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From the Presidents

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Sharon Darkovich, RN, MA, BSN, CPHQ

Passing the Baton

For the past 25 years, the Bioethics Network of Ohio has maintained a "grassroots" educational mission for the many nurses, social workers, physicians, chaplains, long-term care administrators and educators comprising its membership. Through all of these years, BENO's volunteer leaders have been an important facet of BENO's success.

Outgoing BENO President Donna Homenko shares reflections from her early days as a BENO member and from her service as BENO's President. Newly-elected BENO President Sharon Darkovich reflects on the impact BENO's always-successful annual conferences and its Board of Trustees have had on her.

Donna Homenko: BENO President, 2011-2014

When I first joined BENO in the 1990s, it felt as if individuals had gathered together to identify existing resources in ethics and find out what was developing with bioethics in hospitals. Cleveland Clinic had a small department of bioethics at the time and educational programs to train ethicists were sparse. I remember attending a one-week intensive course at Loyola…. leaving with at least awareness for ethical issues beginning to surface in the literature. Suddenly, legislation on physician-assisted suicide and Dr. Kevorkian arrived on the national scene and everyone began to operationalize ethics committees, prospective and retrospective case discussions, and protocols for bedside ethics consultations. The Joint Commission addressed the role of institutional ethics, and federal legislation established guidelines for HIPAA. Not unlike the Hippocratic Oath (440 BCE) that states, *"What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must noise abroad, I will keep to myself holding such things shameful*

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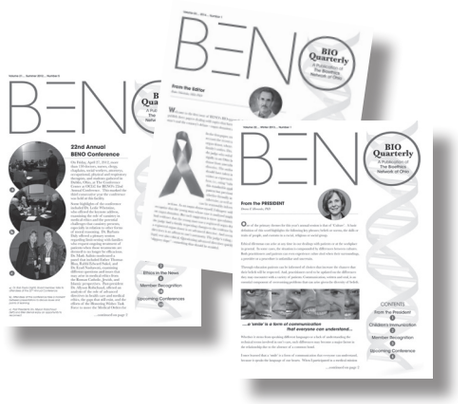

to be spoken about," even the issue of confidentiality remained a concern affecting patient care. Soon, it was clear that having a statewide association was extremely beneficial for professionals dealing with ethical issues on a daily basis.

One of the unique features of BENO is BIO Quarterly. This publication has offered original articles and research based on the educational grants funded by BENO, along with legislative updates and book reviews. A student essay contest was held for many years, with the winning essays published in BIO Q. Participants, from both undergraduate and graduate programs throughout the state, were asked to analyze a case that could come before an ethics committee. The contest connected the academic side of bioethics with the practical applications facing health care professionals and organizations, while providing future professionals the opportunity to weigh-in on a dilemma and learn how to ground their viewpoints utilizing ethical theory and principles. The essay entries were then evaluated by individuals serving on an established ethics committee at a medical center in Ohio. I look forward to reading the results of future contests.

Sharon Darkovich: Current BENO President

BENO's Annual Conference has remained a major focus of our organization's existence, featuring nationally recognized keynote speakers such as Dr. Timothy Quill and noteworthy poet Dr. Rafael Campo. While these were engaging presenters, in time we realized the outstanding talent and knowledge existing among our own Ohio colleagues who knew first-hand what was happening in their health care environments and willingly shared information through conference plenary and breakout sessions. The annual BENO conferences in part helped me decide to further my formal education in bioethics and I ultimately obtained a master's degree in bioethics. After each conference I always had practical information to take back to my organization.

When I was asked to join the BENO Board nearly 10 years ago, I was honored but not sure what impact I might have in doing so. I found through the years that the discussions during board meetings were stimulating and thought provoking as well as educational. The Board monitored and supported the Honoring Wishes Task Force and its work in helping shape patients' rights to make their own decisions at the end of life. Planning annual conferences, determining topics, finding speakers, and working to get the word out about the conferences was and is an exciting part of the Board's functions.

I am honored and privileged to have been elected president of this organization. I believe that we can continue to offer education and thought-provoking discussion and support to those using the concepts and principles of bioethics every day to help patients and their families come to decisions that honor patients' wishes. I welcome thoughts and ideas from you, our members, and I express my thanks to all those board members past and present who have had a positive influence on what I do.

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Sharon Darkovich, RN, MA, BSN, CPHQ
President

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● Regulating Patient-Provider Communications: New State-Mandated Informed Consent Requirements When Prescribing Opioids to Minors

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Cristie M. Cole, JD *joined the Cleveland Clinic's professional staff in the Department of Bioethics in the spring of 2014 as the Regional Bioethicist for four community hospitals. She is responsible for ethics programming and managing these hospitals' ethics consultation services. Ms. Cole is a 2014 graduate of the Cleveland Fellowship in Advanced Bioethics.*

Introduction

Effective September 17, 2014, a new Ohio law requires health care providers prescribing opioids to minors to obtain parental written informed consent [1]. The law also delineates disclosure obligations and authorizes professional disciplinary action against prescribers who fail to comply [1]. This law is part of Ohio's on-going public health battle against the prescription drug abuse epidemic [2, 3].

At first glance, the law seems innocuous. The impact on providers appears minimal and purports to advance the state's interest to protect youth against a public health problem. With limited exceptions, parental informed consent is already required before prescribing opioids to minors. The disclosure requirements and other mandates are also consistent with current practice standards. However, regulating patient-provider communications is not harmless [4, 5]. Stakeholders must be cognizant of the law's potential detrimental effects on other relevant interests. The anticipated benefits should be carefully weighed against identified burdens. Important factors to consider include the scope of the state's interest, effectiveness of already existing regulations and state actions, current practice standards, and any evidence supporting whether those standards are consistently met.

Ohio's Prescription Drug Epidemic and State Action

Between 1999 and 2011 the number of deaths due to drug overdose increased by 440% in Ohio. Unintentional drug overdose has consistently been the leading cause of accidental death since 2007. The trend has not only continued through 2012, but the number of deaths has steadily increased and exceeds national averages. Ohio's youth are particularly vulnerable. Approximately 21% of them reported prescription drug abuse in 2011 and eight of ten reported obtaining the drugs from friends or relatives. Opioids are consistently identified as a primary contributor to the epidemic across age groups [6, 7].

Over the course of three years, the joint efforts of the Governor's Administration, Ohio's General Assembly and other state agencies have (1) tightened regulations of pain management clinics and implemented stricter enforcement, (2) issued new (and continually updated) opioid prescription guidelines in collaboration with clinical professional organizations, pain management specialists, and professional licensing boards, (3) allocated resources for opiate treatment programs, (4) launched a state-wide "take-back" prescription drugs program, and (5) implemented initiatives aimed at prevention. One of the earliest prevention initiatives was the "Start Talking!" program. Launched in 2011 by Governor John Kasich and First Lady Karen Kasich, the program's intent is to decrease drug abuse among minors. Targeting middle and high school age students, it provides information and tools to empower parents, teachers, health care providers, mentors and other authority figures to talk to youth about drug abuse [6].

Building upon these efforts, the Ohio House formed the Prescription Drug Addiction and Healthcare Reform Study Committee to identify and evaluate other potential mechanisms to address the epidemic. The Committee held several hearings throughout the state to elicit feedback from

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stakeholders. In October 2013, the Committee's report recommended, among other actions, that the state require prescribers to obtain parental written consent when prescribing opioids to minors. The Committee identified prevention as an area for additional state action; specifically, educating teenagers and patients about addiction dangers and revising practice standards to prevent prescribing opioids to susceptible populations such as minors. The informed consent process is a prime venue to provide young patients and their parents a comprehensive education about the risks of addiction. A robust informed consent process can also act as a safeguard by providing prescribers an opportunity to assess non-clinical risk factors [3].

Arguably, additional safeguards may not be necessary. Earlier prevention measures seem to have had a substantial impact. Released in June of this year (after the new law was signed by Governor Kasich), the 2013 Youth Risk Behavior Survey shows an approximate 8% decrease in prescription drug abuse among Ohio minors since 2011. Ohio's average is now 5% less than the national average, a substantial improvement from 2011 when the prescription drug abuse rate among Ohio youth was slightly above the national average [7]. Even so, prescription drug abuse, particularly opioid abuse, continues to be the leading cause of accidental deaths in Ohio across age groups [6].

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The Parental Consent Law (Ohio Revised Code Section 3719.061)

The new law applies to all providers authorized to prescribe opioids (physicians, advance practice nurses, physician assistances, dentists) and only applies to opioid prescriptions. Prescribers must evaluate whether the minor has mental health or substance abuse disorders and is being treated with prescription drug(s). Written informed consent must be obtained from a parent, guardian or an adult whom the minor's parent has "given written authorization to consent to the minor's medical treatment." If obtaining consent from an authorized individual other than a parent or guardian, the provider can only prescribe a single 72-hour supply. During the informed consent process, the provider must discuss with the minor and consenting adult: (1) risks of addiction and overdose, (2) increased risk of addiction if suffering from mental and substance abuse disorders, (3) dangers of taking opioids with other substances, and (4) any other information required by federal law [1].

The consent must be documented on a "Start Talking!" consent form. In addition to the consenting adult's signature, this form must include: (1) the name and quantity of the opioid being prescribed and amount of initial dose, (2) a statement that a controlled substance carries the risk of abuse, (3) that the required disclosures outlined above were made, and (4) number of refills, if any. Providers must maintain the form in the minor's medical record, separate from other consent forms. Exceptions to the law include: (1) a medical emergency, (2) out-patient or in-patient surgery, (3) the prescriber determines that following the requirements will be detrimental to the minor's health or safety, or (4) the treatment is rendered in specified institutional facilities or prescribed upon discharge from one of these facilities [1].

Mandating Provider-Patient Communication

While earlier prevention initiatives enabled communication and facilitated education of stakeholders, the new law takes the additional step of legally mandating communication between the provider, patient, and patient's parent. Even early prescription guidelines were not legislative mandates, but rather were used to raise awareness of problematic prescribing practices and educate clinicians about best practice standards. The parental consent law arguably has a similar intent, though it is much more difficult to assess whether communication deficiencies exist than substandard prescribing practices.

As noted by the Ohio State Medical Association and the Ohio Chapter of the American Academy of Pediatrics (AAP), the law's requirements are consistent with current practice standards [5]. The Bill Analysis makes the same observations rooted in state law [8]. Arguably, the penalties authorized in the new law strengthen and supplement enforcement mechanisms, though professional licensing boards could impose those penalties under general professional standard requirements. Thus, the law's main addition is that parental consent must be written using a "Start Talking!" consent form.

A common intent when regulating provider-patient communication is ensuring patients have sufficient information to make informed decisions. However, assessing what information needs to be disclosed inherently requires both medical judgment by the provider and value judgments by the patient. When codifying specific disclosure requirements, the legislature risks substituting its own value judgment for the patient's, limiting or violating personal autonomy. It also inhibits providers from exercising medical judgment, and risks weakening a robust informed consent process by reducing it to bare minimum legal requirements [9].

...the new law takes the additional step of legally mandating communication between the provider, patient, and patient's parent.

In the context of minor patients, requiring parental consent and disclosures can complicate an already challenging dynamic. The AAP emphasizes obtaining parental assent, as opposed to parental consent, prior to the provision of medical treatment, to highlight limitations in parental authority recognized in both ethical and legal frameworks [10]. While parents generally have their child's best interests at heart, in some circumstances parental consent requirements are more detrimental than beneficial to the child. For example, obtaining parental consent from a parent with a history of opioid abuse may be detrimental to the child's well-being. Exceptions that take into account such circumstances are important to optimize the therapeutic relationship between the provider and the minor patient [10]. Here the law does not require a prescriber to fulfill its requirements when doing so is detrimental to the child's health or well-being – it allows clinicians to exercise professional judgment, though the courts will likely play a role in interpreting its scope.

An additional risk is altering physician behavior [9]. This may result in appropriate medical treatment being delayed or denied to some patients. Requiring written informed consent with associated disclosure requirements is a double-edged sword. Practically, it emphasizes the importance of the information required. It may cause some prescribers to pause before prescribing opioids and take more care in their own prescribing practices. However, providers may also become overly cautious for fear of legal liability, thereby preventing some patients from receiving medically-appropriate treatment. For instance, some sports injuries are appropriately treated with opioids, even if the injury does not require surgery. Prescribers may be more hesitant to prescribe opioids or may prescribe an insufficient dose. Even with exceptions in place, providers may be hesitant to exercise those exceptions for fear of liability, opting not to prescribe opioids.

Conclusion

Regulating patient-provider communications can have a detrimental impact on the therapeutic relationship, but may be justified when intended to advance an identified state interest. Stakeholders need to be cognizant of both the anticipated benefits and potential burdens or risks. In this case, Ohio's intent is to prevent diversion and abuse of prescription opioids by (and from) minors - an identified vulnerable population in a broader prescription drug abuse epidemic. The potential burdens include harms to the informed consent process, limiting or violating patient autonomy, and exacerbating challenges in an already complex relationship among health care providers, minors, and parents. Legislatures must carefully draft regulations regarding provider-patient communication to meet identified goals and include safeguards to mitigate potential harms. Providers must also be cognizant of the practical impacts, including potential unintended effects on practice behaviors that can detrimentally impact patient care.

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● A Life Out of Balance?

Matthew Greer *is a third-year medical student at the Cleveland Clinic Lerner College of Medicine and is from St. Johns, AZ. He plans to pursue a career in oncology both for the scientific possibilities and the depth of the human experience inherent to the field.*

The SOAP note (an acronym for Subjective, Objective, Assessment, and Plan) is a common format used by health care professionals when documenting in patients' medical records. For me, it also serves as a helpful tool for structuring my reflections (and struggles) after a patient encounter.

Subjective:

What you want to hear is that "my knee hurts." But life is not so limiting as to describe how I feel in three words. There is so much more influencing our bodies, our lives, our essences than just pain. Of course pain exists. I feel pain, you feel pain, everyone feels pain. But pain is not always what you doctors say it is. It is the product of a life out of balance, a yin and yang that do not equally oppose one another. Pain is merely the manifestation of that imbalance. I may have aggravated my knee while running, but the pain I feel indicates more than just bone grinding on bone or whatever you doctors say it is.

How can you help me? You can't. My dad insisted that I come to see you, so I am here for him.

Sure, I'll describe how long my knee has hurt. When I was a young girl I grew up like a little Indian, playing in the woods, eating berries, eating only the whole and real foods that my mother made for us. We had a large family, and we played all day long, hardly bathing. That was the good side. On the other side, my parents were together in name only. We either did something with mom or with dad, but never with our whole family. My parents fought often. My dad wanted my mom to be just a little more "traditional." My mom followed her inner calling with a beautiful passion. Sometimes that inner calling asked her to leave for a while; we didn't really know where she would go. In the middle of this I sometimes became the mother of the home, cooking and cleaning for my younger and older siblings. Not to say my mom was a bad mom. I understand that sometimes you can't always be there in the way that someone else needs you to be. I was always torn emotionally, by my conservative, traditional side with my father. His family was a farming family, all overweight, all critical of my mother. My mother is so free and dedicated to finding real truth. I became at times melancholic, at other times sanguine, not just by this, but by all of life, the balance I was talking about before. I pushed myself to be my best, waking up at 4 am to do my yoga, starting on my homework through the day, cleaning the house in the afternoon, helping my younger siblings with their homework, usually getting to bed by midnight. At times I had so much energy, at other times I was so emotionally depleted I would sit in front of a mirror and watch myself cry.

I had an older sister who I absolutely adored and who passed away a year ago. It's been hard on me. It has thrown my aura into a radical imbalance. I try to recover it, but the imbalance manifests itself in so many ways. This time it is with knee pain.

When does my knee hurt? When something in my life is not right. It's never predictable, I notice it more when I run, but not always. Sometimes when I sit, or lie down, or sometimes never. Just my knee has been hurting for a couple of weeks. What might have triggered it? Haven't you been listening to anything I say? I need to find equilibrium in my life. I don't need your powerful, synthetic medications to suppress my feelings. I need to find real balance. My knee will then feel better.

Objective:

21 year old female with a chief complaint of knee pain. Sharp pain, 5 out of 10, left knee on lateral side, worse with activity, especially running. Began 2 weeks ago. Ran a marathon 2 weeks ago with little training. Not taking any meds. Sometimes hurts with rest. No noticeable alleviating factors. No pain in other joints/locations. Physical exam: negative anterior and posterior drawer test, pain induced with varus force on left knee. Intact sensation and motor function in lower extremities.

Assessment:

The way I perceive the truth of this case, especially related to the chief complaint of knee pain, is simply a woman with knee pain from over exertion after a marathon. I think immediately of inflammatory pathways, innervation of the knee, possible ligaments that may be stressed, further imaging studies I could do to indicate which ligament might have a tear, which medications might be the best to prescribe, how long before any further evaluation might need to be done. Basically, what I see is a knee that needs to be fixed. Just the beginning of her story and the implication that her parents' marital issues might have something to do with her knee pain when she runs makes me roll my eyes and laugh.

Of course, that's just a defense mechanism. What if there really is something to this patient's perception of her pain and how her whole life story, her whole being, is wrapped into and really is manifesting itself with her knee pain? That is a truth I do not want to admit might exist. It's too complex. It's too overwhelming. Perhaps that may indicate a certain level of truth beyond what I am seeing.

"The pure and simple truth is rarely pure and never simple."

...but a key truth I learned from her is that people are more than spare knees and joints thrown together to be medicated and fixed, but whole creatures with complicated and beautiful stories.

My world needs to be more mechanical, more fixable than what this patient describes. In many ways it's a knee jerk reaction to how I perceive her background. I grew up in a red state, eating red meat, and doing red-blooded American things like driving large trucks and shooting guns and blowing things up. The thought of yoga and whole foods and tree huggers brings out the conservative side of me more than I care to admit even exists. I believe in a higher power, but I also believe a higher power made ligaments and inflammatory cascades.

Perhaps in that way, I shy away from truth; I like the simple.

Plan:

The treatment plan for this patient was to ice and heat her knee, refrain from running for one week, and gradually work in exercise. If pain persisted, decrease activity and consider ibuprofen. If pain remained continued, return for further work up.

Clearly my truth of a broken knee is very limiting with this patient. There is more going on in her life than a knee. Whether the death of a sister causes knee pain or not is beyond the scope of my expertise, but a key truth I learned from her is that people are more than spare knees and joints thrown together to be medicated and fixed, but whole creatures with complicated and beautiful stories. I believe her that the knee is not the main concern. I also believe her that medicine will not be the whole answer to what she is seeking. Medicine may ensure catastrophic damage is not occurring in her knee, and help her establish a stable emotional baseline, but medicine is more of a safety net then a ladder; it protects against catastrophes, but only rarely provides an avenue for growth.

Perhaps the best treatment for her knee would have been in the language that she speaks. Maybe it would have been a referral to a holistic healer or a yoga center. Pain and disease are amalgamated into groups for our treatment purposes, but no one pain or one disease is the same as another. Each occurs in the context of a much larger experience.

● Pharmaceuticals and Lethal Injection

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Earlier this year I read media reports about an Ohio death row inmate who took an unusually long time to die when a new mix of drugs for lethal injection was used. A rather dark subject, this is interesting to me because of the interplay between pharmaceutical and ethical issues. Dennis McGuire was executed on January 16, 2014, the first time a new two-drug combination of hydromorphone and midazolam was used in Ohio. McGuire reportedly gasped, snorted and exhibited irregular breathing before he died-nearly 25 minutes after the drugs began to be administered. His family and lawyers later reported that he appeared to be suffering and that the execution represented cruel and unusual punishment. [1]

Drug shortages and restricted drug distribution have forced states to change their execution protocols. Prior to 2010, Ohio used a three drug combination of pancuronium, sodium thiopental and potassium chloride. Sodium thiopental had only been made by one Italian pharmaceutical company, Hospira. In January 2011, Hospira announced it would stop producing the drug. The European Union (EU), which officially opposes the death penalty, will not allow the export of drugs known to be used for capital punishment to countries such as the U.S. where they might be used for lethal injection. [2] In the past, sodium thiopental was commonly used in surgical cases for anesthesia. Since Hospira withdrew this drug from the market, it has not been available in the U.S. for any purpose.

In 2011, Ohio was the first state to use pentobarbital (another barbiturate related to sodium thiopental) in a one drug protocol for lethal injection. Other states, including Texas, have also used pentobarbital in various protocols. Pentobarbital was previously made by Danish company Lundbeck which also sought to prevent its use for lethal injection. Lundbeck later sold this product to Oak Pharmaceuticals, a subsidiary of Akorn, Inc.,

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which retained these restrictions. Distribution of the drug is restricted for medical uses and is not available to prisons. Thus, all of the pentobarbital injection supply that was on hand in prisons in Ohio, Texas and elsewhere expired in 2013 and the drug can no longer be obtained from the manufacturer for that setting. [2] Pentobarbital can still be acquired for hospital settings because it is indicated for sedation and for emergency control of seizures.

Some states have sought to obtain pentobarbital from compounding pharmacies or from foreign distributors. [2] But compounding pharmacies have new regulations from the Food and Drug Administration (FDA) and it seems unlikely that they could legally produce products for lethal injection. Compounding pharmacies are not bound by the same manufacturing standards as licensed pharmaceutical companies, raising questions of quality and purity. FDA restricts importation of drugs, and because these barbiturates are controlled substances, the Drug Enforcement Administration (DEA) would also restrict importation. Foreign companies doing business in EU countries would face EU sanctions for improperly shipping drugs on the list of restricted items.

Pancuronium is an injectable neuromuscular blocking agent which is also used in the surgical or intensive care setting to assist, for example, mechanical ventilation. Because it causes paralysis but does not relieve pain or cause sedation, there is a real risk that a person receiving the drug might be aware of and in pain but unable to move or cry out. We might imagine that using pancuronium for lethal injection could result in the mere appearance of a peaceful death while the prisoner experiences pain and distress. Hospira is the only current supplier of pancuronium. A group of European doctors published an open letter to Hospira in 2012 urging the company to restrict distribution of pancuronium so that it cannot be used in lethal injection. [3] There is currently a shortage and manufacturing delay, making pancuronium unavailable to hospital pharmacies, according to FDA drug shortage information.

The execution of Joseph Wood III in Arizona on July 23, 2014 was described as "botched." The combination of hydromorphone and midazolam was used in this execution, in which it took the prisoner nearly two hours to die. Witnesses reported that Wood gasped and snorted over 600 times before he died, but state officials stated he was comatose and not in pain. Of note, Wood received 15 doses of the lethal injection drugs, much more than the single dose followed by a second dose if needed, called for in the Arizona protocol. This points to another pharmaceutical dilemma with lethal injection: What is the appropriate dose of a drug for lethal injections?

There would be no way to test dosing of drugs for lethal injection except by trial and error. We can only guess the right dose.

Available drug information describes therapeutic dosing for various indications, with information gleaned from clinical trials in the drug approval process and after drugs are marketed for medical use. There would be no way to test dosing of drugs for lethal injection except by trial and error. We can only guess the right dose. Ohio's current lethal injection protocol (available online) calls for 50mg of hydromorphone and 50mg of midazolam, followed by additional doses if necessary. These doses were increased from the previous ones of 40mg and 10mg respectively, as a result of the review of McGuire's execution. [2]

Another "botched" execution involved Clayton D. Lockett in Oklahoma on April 29, 2014. The executioners had difficulty finding a usable vein. A sequence of three drugs for lethal injection was administered, but the prisoner was not rendered unconscious as expected. The procedure was halted, but Lockett died from a heart attack 43 minutes into the procedure.

Such episodes of "botched" lethal injections call into question the competence of officials performing executions. The question of who should perform executions raises conflicting arguments. The codes of ethics of the American Medical Association and other professional societies forbid the participation of its members in executions. In the traditional view, healthcare professionals are committed to "first do no harm." Execution is not a medical procedure. [4] On the other hand, a recent report from The Constitution Project's Death Penalty Committee recommends that execution team members be licensed medical professionals who are qualified to perform the medical tasks involved. The committee recognizes that this requirement would directly conflict with professional ethics, but believes that it is a necessary requirement in light of the high risk of performing executions by lethal injection without qualified personnel. [5,6] Some states also take this view and seek to protect medical professionals from sanctions if they participate in executions.

In light of the logistical challenges to carrying out a quick and humane execution by lethal injection, some have even suggested that we revert to older methods of capital punishment such as hanging or the electric chair. In his 2014 book, *Gruesome Spectacles: Botched Executions and America's Death Penalty*, Austin Sarat describes the many problems these earlier methods revealed. Along with gruesome case examples, he estimates that 3% of all executions in the U.S. from 1890 to 2010 were botched. [7] Knowing this history, we should not go back to other unacceptable methods of execution.

A debate about the morality and utility of capital punishment is beyond the scope of this article. At the same time, we must remember that those who were executed were convicted murderers who committed heinous crimes. The families of their victims have rightly pointed out that the victims of their crimes were hardly afforded humane or painless deaths. With regard to the protocol for McGuire's execution, State Attorney General Thomas Madden was quoted as saying, "you're not entitled to a pain-free execution." [1] As a result of a review of McGuire's execution and Ohio's protocol, U.S. District Judge Gregory L. Frost has stayed the next three scheduled Ohio executions until at least January 2015 while a protocol is developed. [2] There are currently over 3,000 inmates on death row in 32 states allowing capital punishment. In Ohio there are 138 men and one woman on death row. We will definitely hear more about pharmaceuticals and lethal injections as other executions are scheduled.

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● Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants

All those who are engaged in or interested in the practice of health care ethics consultation are invited by the American Society for Bioethics and Humanities (ASBH) to use the ASBH Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants.

The first edition of the Code was approved by the ASBH Board of Directors in January 2014. The Code grew from the work of the Advisory Committee on Ethics Standards, and was informed by the first and second editions of the ASBH *Core Competencies for Health Care Ethics Consultation*, and the Draft Canadian Model Code of Ethics for Bioethics. The Code includes statements of responsibility with interpretive paragraphs. As the practice of healthcare ethics consultation matures, the Code will likely evolve. ASBH and the members of its Clinical Ethics Consultation Affairs Committee welcome comments and feedback about the code (at www.asbh.org).

Preface

The statements in this code set out the core ethical responsibilities of individuals performing healthcare ethics consultation (HCEC). The content largely but not exclusively addresses *patient-focused* consultative activities, often referred to as clinical ethics consultation. The code does not focus explicitly on the ethical obligations entailed in the range of additional (nonconsultative) ethics services that healthcare ethics (HCE) consultants may provide for an organization.

HCEC is "a set of services provided by an individual or group in response to questions from patients, families, surrogates, healthcare professionals, or other involved parties who seek to resolve uncertainty or conflict regarding value-laden concerns that emerge in healthcare" (American Society for Bioethics and Humanities [ASBH], 2011, p.2). HCE consultants seek to identify and support the appropriate decision maker(s) and to promote ethically sound decision making by facilitating communication among key stakeholders, fostering understanding, clarifying and analyzing ethical issues, and including justifications when recommendations are provided. They address the ethical concerns of persons involved in healthcare decision making and healthcare delivery, including patients, family members, healthcare providers, institutional leaders, and those who set guidelines and create policies.

1. **Be competent.** HCE consultants should practice in a manner consistent with professional HCEC standards.

In order to acquire the knowledge, skills, and attributes to be effective, the HCE consultant needs education and experiential training. Continuing

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education and training are essential to maintain these competencies and to foster professional development. Competence also requires a commitment to subject one's work to peer review and scrutiny for quality improvement. The core competencies for performing ethics consultation are evolving. HCE consultants should meet standards that have achieved fieldwide acceptance, including those in ASBH's *Core Competencies for Healthcare Ethics Consultation* (2011).

2. **Preserve integrity.** HCE consultants should consistently act with integrity in the performance of their HCEC role.

HCE consultants should strive to be worthy of the trust placed in them by patients, family members and caregivers, healthcare staff members, and the institutional leaders who seek their help in addressing ethical questions and problems. Personal integrity involves acting in a manner that is consistent with one's core beliefs and values. Professional integrity involves commitment to the core values underlying the practice of HCEC and to the cultivation of attributes, attitudes, and behaviors that enable one to perform HCEC well, such as self-awareness, fair-mindedness, humility, and moral courage.

The statements in this code set out the core ethical responsibilities of individuals performing healthcare ethics consultation.

Consultants should strive to safeguard the process of moral deliberation in the institutions where they provide ethics consultations. They should foster learning and facilitate respectful interactions among involved parties in the ethically complex, emotionally fraught, high-stakes situations they often face. Consultants should preserve professional integrity by not engaging in activities that involve giving an ethical justification or stamp of approval to practices they believe are inconsistent with agreed-upon ethical standards. If a conflict involving the consultant's personal core beliefs or values arises in the course of performing HCEC, the consultant should recuse himself or herself from the case after securing the services of a replacement. For example, HCE consultants who have a strong moral objection to artificial reproductive technologies (ARTs) should recuse themselves in consultations involving ARTs and should not agree to provide HCEC in a setting where issues related to ARTs routinely arise. If no replacement is available, the primary obligation of the HCE consultant is to maintain professional integrity.

HCE consultants promote integrity when they are transparent about the conditions under which they perform HCEC, for example, whom they report to, who funds their HCEC work, and where the boundaries of their responsibilities lie. (See also the discussion of Responsibility #3: Manage conflicts of interest and obligation.)

3. **Manage conflicts of interest and obligation.** HCE consultants should anticipate and identify conflicts of interest and obligation and manage them appropriately.

Conflicts of interest involve situations in which the professional judgment of an HCE consultant is, or may appear to be, affected or compromised by competing interests such as personal, professional, or financial interests. For example, consultants employed by an institution may be reluctant to disagree with someone of authority and influence within that institution; they must handle competing interests of preserving their employment and competently performing consultation. Conflicts of obligation involve situations in which HCE consultants' work is or may appear to be affected or compromised by competing professional or personal responsibilities. For example, a consultant who is also a social worker or the director of an intensive care unit may experience pressure in that role to limit a patient's length of stay, which may not be in the patient's best interests. Personal and professional obligations may also be in conflict, when, for example, one has a duty to keep other work-related or personal commitments and a competing duty to complete an ethics consultation in a timely manner.

HCE consultants should minimize the likelihood that conflicts will interfere with their duties toward those who seek their advice and support through HCEC. Principal strategies include avoidance, recusal, and disclosure. An ethics consultation service with multiple consultants can, for example, assign cases with attention to avoiding conflicts. Consultants may recuse themselves from the consultation when another qualified consultant is available, or they may simply disclose the conflict. For example, some HCE consultants who are employed or paid by the facility where the ethics consultation request occurs disclose this potential conflict of interest to patients or family members at the onset of a case consultation. Consultants should make efforts to negotiate terms of service that minimize the occurrence of conflicts of interest and obligation and allow them to be managed appropriately.

In addition to their role as HCE consultants, some individuals are members of other professions and may be accountable to different codes of ethics. While engaging in ethics consultation, individuals

should adhere to the "Code of Ethics and Professional Responsibilities for Healthcare Ethics Consultants."

4. **Respect privacy and maintain confidentiality.** HCE consultants should protect private information obtained during HCEC, handling such information in accordance with standards of ethics, laws, and organizational policy.

Confidentiality is the duty to respect others' right to control access to their private information. In the consultation process, HCE consultants are entrusted with private information about patients, families, providers, and institutions. Respecting privacy and maintaining confidentiality is a high priority. HCE consultants are subject to laws, such as the Health Insurance Portability and Accountability Act in the United States, and institutional policies regarding the handling of private information.

At certain times, however, HCE consultants *should* divulge confidential information. When it is necessary to provide significant benefit (e.g. to protect life or prevent serious harms), HCE consultants may be obligated to share relevant private information with others including healthcare leaders and staff members, agents appointed in an advance directive, child or adult protective services agencies, and law enforcement personnel. Only the minimum amount of information necessary should be shared, and the information should be communicated discreetly, only to those who need to know. When appropriate, HCE consultants should prospectively communicate the limits of confidentiality protection.

Information obtained during HCEC may legitimately be used for a variety of other purposes, including those related to peer review, quality improvement, education, and scholarship. Management strategies for maintaining confidentiality vary among these purposes. For example, one may seek to maintain confidentiality by removing identifiers, using pseudonyms, or altering inconsequential information. In some situations, consent should be obtained from those whose identity may be revealed to others not involved in the consultation.

5. **Contribute to the field.** HCE consultants should participate in the advancement of HCEC.

To be a member of a profession means, in part, to foster the collective good of that profession and the constituencies it serves. Toward that end, in addition to maintaining their competence as described in Responsibility #1, HCE consultants should advance the quality and effectiveness of HCEC by supporting activities that contribute to the field: conducting and participating in research, publishing in the field, mentoring other ethics consultants, teaching others about HCEC, conducting community outreach related to HCEC, and participating in professional organizations. These contributions may be institutional, regional, national, or international in scope.

6. **Communicate responsibly.** When communicating in the public arena (including social media), HCE consultants should clarify whether they are acting in their HCEC role and should communicate in a manner consistent with the norms and obligations of the profession.

Communicating responsibly obliges HCE consultants to be sufficiently informed about issues on which they communicate publicly, including facts and scholarship relating to the specific topic. If HCE consultants do not have sufficient knowledge in a particular area, they should decline to comment and consider referring the task of communication to others. Public comments should acknowledge uncertainty about norms and lack of consensus where they exist. Consultants should recognize that the topics upon which they are asked to comment can generate strong reactions. Communicating responsibly should promote reflection in others and offer an opportunity to consider different points of view. HCE consultants should demonstrate cultural humility and sensitivity to differing values when communicating about HCEC-related issues in the public area.

7. **Promote just health care within HCEC.** HCE consultants should work with other healthcare professionals to reduce disparities, discrimination, and inequities when providing consultations.

When engaged in ethics consultation, consultants need to be attentive to the role that healthcare disparities, discrimination, and inequities play. Consultants should ensure that all stakeholders have access to the HCEC process and that the process is fair. Issues of power, privilege, and organizational culture may make the process of ethics consultation more challenging and may complicate efforts to promote just and equitable recommendations and outcomes. Consultants have a responsibility to identify and include relevant voices in the discourse, particularly marginalized voices. Recommendations of the consultation should not reinforce injustice. When possible, consultants should identify systemic issues constraining fair outcomes in HCEC and bring these issues to the attention of individuals or groups in a position to address them.

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American Society for Bioethics and Humanities. (2011). *Core Competencies for Healthcare Ethics Consultation* (2nd Ed.). Glenview, IL.

Medical Humanities: Origins, Developments, and Recommendations

Martin Kohn, PhD *is director of the Program in Medical Humanities in the Center for Ethics, Humanities and Spiritual Care, Cleveland Clinic, and Associate Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. He co-founded Hiram College's Center for Literature and Medicine with Carol Donley, PhD, and together they served as founding editors of the Literature and Medicine series at Kent State University Press.*

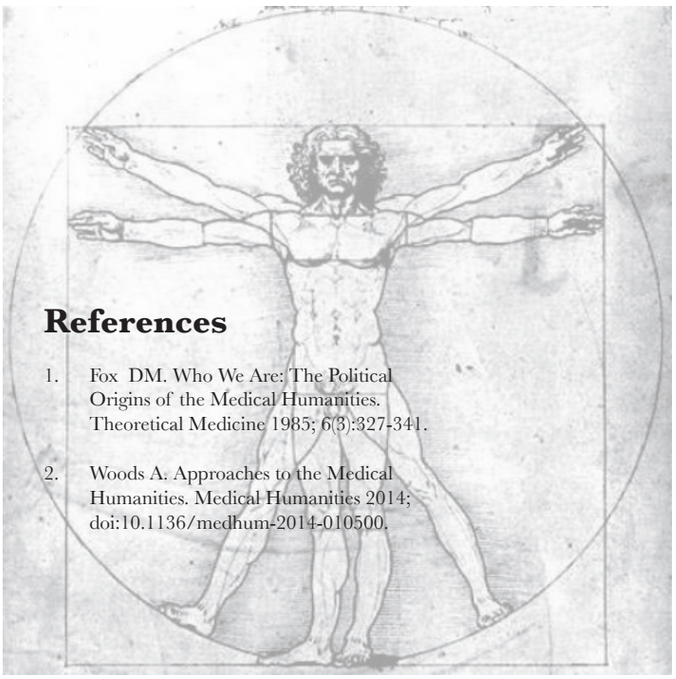
Contemporary medical humanities traces its origins to the year 1960 when troubled medical students, concerned about the effect of medicine's powerful tools on the patients for whom they were caring, turned to the one group of care-givers they thought would understand them and the issues they were facing: Ministers in Medical Education [1]. By the end of that decade, medical humanities (as well as bioethics) was, if not in full bloom, on its way to becoming a recognizable part of the healthcare landscape and health-professions education. With new streams of work in "arts and medicine," with narrative medicine springing forth during the past 25-30 years, and with growing interest in critical studies more recently (e.g., disability, feminist, queer), we are probably nearing flood stage. Perhaps we should not be surprised that the author of a recent book review noted that those in our field have an indefatigable desire to engage in exploration of the identity, purpose and value of our work [2]. Nor should we be surprised that the sign above the entrance to the big tent of our work is also a source of contention: Will the old guard (*medical humanities* "exclusionists") win out over the upstarts (*health humanities* "inclusionists")? Stay tuned.

To give you a flavor of the breadth and depth of some of the important critcical pedagogical work being produced in our field, I briefly annotate three articles worth reading:

Kumagai AK, Wear D. "Making Strange": A Role for the Humanities in Medical Education. Academic Medicine 2014; 89(7):973-977. The authors make a strong case that the humanities and arts are effective tools for the necessary work of disruption of embedded assumptions. The "making strange" of that which is too often automatically accepted can lead to new ways of seeing oneself, acting in, and facing the challenges of the world.

Boudreau JD, Fuks A. The Humanities in Medical Education: Ways of Knowing, Doing and Being. The Journal of Medical Humanities 2014; DOI 10.1007/s10912-014-9285-5. Reaching back to Aristotelian concepts, these authors speak to the formation of the professional identity of the physician, arguing for a combination of *techne* (doing) and *phronesis* (being). The humanities and social sciences have a role in developing character in addition to their instrumental value.

Metzl J, Hansen H. Structural Competency: Theorizing a New Medical Engagement with Stigma and Inequality. Social Science and Medicine 2014; 103:76-83. Stigma and inequalities exist and must be addressed not just on an individual or cultural level, but at their structural roots. Built into this manifesto for curricular reformation, however, is the cautionary note (as has happened in regard to critiques of narrative and cultural competencies) for structural humility as well. One may begin to understand the complexity of structural influences on health, but it is, the authors note, just a beginning point. The conversation must continue.



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● Book Review

Margot M. Eves, JD, MA, *is the Director of the Regional Clinical Bioethics Program (West) for the Cleveland Clinic Health System. She is a graduate of the Cleveland Fellowship in Advanced Bioethics (2009, inaugural class). Prior to pursuing a career in Bioethics, she served as a patient advocate and an Administrator-on-Call at New York-Presbyterian Hospital. She earned her Juris Doctor (Health Law and Policy concentration) from Seton Hall Law School. She has served on the BENO Board of Trustees since 2012.*

James J. Rusthoven, **Covenantal Biomedical Ethics for Contemporary Medicine: An Alternative to Principles-Based Ethics**, Pickwick Publications, 2014. ISBN 13:978-1-62564-002-4. 278 pp.

> *A biblical covenantal ethic is supportive of intercommunity interactions…. [A] community truthful to itself and its moral authority will carefully reflect on the moral worthiness of their own beliefs when confronted with persuasive moral challenges from other communities. Implementing such a communicative ethic in medicine would likely enrich practice engagement, drawing on the insights and wisdom of various faith traditions toward policies that might better serve humankind.*

In **Covenantal Biomedical Ethics for Contemporary Medicine**, Dr. Rusthoven provides a substantively dense and considered argument for adopting a biblical covenantal ethic based in the tradition of Reform Christianity as a moral foundation for contemporary bioethical analysis. An appeal toward the pluralistic nature of modern society can be found both in the Introduction as well as in the back-cover book summary, with an acknowledgment that appreciation of covenantal commitment extends beyond the boundaries of Christianity into Judaism, Islam, and some pagan traditions. Thoughtful, thought-provoking and well-researched, this book is best-suited for advanced bioethics students and scholars, especially those with more secular academic backgrounds and viewpoints.

The book is divided into two parts. Part One is entitled *The Rise and Dominance of Principles-Based Biomedical Ethics*. This section accounts for just under half of the book, with a third of these pages describing historical context, including the U.S. Presidential administration's charge that led to the Belmont Report (1979), and a discussion of history that rests moral authority in theology. This section is informative but could also be frustrating for readers lacking knowledge of theological history (like this reviewer). Additional footnotes could have decreased this frustration and added significant depth to the reader's contextual understanding without adding unnecessary length.

> ***...appreciation of covenantal commitment extends beyond the boundaries of Christianity into Judaism, Islam, and some pagan traditions.***

The remainder of the first part of the book discusses why the "secularization of bioethics" led to the dominance of a framework for ethical analysis devoid of substantive moral theory. Rusthoven argues that Principilism, or the focus on the four principles of autonomy, beneficence, non-maleficence, and justice (Beauchamp's and Childress's model) provides little guidance on how to resolve conflicting principles. He supports this argument by comprehensive summaries of preeminent Bioethicists' criticisms along with his analyses of approaches proposed by those bioethicists.

The final chapter in Part One purports to describe representative perspectives about the Principles framework from diverse religious traditions. Roman Catholic, Eastern Orthodox, and Protestant perspectives (as represented by respected bioethicists Edmund Pellegrino, H. Tristram Engelhardt, and Paul Ramsey) are discussed and critiqued with impressive depth. Judaism and Islam receive only slightly more than three pages of this 30-page chapter, without any recognition of divergent viewpoints within these religious traditions (e.g., differing positions among Orthodox, Conservative and Reform Judaism; or Sunni and Shiite Muslims). The substantive paucity of discussion of non-Christian faith perspectives undermines the apparent respectful intent of their inclusion.

Part Two of this book is entitled *A Modest Proposal for a Biblical Covenantal Biomedical Ethic*. Rusthoven commits great energy and text to establishing the interfaith religious applicability of a biblical covenant as primarily a relational ethic, based on a foundational covenant with God that is affirmed by the three dominant world religions. The respect for and openness to differing moral beliefs and diversity of faith communities are clear under Rusthoven's conceptualization of a biblical covenantal ethic. He embraces the covenant framework, stating that

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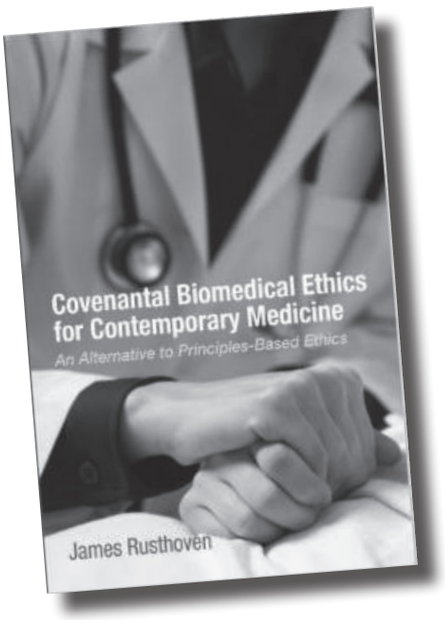
Book Review *continued...*



it "reacquaints us with a language of duty suppressed in a culture obsessed with a language of rights."

Rusthovan's *modest proposal* rejects a legal concept of covenant on the basis that a legal covenant reduces the significance of relationships to that of a contract. Here he is not entirely incorrect because legal recourse for breaking a covenant may be similar to that of a contract. However, unlike a contract, a legal covenant may lack consideration and still be enforceable (or the "bargained for" aspect of the agreement without which a contract is legally unenforceable). At its core, a legal covenant is essentially a promise to do or refrain from doing something, i.e., an acceptance of duties or obligations. Rusthovan also rejects as inadequate a relational covenant of trust. However, it is unclear why these two conceptual applications of covenants are insufficient and that a biblical covenantal ethic secures a patient care approach that is either superior to or unavailable through other ethical frameworks.

In a very important chapter, Rusthovan links the biblical covenantal ethic to the current practice of medicine. As a relational ethic, the application focuses on caregiver-patient relationships and relationships within the team of healthcare professionals. Rusthoven argues that by embracing the characteristics of God's covenant with humans, such as a steadfast and reconciling love, each person can better engage in the relationships necessary for clinical practice. Under the framework of this biblical covenantal ethic, health care professionals and patients will facilitate respectful, clear communication.

The final chapter returns to the four principles (autonomy, beneficence, non-maleficence and justice) to illustrate how the biblical covenantal ethic addresses the foundational considerations that gave rise to the popularity of the Principles framework. For example, respect for persons softens the individualistic and sometimes selfish stance of rights-based autonomy, focusing on the individual in relationship to a community, society, the world and God. Concepts of justice are folded into this application of the ethic.

For many, adoption of a biblical covenantal ethic for bioethics grounds a commitment to open, thoughtful and respectful communication and approaches to moral dilemmas in duties arising from a Christian's covenant with God. In grounding duties in this manner, this framework may create a place of moral safety and understanding of one's own moral foundation for respectfully inquiring about another's moral beliefs and values. However, this approach faces the same challenges as other approaches in a pluralistic society: when intractable values-conflicts occur, these frameworks fail to provide guidance on how to determine which ones should prevail.

Dr. Rusthoven's proposal for a biblical covenantal ethic is not particularly offensive nor is it particularly persuasive. It contributes another perspective for considering complex ethical issues, whether theoretically or in a clinical setting, to promote robust, nuanced ethical analyses. Bioethicists and scholars who lack this content background can benefit from this different viewpoint, and with a little reflection will appreciate the heightened awareness of biases inherent in all humans, whether religious, societal, or a consequence of academic discipline.

● Moral Distress Resource

The Moral Distress Education Project

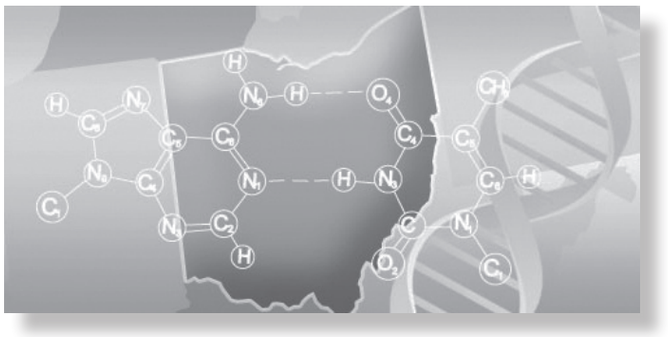
(www.moraldistressproject.org) is a multimedia resource on moral distress produced by the University of Kentucky, in partnership with East Carolina University. This resource is a self-guided documentary on moral distress in which experts on moral distress were interviewed and filmed at the March 2013 "Ethics of Caring" conference in Los Angeles.

To see the Project Promo, visit the YouTube link: www.youtube/QdPmloh4XMk

For the project website, go to: http.www.moraldistressproject.org or http://www.cecentral.com/moraldistress

To View the list of Expert Interviewees: www.cecentral.com/node/1113

Questions and comments can be addressed to: M. Sara Rosenthal, Ph.D, Professor and Director, Program for Bioethics, Departments of Internal Medicine, Pediatrics and Behavioral Science, Chair, Hospital Ethics Committee. 859-257-9474. Email: m.sararosenthal@uky.edu



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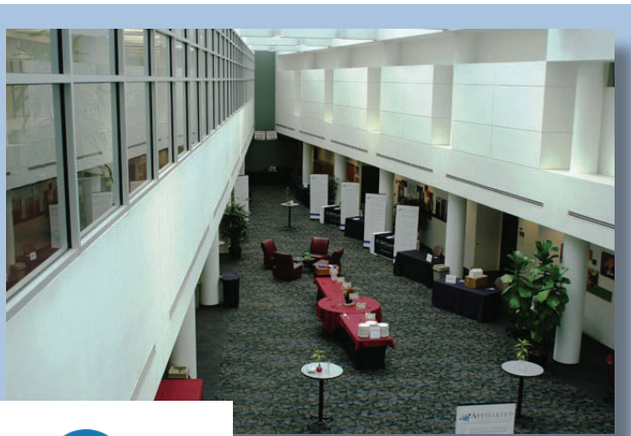

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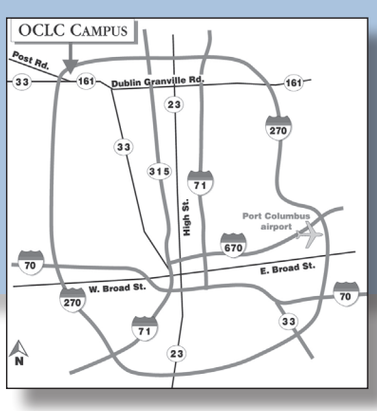

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