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IN THIS ISSUE

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P4P and physician judgment: Is there an ethical conflict?

Opinions differ throughout health care community

Just as in certain consumer-driven businesses, the mantra was always "the customer is always right," in health care, the mantra — at least the one attributed to physician attitudes and principles — historically has been "the patients' needs come first."

But the issue of reimbursement complicates many life situations, and so it does with health care. Unless all patients in the United States had all the means at their disposal to pay for all of their health care needs, payment models would seem destined to create thorny issues associated with the provision of health care services and care.

While fee-for-service has in recent years been the standard model for physician payments, a newer payment model, pay-for-performance, is slowly but surely gaining ground. With pay-for-performance, the stated goal is to improve the quality of patient care in this country.

The implementation of this concept comes when physicians are rewarded with payments for providing quality care based on certain quality measures, which have been determined based on evidence of their effectiveness.

Last December, a position paper authored by physicians with the American College of Physicians (ACP) in Philadelphia, and developed by the ACP's Ethics, Professionalism and Human Rights Committee, raised questions about the potential conflict of interest between pay-for-performance principles and physician decision-making. That paper was titled "Pay-for-Performance Principles That Promote Patient-Centered Care: An Ethics Manifesto."[1]

"The major issues with pay-for-performance is that there is a conflict of interest between the interests of the payers, physicians and patients," **Frederick E. Turton**, MD, MBA, FACP, chair-elect, Board of Regents, American College of Physicians, and former chair of the ACP Ethics, Professionalism and Human Rights Committee, tells *Medical Ethics Advisor*. "Payers want to pay as little as they can for health care; patients want to get as much health care as possible; and

the physician is somewhere in between."

Turton continues, saying, "[The physician] wants to take care of his patients well. He's not concerned about how much money the payer makes, or the payer retains; he or she is stuck here in the middle trying to balance this conflict between payer and patient. And what that does is stress his professionalism. If incentives aren't aligned perfectly, what keeps the physician doing the right things is professionalism."

The paper suggests that the pay-for-performance model has "potential unintended consequences for the patient-physician relationship." The organization, in the paper, expressed concern "that the design of pay-for-performance systems will lead to worse care despite measurements that imply good care."

Also, the paper suggests that "pay-for-performance initiatives that provide incentives for good performance on a few specific elements of a single disease or condition, may lead to neglect of other, potentially more important elements of care for that condition or a comorbid condition."

In such a scenario, the papers suggests that elderly patients, who tend to have more than one chronic condition, would be "especially vulnerable."

Physicians also argue that quality measures in certain programs, such as the Centers for Medicare & Medicaid's effort to initiate pay-for-performance measures through its Physicians Quality Reporting Initiative (PQRI), first implemented in 2007, do not keep an individual patient's care in mind.

"Physicians have a professional duty to provide high-quality care to each patient," the manifesto states. "Pay-for-performance and other programs that create strong incentives for high-quality care set up a potential conflict between this duty and the competing interest of trying to comply with a performance measure — whether the measure is a priority for the patient or not."

Potential pitfalls

Specifically, the ACP manifesto states that it is concerned with the following "potential ethical pitfalls and unintended consequences":

— **deselecting difficult patients**, i.e., because patients with more than one chronic condition could cause scores, and therefore a physician's income, to decrease, physicians might be tempted to tell certain patients to go to another doctor.

— **"playing to the measure"** or "gaming the system" rather than focusing on the patient, i.e., the concern that physicians may emphasize getting goods scores on specific performance measures and not on care — which the patient also may need — that is not measured.

— **misalignment of perceptions between patients and physicians**, i.e., the concern that patients may come to believe that their physician is not acting in their interests, but rather the physician's own interests.

— **increase in unnecessary care and medical cost**, i.e., categorizing certain patients, for example diabetic patients, along with the assumption that such patients all require the same level of

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care, "could encourage unnecessary care."

Other views of P4P programs

Robert Haralson III, MD, MBA, medical director of the American Academy of Orthopaedic Surgeons, in Rosemont, IL, tells *MEA* that he does not believe that there is an ethical conflict between pay-for-performance principles and the ability of a physician to conduct himself or herself based on ethical principles. Haralson also serves on the American Medical Association's Physicians Consortium for Performance Improvement (PCPI) and is the chair of the Health Professionals Council of the National Quality Forum (NQF).

"I think the quality initiative is the best thing that's happened to medicine in the last 50 years, and I'm a little embarrassed that we have had to be dragged into this kicking and screaming with money as the thing that entices us to do it, because I've been saying all along that we should be evaluating what we're doing to our patients."

Haralson says that "…I think that beginning to look at what we're doing in our practices is really a great thing for humanity and will make the quality of medicine much better. And frankly, [it will] make us as physicians must happier, because I think most of us really want to provide quality medicine."

He suggests that most performance measures under the pay-for-performance model encourage physicians to provide more health care — not less.

While there are several pay-for-performance measures in orthopedics, he says, one in particular illustrates how measuring care can lead to cost savings while still providing quality care. That example is the requirement that orthopedic surgeons select "second-generation cephalosporin, which means that you selected an antibiotic that was not so expensive, but that the literature shows is good enough to be a prophylactic antibiotic."

Also, pay-for-performance measures call for surgeons to stop the antibiotic after 24 hours, because, again, data show that it is one, not necessary, and more expensive for the care of that patient to continue it.

Christine K. Cassel, MD, MACP, president of the American Board of Internal Medicine (ABIM), an independent certifying organization for internists and various subspecialities in Philadelphia, says the ABIM is meant to be "really independent and in the public interest." Therefore, it does not have "explicit policies about medical payment or reimbursement or financing policies."

"That's not our arena," Cassel says. "Our arena, though, is quality of care, so in order for physicians to be board-certified, they have to meet certain standards in how they stay up-to-date with medical knowledge. And they have to submit to us data about how they deal with certain kinds of patients — clinical performance data."

So, where the ABIM interacts with pay-for-performance is that the ABIM, when it receives data from physicians for certification purposes, the organization in turn transmits that data to insurance companies or purchaser programs like Bridges to Excellence, which have pay-for-performance requirements.

The ABIM does this, Cassel says, "really just in the spirit of reducing the redundancy of all this measurement burden."

"So, I don't have an opinion about it one way or the other, but as a person who studies the evidence, I can say . . . there's no evidence to date that it has improved quality of care," Cassel tells *MEA*.

"And I think a lot of people are thinking that in and by itself, [pay-for-performance] is inadequate to get us to where we need to be as a nation in terms of improving quality of care, but it's a tool among many that are being used," she adds.

In fact, a study published in *Health Affairs* earlier this year,[2] of pay-for-performance on the state of Massachusetts health system, stated in its abstract that "Overall, P4P contracts were not associated with greater improvement in quality compared to a rising secular trend."

"Future research is required to determine

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whether changes to the magnitude, structure, or alignment of P4P incentives can lead to improved quality," the study states.

According to the ACP's Turton, "incentives are everything" and "the key" is to have incentives that are aligned between physician, the patient, and the payer. Toward that end, the group's ethics manifesto suggests that the "best way to avoid pitfalls is to acknowledge their potential to induce unwanted behavior and develop systems that ensure accountability for professional behavior…"

The three steps it suggests are the following:

— **ensure transparency**, i.e., make sure patient are aware not only about those incentives underw which the physician may be operating, but also how their physician performs on all quality measures;

— **measure what is important to patients**;

— **monitor unwanted behavior and intervene.**

Crisis of public confidence possible

The conclusion of the ACP's position paper suggests that "pay-for-performance and other strong incentives can increase the quality of care if they purposely promote the ethical obligation of the physician to deliver the best-quality care to her or his patient."

However, the paper also suggests that current evidence doesn't place "sufficient emphasis on protecting the interests of patients," and therefore the payment models could unleash a "crisis of public confidence" in the provision of health care.[1]

Cassel also highlighted the skills that an individual physician brings to each patient.

"One of the things that doctors do that is very underappreciated is they make a diagnosis," she says. "The patient doesn't come in with diabetes on their forehead. They come in saying, 'I'm tired and run down — you know, I'm losing weight. And then the doctor has to figure out what's wrong with them.

"There's no quality measure that evaluates that," Cassel says.

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Bridges to Excellence CEO responds to P4P and ethics

De Brantes says P4P is a 'misnomer'

Bridges to Excellence (BTE) CEO **Francois de Brantes** doesn't mince words when asked if he thinks there is an ethical conflict between the payment model of pay-for-performance — essentially giving physicians additional payments for good performance based on certain quality measures — and ethical decision-making by physicians.

de Brantes heads a not-for-profit organization, started in 2002, that utilizes the pay-for-performance model. Its members include physicians, health plans, quality experts, consultants and large U.S. employers, with its charter members including General Electric, IBM, UPS and Procter & Gamble. The BTE literature suggests that by meeting performance measures, its physicians "could see income gains of up to 10% in the form of annual bonuses paid by participating employers and health plans."

"First of all, just from my perspective and context, I really dislike the term 'pay-for-performance,'" de Brantes tells *Medical Ethics Advisor*. "And the reason why I dislike the term pay-for-performance is that it's actually a misnomer. Payment is always for performance. The question is: performance of what?"

In today's health care payment environment, he says, about 80% of payment is for transactions, which means that physicians are incented to complete more transactions, i.e., their "performance is based on the volume of transactions that [they] bill."

With capitated fees, which comprises the remaining 20% of physician visits, the incentive with the capitation model is to remain within a set budget, or, de Brantes says, "the performance that's motivated is lack of volume, or fixed volume."

"Fee-for-service motivates lots of volume, or I think, there is irrefutable evidence that there's massive amounts of excess volume, which is being delivered in the country. Is that good for patients?" he asks. "I mean, that's an ethical question, right? . . . no one, unfortunately, bothers asking the question, but does fee-for-service inherently encourage providers — physicians and other clinicians — to do things

that would otherwise go against their professional behavior?"

de Brantes contends that there are numerous examples — from over-prescribing antibiotics just because a patient asks for one — to infections that occur in hospitals when they shouldn't that result in additional costs for insurance companies.

In other words, de Brantes contends that none of the existing payment models are ethical, because behavior is always being incented toward a desired end.

"I think it's a fool's dream to think otherwise," de Brantes says. "So, once you [view] that as the context, now you have to think about, ultimately, how do you craft payment incentives that are going to — more optimally — reward the right type of behavior?"

To correct what he thinks is the misnomer of pay-for-performance, de Brantes, instead, focuses on what he calls "payment for results."

de Brantes suggests that rewards for results are not the same as rewards for financial results. Instead, payment for results emphasizes "measurable results of the effect of all these services that have been delivered by the clinician to the patient."

"So, at that point, the question becomes, is that better or worse than what we have today? And how is it different, and what kind of behaviors might it encourage? And is there a way to mitigate for those negative behaviors?" he asks.

de Brantes says one of the typical arguments from physicians who are considering entering into pay-for-performance models is that, by being held to evidence-based medicine, he or she will not be able to deliver care that addresses each patients unique needs, because his or her professional judgment is now held hostage to what evidence-based medicine would indicate for care. But being guided by evidence vs. "guesswork" in the delivery of care is a good idea.

de Brantes does agree with the critics of pay-for-performance that when physicians' results are measured for a particular condition as a group, those patients with multiple conditions may affect the results for a particular condition.

But his answer is simple: "You don't count certain patients. You exclude them from the measurement scheme."

That's because, unlike what many physicians assume, the pay-for-performance model doesn't measure in absolutes, he says.

SOURCE

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"What you're looking for is — are the majority of patients being controlled adequately," he says.

Another common argument that he says physicians present against pay-for-performance, that because they will be judged based on their patients' outcomes, they may be encouraged to stop seeing non-compliant patients who are less likely to do well.

Again, de Brantes says, "no one" that he knows who endorses pay-for-performance judges physicians by their measures of outcomes in absolutes.

He also suggests there are more allowances being considered for socioeconomic factors in recognition that some patients from various socioeconomic backgrounds are going to have more difficulty complying with their doctor's directives.

de Brantes suggests that in those instances, if a physician is having difficulty communicating with a patient, the patient may be better served by going to a different physician.

The unethical behavior, in such an instance, occurs when a physician will not admit that he or she is having difficulty with a patient and continues treating that patient with, perhaps, poor results.

"The ethical thing is to look squarely in the face of the facts and understand and recognize that there are some patients in the practice with whom you're having a tough time," he says. "That's the ethical conduct." ■

P4P at work with CMS 'never' events policy

Policy relates to organizational ethics

In addition to physician ethics, the pay-for-performance concept also has been instituted by the Centers for Medicare & Medicaid (CMS)

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related to its statement that its policy will be to no longer pay for any on a list of so-called "never" events that occur at hospitals. The policy became effective Oct. 1.

CMS is suggesting that if a never event does occur, the hospital will not be compensated, which is one method of implementing pay-for-performance policy within the hospital settings, relying on organizational ethics as a backdrop.

"The reason, in my view, that the policy falls under an ethical umbrella is that patients legitimately have certain expectations — when they are admitted to a hospital or treated as an outpatient — that they will receive effective, efficient, timely, patient-centered care that is safe," says **Paul B. Hofmann**, DrPH, president of Hofmann Healthcare Group in Moraga, CA.

Hofmann is an editorial advisory board member of *Medical Ethics Advisor*.

"That is a reasonable expectation of patients, that they will become the beneficiaries — not the victims — of care provided by a hospital," Hofmann explains.

As a result of the new CMS policy implementation, Hofmann believes this new incentive, which he calls a "very significant economic sanction," will improve patient care from an organizational perspective — not just in the physician-patient relationship, around which P4P is often discussed. And he believes it will go a long way in achieving its desired result, i.e., to improve quality of care within these facilities.

"I think [hospitals] are incentived as a result of the CMS policy to accelerate their efforts to prevent clinical errors, and that is an ongoing, existing commitment that hospitals have . . . because clearly there is going to be a higher economic cost if they are not consistently successful in reducing the number of preventable adverse events," Hofmann says.

Nancy Berlinger, PhD, Mdiv, deputy director and research associate, The Hastings Center, Garrison, NY, says that CMS is simply "using reimbursement mechanisms to make systems safer." Berlinger also is a member of the editorial advisory board of *MEA*.

Through its no-payment policy for never events, CMS is "taking the idea of, "Do no harm,' — the absolute standard of 'Do no harm' – and you are writing it into policy in a way that isn't just aspirational, but it has real teeth," she says.

Berlinger suggests real teeth because regardless of whether there is a risk management or malpractice litigation issue associated with a never event, as there often is, the CMS bill is going to come back "denied."

"Sometimes, you can talk about 'do the right thing' or 'don't do the wrong thing' and have check lists and such, but sometimes the way you get the [attention of] business — because healthcare is a business — well, here's the business ethics case," she says. "You want to keep the ship afloat? You want to say 'no margin, no mission'" This is going to hurt you in your margin, because hospitals operate on a 2% profit margin."

While the new policy is punitive, it may be that it was a measure of last resort to improve quality and reduce adverse events in the hospital setting, as other approaches, from ethics to the call of improving quality to professional obligation had been tried as positive incentives. Yet adverse events continued to occur.

"Some people say, 'This is something the bean counters can understand.' But really, in some hospitals it could be that that's how maybe you get their attention, " Berlinger says. "It doesn't mean they're bad people, it may just be that that is the way they see the world."

Unintended consequences?

While the policy is intended so that hospitals responsible for adverse events will not add insult to injury to a patient who was the victim of an adverse event, there may be unintended consequences of the policy for other patients at large, Hofmann says.

"What the general public probably doesn't recognize is the cost that the hospital can no longer bill to Medicare and to a number of other payers that have adopted similar — and in some cases even more extensive — sanctions, will inevitably be passed on to other patients," he says.

So, the cost of adverse events will be transferred, he says, "to either self-paying patients or patients with insurance."

Still, he says, every hospital, when an adverse

event occurs, "has an obligation to reduce the burden" to that patient.

When such events do occur, the hospital has an "ethical responsibility" not only to disclose that a mistake has been made and to apologize, but also to inform the patient and his or her family "what steps are being taken to prevent similar occurrences, and when appropriate, offer compensation to the patient or the patient's family when a significant event has occurred."

Again, however, Hofmann suggests that such sanctions are likely to produce positive results related to quality of care.

"Both organizations and individuals respond to incentives, and that's the nature of both organizational culture and individual attitudes and behavior," he says. ■

Core competencies for ethics consultations

The goal is to have all voices heard

Decision making in health care ethics consultation cases often involves difficult, complex issues and mediating differences of opinion.

So, too, does deciding the standards for those who perform ethics consultation, as well as how an ethics consultation should be completed, including questions such as who has access, how to document, and what constitutes a "good" ethics consultation.

Those are among the questions being considered in the process initially begun as an effort to update the Core Competencies for ethics consultants from the American Society for Bioethics and Humanities (ASBH) in Glenview, IL.

Anita J. Tarzian, PhD, RN, an ethics and research consultant in Baltimore, with affiliations with both the University of Maryland School of Law and the University of Maryland School of Nursing, is heading the ASBH task force on this effort, which began two years ago, when, as secretary of the organization, she noted that the document outlining the Core Competencies was completed in 1998. Thinking that much has changed in the field, she decided — "naively," she now jokes — that an update was necessary.

"In that document, the '98 version, the task force took a stand on endorsing a model for ethics consultation – what they call not a pure facilitation model, but the facilitation model — that was the role of the ethics consultant," she says.

In other words, it was not the role of the ethics team to tell the patient or family or clinicians what the right answer was, but "to just get all the stakeholders together and to make sure that all voices are heard, and to facilitate that fact-finding and coming to some conclusions about what would be an ethically justifiable action to take."

But, with that model, "there's been some controversy over that," and, Tarzian says, as well as "some misinterpretation."

It's due to the variety of opinions expressed that the initiative to update the Core Competencies is behind schedule. But being behind schedule is not necessarily a bad thing in this case.

"It would be important to have the right process, and you would come to some consensus in the field in order to not be guilty of what we're saying you shouldn't do in an ethics consult and say, 'We're going to say this is the right way,' and not listen to alternative views," Tarzian says.

It was her expectation at the outset of this process that the task force could complete a comprehensive document to include not only the core competencies for individual consultants, but also to the standards for an ethics committee.

That probably isn't going to happen this time.

"I'm starting to realize that — again, anything in the field of bioethics . . . by definition involves lots of different opinions," she says.

Ellen Fox, MD, chief ethics in health care officer, Department of Veterans Affairs National Center for Ethics in Health Care in Washington, DC, who also serves on the task force, agreed that this document may not be as comprehensive as task force members originally had hoped.

"It remains to be seen exactly where the final draft will end up, but I don't think that this particular effort will solve the problem of a lack of standards for how to do ethics consultation," Fox says.

Fox contends that the problem with ethics consultation in the United States is a "lack of standards."

"For almost everything we do in a health care organization, we have specific quality standards for how those things are done," Fox says. "And in the area of ethics consultation, there's no clearly recognized national standards for how to do ethics consultation.

"The closest thing" to a set of guidelines and standards is the ASBH's 1998 document, she says.

SOURCES

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Fox et al. completed a study published in *The American Journal of Bioethics* in 2007 that found that there was wide variability in ethics consultation services.[1]

"Well, there was a complete lack of knowledge about what was going on in U.S. hospitals with regard to ethics consultation, so . . . the purpose of the study was to help fill that gap," Fox says.

Debate centers around models

Tarzian indicates that the debate centers around how the facilitation model is described in the original core competencies document, and how it is interpreted.

She provides an example of the complexities involved: what if an individual completed a living will that indicated they did not want to be kept alive under certain circumstances, and that will was questioned, with others saying, perhaps, that the individual still could be kept alive by a ventilator, despite the fact this would be counter to what that individual declared in a living will.

Some would say that an ethics consultant or ethics committee "shouldn't facilitate a resolution that runs counter to that standard."

"There are some people who think facilitation is sort of a way of saying you're completely neutral, and that you're going in, and you're just sort of facilitating communication and not providing input — and not drawing a line and saying, 'Actually, that's not an acceptable outcome or response."

Others "really denounce this whole recommendation model," or the model of the professional ethicist, who has specific training in ethics study or a degree in philosophy, or closely relate discipline, who may be a consultant or on staff as an ethicist at an institution, unlike many who are clinicians who serve voluntarily on ethics committees within their institutions.

"That comes from the sort of paternalistic history of people that got involved in ethics being [in] the 'I'll tell you what the right answer is' mode," Tarzian says. "It was in the physician model, with physicians not wanting to be told what to do, and there was this sense of 'We know what the right answer is, and we're going to enlighten people.'"

Another debate taking place centers around some people who feel that there is no one right way to do ethics consultation, and one model will not fit the bill for every hospital.

For example, the VA system has standardized its approach systemwide to ethics consultation for all its facilities across the country.

And Fox says the VA has seen "tremendous interest" in those standards from many health care organizations.

While there's still no consensus, many agree that the role of ethics committees will continue to evolve. And there's been a great deal of attention "drawn to the fact, for example, that the field doesn't have a credentialing process."

Such a credentialing process may be yet to come.

In the meantime, Fox says, "I think in the natural evolution of a field, there's progress toward increased specificity in terms of standards, and I think we're on the cusp of seeing a standardized approach — not just by individual health care institutions, but across the field nationally and internationally." ■

Eli Lilly, Merck to disclose payments to physicians

Legislation would create payments registry

(*Editor's note: Look for continuing coverage of the Sunshine Act in future issues of* Medical Ethics Advisor.)

More and more questionable ties between physicians and drug companies are being uncovered in an investigation into such financial relationships conducted by Sen. Charles Grassley (R-IA).

As those come to light, legislation called the Physicians Payment Sunshine Act has been proposed by Grassley, along with Sen. **Herbert Kohl**

(D-WI). It was introduced in September 2007.

That legislation would create a national registry of payments to physicians by not only biopharmaceutical companies, but also medical device and medical supply companies.

In advance of passage of this legislation, two major drug companies, Eli Lilly & Co. and Merck, reported recently that they would disclose certain payments that they make to physicians.

Lilly says in a news release that it was the "first pharmaceutical company to endorse" the bipartisan, so-called Sunshine Act.

At a speech in late September before the Economic Club of Indiana, Lilly president and CEO, John Lechleiter, PhD, set forth the company's intention to launch an online registry of physician payments in 2009. In outlining the plan, Lechleiter said, that the company has ". . . learned that letting people see for themselves what we're doing is the best way to build trust."

Under the plan, an Internet database listing Lilly's payments to physicians will be made available to the public. The company expects to launch the registry "as early as the second half of 2009," it said.

Initially, the contents of the database will include 2009 payments to physicians who serve as speakers and advisors to the company. But Lilly says it expects that by 2011, the reporting capabilities of the database will "resemble the Sunshine Act legislation."

"Eli Lilly is leading the charge for transparency in the relationship between pharmaceutical companies and doctors by fulfilling the obligations of the Physician Payments Sunshine Act before it has been enacted," said Kohl, in a Lilly news release. "It takes a lot of courage to be the first. They have made a principled decision that I believe will benefit both their business and the consumers of their products."

Lilly also says that in 2004, the company marked another "first" by voluntarily making public its clinical trials and its clinical trials data. In 2007, Lilly says it also became the first to publicly report all of its educational grants and charitable contributions, which the company posts quarterly on a specific web site.

Merck, too, has endorsed the pending Sunshine Act, which will require disclosure of financial relationships with physicians.

"Even in the absence of a legislation requirement, however, we are committed to begin disclosure in 2009 of payments to physicians who speak on behalf of our company or our products," Merck says in a news release.

However, it maintains that "the engagement of the physician community with industry is in the best interests of patients and promotes information sharing and education about the newest medicines and treatments and patient experience."

Physician response to the Act

The American Medical Association in Chicago, as well as 20 other physician membership organizations, in June signed and sent a letter in support of the Physician Payments Sunshine Act — "as revised" — to both Sens. Grassley and Kohl.

"We believe that the Physician Payments Sunshine Act would establish a framework that allows patients, researchers, physicians, and others to obtain accurate and complete information on the nature of interactions between industry and physicians," the letter states. It notes that the legislation, as revised, will not only establish national reporting standards, but it also will allow "the opportunity for physicians to correct erroneous, false, or otherwise misleading information — so patients and others can reasonably rely on the quality of the reporting in the proposed public database." ■

Court order raises ethical questions about research

Treatment INDs should be balanced decision

When a judge recently ordered a pharmaceutical company to provide an investigational drug to a teenage boy who had not met the enrollment criteria for a phase II trial, the IRB world took note.

The case raised ethical questions about the court's involvement in research, as well as about how the sponsor, investigators, and IRB handled subject recruitment.

Judge William J. Martini of the United States District Court in Newark ruled on Aug. 20, 2008, that 16-year-old Jacob Gunvalson of Gonvick, MN, should be allowed to receive an experimental drug called PTC124 even though the teenager does not meet the criteria for clinical trial eligibility, according to published reports.[1]

PTC124 is being studied by PTC Therapeutics of South Plainfield, NJ, a small pharmaceutical company that has been enrolling subjects in phase IIa trials to study the drug's potential as a therapeutic agent for patients with Duchenne muscular dystrophy.

PTC Therapeutics will appeal the court's decision, says **Stuart Peltz**, president and chief executive officer, in a statement issued Aug. 20, 2008.

"The issue here is that a judge can't order a pharmaceutical company to supply a drug to an individual without the FDA's approval, and because the drug is available only under an IND [investigational new drug], IRB approval is also required," says **Mark S. Schreiner**, MD, an associate professor of anesthesia in pediatrics at the University of Pennsylvania. Schreiner is the chair of the committee for the protection of human subjects at The Children's Hospital of Philadelphia.

The court's order remains subject to FDA approval, just as all individual treatment INDs need to be approved by the FDA before the test article can be used outside of the clinical trial, says **LaDale K. George**, JD, a health care attorney with Foley & Lardner in Chicago, IL.

The FDA allows sponsors to apply for an individual treatment IND, which some people call "compassionate use" drugs.

"But these applications typically are made after a drug has some proven efficacy, [via] phase II or phase III trials," Schreiner says.

Whether an individual treatment IND is requested by a physician or a sponsor, it has to be approved by the FDA, George explains.

This case has moved the decision-making process from the sponsor and thrust it right on the FDA's doorstep, he notes.

One ethical problem with the court decision is that neither the patient nor the judge are equipped to assess the risks and benefits of an investigational drug, and yet these should be assessed before an individual is allowed to take the IND, experts say.

"I have a problem with a judge mandating clinical care," says **Merit E. Cudkowicz**, MD, an associate professor of neurology at Harvard Medical School and Massachusetts General Hospital in Charlestown, MA.

"This is a drug with no known efficacy, and it's early in development," Cudkowicz adds. "There is no knowledge of what dose to give, and it's not right for a non-medical person to mandate the treatment."

CME Questions

41. The American College of Physicians contended in its "Pay-for Performance . . .: An Ethics Manifesto" that this payment model presents potential ethical pitfalls for physician decision-making.
A. True
B. False

42. The Hastings Center's Nancy Berlinger suggested that with the CMS' policy of non-payment for certain "never" events at hospitals, that the CMS is using reimbursement mechanisms to:
A. Make health care systems safer.
B. Keep the hospital ship afloat.
C. Deny care to patients.
D. Prevent malpractice lawsuits.

43. Bridges to Excellence CEO Francois de Brantes contends that no existing payment model is ethical.
A. True
B. False

44. For what organization is Anita J. Tarzian heading a task force to update the core competencies for ethics consultation?
A. CMS
B. VA
C. HHS
D. ASBH

CME answers

41. A; 42. A; 43. A; 44. D

When a drug still is in phase II testing, as is PTC124, it is difficult to make a risk-benefit assessment, which is the whole point of conducting clinical trials, Schreiner says.

"There could be an individual treatment IND with a phase II drug, but it depends on the strength of evidence and rarity of condition and alternatives available," he adds.

"A lot of these treatment INDs happen in drugs in phase III trials and they're for life threatening conditions where the patients wouldn't qualify for the trial," Schreiner explains. "I believe we should not release agents

until there is some more substantive evidence of efficacy from clinical trials."

IRBs face ethical quagmire

For IRBs, this situation is fraught with ethical conflicts.

For example, is it ethical to permit a sponsor to release an investigational drug to non-trial patients when it's still a major risk that the drug could cause the patient more harm than benefit?

"Ultimately, we could end up doing more harm to the individual and more harm to other patients if we were to permit uncontrolled access to unproven, potentially toxic medications," George says.

And if a judge does order a sponsor to make the drug available to patients who do not meet the study's criteria, how will these patient's experiences impact the overall study's recruitment and adverse event reporting?

"Randomization is the hallmark of clinical trials, and if you remove the randomization element from a clinical trial then you have no control group, and therefore no evidence is being produced," George says.

In addition, investigational drugs cannot be sold because they haven't received marketing approval from the FDA, so on what basis would these free drugs be denied to the many sick people who think they need them, he asks.

"So a pharmaceutical company would have to produce a product that's unproven and for which they have to give it away without compensation," George says. "That's the wrong outcome for everyone, and in the long term it's detrimental."

This court case has been a hot topic because it puts drug companies in an awkward position, says **Stephanie J. Zafonte**, MSN, RN, CCRP, CQA, RAC, director of operations at George Washington University, biostatistic center, in Rockville, MD.

"If you allow compassionate uses of an IND, you don't know what the implications will be," Zafonte says. "What if something happens to this boy after he takes the drug?"

The judge's decision could put the boy in risk and even result in the company stopping drug development because of an adverse event that occurs to a patient who should not have been included in the study, Zafonte adds.

"This could impede drug development that could, in fact, help hundreds or thousands of others," she adds. "So how do you choose this single person vs. society?"

Reference

1. Grynbaum MM. Judge orders drug maker to provide experimental treatment to terminally ill teenager. *NY Times*. Aug. 21, 2008. ■

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a credit letter will be mailed to you. ■

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- learn how bioethical issues specifically affect physicians, patients, and patients' families. ■

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