subjects*, RIHSC (FDA-IRB), April 12, 2008
- Lecturer, *Historical and Current Perspectives on the Declaration of Helsinki,* RIHSC (FDA-IRB), May 7, 2008
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, August 12, 2008

- Lecturer, *Ethical Dilemma Associated with Sham Procedures/Treatments*, CDRH, October 17, 2008
- Panelist, *Real Cases, Hard Choices when Balancing Ethics and Regulations,* PRIM&R Annual HRPP Conference: Balancing the Needs of Human Subjects and Science, November 17-19, 2008
- Co-presenter, *Tools for Talking to Parents and Children about Research*, PRIM&R Annual HRPP Conference: Balancing the Needs of Human Subjects and Science, November 17-19, 2008
- Speaker and co-developer, *The Ethics of Studying Drugs and Biologics in Pregnant Women*, CDER Scientific Rounds, April 20, 2009
- Participant, *The Second Wave: Toward Responsible Inclusion of Pregnant Women in Clinical Research*, Georgetown University Medical Center, May 2009
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, March 11, 2009
- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 22, 2009
- Speaker, *Federal Update: What's New from the Feds?,* OHRP Research Community Forum "On the Legal and Ethical Frontline", September 11, 2009
- Panelist, *Ask the Feds,* OHRP Research Community Forum "On the Legal and Ethical Frontline", September 11, 2009
- Break Out Session Moderator, Workshop on Ethical and Regulatory issues in Global Pediatric Trials, September 21-22, 2009
- Panelist, *Regulatory issues Associated with Multi-Regional Trials*, The Fourth National FDA Regulatory Symposium, September 30-October 2, 2009
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2008 Course, October 15, 2009
- Speaker, *Are the FDA regulations and guidance that different from the WMA Declaration of Helsinki?,* American Society for Bioethics & Humanities, October, 18, 2009
- Lecturer, *Informed Consent and Elements to Assure Safe Use in REMS*, Division of Risk Management Roundtable, CDER, October 20, 2009
- Speaker, *Ethical Issues in Studying Rare Disease*, Inborn Errors of Metabolism/CNS Workshop, Division of Gastroenterology Products, CDER, December 7-8, 2009
- Speaker, *Issues to Consider for Trials Conducted Under 21 CFR 50.24 (Exception from informed consent for emergency research)*, CBER, January 4, 2010
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2010 Course, March 3, 2010
- Prepared presentation, *Part 50-Informed Consent Process,* Center's Bioresearch Monitoring Course, April 9, 2010
- Speaker, "What's New and Important from the Feds?", OHRP-FDA Educational Conference, May 21, 2010
- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 29, 2010

- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2010 Course, August 25, 2010
- Speaker, *Inside FDA (and emergency research with the exception from informed consent),* PECARN, September 15, 2010
- Speaker, *REMS, Pregnancy, and Ethics,* DIA Maternal and Pediatric Drug Safety Symposium, October 13, 2010
- Speaker, *Pregnancy Women and Clinical Trials: Scientific, Regulatory, and Ethical Consideration,* Research Forum on Issues in Clinical Research: Enrolling Pregnant Women, October 18, 2010
- Panelist, *Pregnancy Women and clinical Trials: Scientific, Regulatory, and Ethical Consideration,* PRIM&R Plenary XIII-Research on Pregnancy: a Necessary Risk?, December 8, 2010
- Speaker, *Ethical Consideration in Trauma,* Public Workshop on Product Development Program for Interventions in Severe Bleeding due to Trauma and Other Causes, December 9-10, 2010
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2011 Course, January 20, 2011
- Lecturer, *Ethics and Device Clinical Trials*, CDRH, January 24, 2011
- Speaker, *Ethical Challenges and FDA's Experience with EFIC Applications*, HRSA sponsored WEBCAST, 2/28/11
- Presenter, *Ethical Issues Associated with a Drug Study in a Foreign Country,* CDER's Regulatory Briefing Meeting, February 25, 2011
- Speaker, *Ethical and Scientific Considerations in Including Pregnant Women in Clinical Trials,* FDA Office of Women's Health Symposium on "Pregnancy and Prescription Medication Use", May 17, 2011
- Speaker, *Ethical and Scientific Considerations in Research (particularly involving vaccines)on Pregnant Women,* CBER, May 24, 2011
- Speaker, *Ethical Issues in International Clinical Trials*, Fogarty International Training Program Seminar, June 20, 2011
- Speaker, *FDA Guidance on Emergency Care Research and IRB Review Processes,* Assistant Secretary for Preparedness and Response, Workshop on IRB Options for Emergency Care Research, 9/19-9/20/11
- Speaker, *Exception from Informed Consent for Emergency Research,* PRIM&R Didactic Session, B11, December 2, 2011
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2011 Course, February 8, 2012
- Panelist, *Innovative models for clinical trials-how do we ensure data quality and appropriate protections while facilitating innovation,* CDER Scientific Rounds, February 8, 2012
- Speaker, *Ethical Considerations in the Clinical Development of Therapeutics for Rare Diseases,* FDA Meeting the Challenges of Rare Disease Drug Review, February 28, 2012
- Speaker, *Current FDA Activities,* Society of Clinical Research Associates FDA Clinical Trials Requirements Conference, March 7-8, 2012
- Speaker, *Ethical Considerations in the Clinical Development of Therapeutics for Rare Diseases,* Office of Orphan Drug Products, May 14, 2012

- Speaker, *Defining the Status of the Research Subject in Resuscitation Research*, PRIM&R Didactic Session, D14, December 5, 2012
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2012 Course, December 11, 2012
- Develop content for interactive educational modules on informed consent, 2013
- Panelist and moderator, *The Ethics of Self-care: Avoiding Provider Fatigue and Maintaining Medicine as a Calling,* Embracing the Principle of Justice in Healthcare, 2013 Annual Healthcare Ethics Symposium, Walter Reed National Military Medical Center, May 15, 2013
- Speaker, *Background on Informed Consent Issues and HIV "Cure" Research,* FDA Meeting on HIV Patient-focused Drug Development and HIV "Cure" Research, June 14, 2013
- Lecturer, *Regulatory Science and Bioethics,* Georgetown University, Introduction to Regulatory Science Graduate Course, September 11, 2013
- Speaker, *Everything statisticians want to know about 50.24 studies but are afraid to ask,* ASA Pharmaceutical Section, FDA-Industry Statistics Workshop, September 17, 2013
- Speaker, *Hot Topics in Bioethics and Human Subject Protections*, Human Subject Protection Multi-institution Sponsored Regional Meeting, September 20, 2013
- Co-moderator, *Emergency Research and Community Consultation,* PRIM&R, November 8, 2013
- Speaker and panelist, *Tobacco Cessation Studies and Studies Involving Potential Reduced Risk Products in Pregnant Women: Ethical & Scientific Considerations,* Tobacco and Reproductive Health Workshop Sponsored by FDA-NIH-CDC, January 21-22, 2014
- Lecturer, *FDA Institutional Review Board and Informed Consent Regulations*, Basic Bioresearch Monitoring 2014 Course, March 4, 2014
- Speaker, *Overview of Federal Regulations on Emergency Care Research*, Ethical and Regulatory Challenges to Emergency Care Research, NIH-sponsored conference, March 5-6, 2014
- Speaker, *Centralized IRB Review and Emergency Care Research*, Ethical and Regulatory Challenges to Emergency Care Research, NIH-sponsored conference, March 5-6, 2014
- Speaker and panelist, *Comparative Effectiveness Research,* Challenges in Military Medical Ethics, 2014 Annual Healthcare Ethics Symposium, Walter Reed National Military Medical Center, June 5, 2014
- Speaker, *Impact of poor informed consent processes on clinical trials (including information sharing),* National Academy of Sciences, Institute of Medicine, Roundtable on Health Literacy, July 28, 2014
- Speaker, *FDA's perspective on investigator-initiated research and navigating the need for an IND or IDE,* Achieving Excellence in Clinical Research Conference, Advocate Center for Pediatric Research, September 19, 2014
- Speaker, *Ethics of Research with Children*, NIH Course: Ethical and Regulatory Aspects of Clinical Research, October 8, 2014

- Keynote Address, *Physician Aid-in-Dying: A Survey of the National Landscape*, Walter Reed National Military Medical Center, Annual Ethics Symposium, May 13, 2015