Conflicts on Prognosis Occur Over Half the Time Between Physicians and Surrogate Decision-Makers

Conflicts between physicians and surrogate decision-makers involving the patient’s prognosis occur more than half the time, according to a recent study.¹

J. Randall Curtis, MD, MPH, one of the study’s authors and director of Cambia Palliative Care Center of Excellence at University of Washington School of Medicine in Seattle, says the extent of the discordance surprised him. “More than 50% of the time, there was a greater than 20% difference in prognostic estimates,” he notes.

Researchers conducted quantitative surveys and qualitative interviews at four ICUs at a major U.S. medical center, with 299 surrogate decision-makers and 99 physicians caring for 174 critically ill patients, from 2005 to 2009. Some key findings include the following:

• Physician-surrogate discordance occurred in 122 (53%) instances.

**EXECUTIVE SUMMARY**

Conflicts between physicians and surrogate decision-makers involving the patient’s prognosis occur more than half the time, according to a recent study.

• Some conflicts involved differences in belief about the prognosis, as opposed to lack of information or misunderstandings.
• The need to maintain hope was a common reason for surrogates being more optimistic about prognosis than physicians.
• Misunderstandings stem from complex medical terminology used by physicians.
Difference in Opinion

Douglas B. White, MD, MAS, the study’s lead author, says, “The study’s findings point out very clearly that when doctors and families have different expectations about prognosis, it’s not always due to a misunderstanding.” White is the endowed chair for ethics in critical care medicine and director of the program on ethics and decision-making in critical illness at University of Pittsburgh Medical Center.

Sometimes, conflicts occurred simply because physicians and surrogates had different opinions. “It’s pretty clear that different judgments and beliefs were prevalent in this cohort,” says White.

The study’s findings “remind physicians and bioethicists that there’s a difference between the informed consent steps of understanding and appreciation,” says White. Surrogates can understand exactly what a doctor says, and still not appreciate how, and whether, it relates to the patient.

“For clinical ethics consultants, it may be worth conceptualizing part of their role as helping surrogates to think about how the prognosis does, or doesn’t, fit with their own perceptions,” says White. Bioethicists can explore why that difference exists. This could lead to further dialogue, allowing both parties to resolve the difference.

“Sometimes it will lead to the physician modifying his or her estimate, and sometimes it will lead to the family doing so,” says White.

The study highlights the importance of physicians exploring discrepancies in prognostic predictions and the reasons underlying those discrepancies, Curtis says. “In order for family members to be able to participate in surrogate decision-making for critically ill patients, it is important that we do our best to ensure they understand the patient’s prognosis,” he explains. This includes not just providing information, but also exploring beliefs that may cause discordance.

The study found that some conflicts were rooted in the family’s inability to face the reality of the prognosis.

White says, “That’s an area for ethicists to intervene on.” The ethicist can find ways to preserve hope that don’t rely on ignoring the gravity of the situation. “There are many different things that one can hope for, in the face of terminal illness, that don’t rely on the patient being magically cured,” says White.

Physicians often use complex language to talk about prognosis, and rarely check to see if surrogates understood what they said, found a 2009 study. “They may focus on small improvements in kidney function, but don’t make it clear that things have not changed overall with regard to the patient’s prognosis.”
says White, the study’s lead author.

Janice Firn, PhD, MSW, a clinical ethicist at the University of Michigan Health System, says there is a clear need for improvement in communication skills about prognosis, “from trainees all the way up.”

Clinicians often choose to use medical terminology, such as stating, “she has a poor prognosis,” instead of saying, “She will not survive. She is dying.”

“It’s easy to get used to the language we use in medicine, but it might not make sense to the layperson,” says Firn. “We often hear from the family, ‘If only I had known that.’”

In family meetings, clinicians often say, “He’s not doing very well.” Hearing this, says Firn, “The family might think, ‘Yes, that’s why we brought him to the hospital!’” They fail to realize that the clinician really means the patient is expected to die soon.

Clinicians may ask the surrogate, “What do you want us to do when she codes?” when they mean, “How should we care for her when she is dying?” Similarly, providers may say “dialysis is indicated” for an ICU patient in multisystem organ failure, meaning the lab values are not good and clinical guidelines indicate initiating dialysis.

Families may take this to mean that the intervention will change the patient’s outcome, or hear the word “stable” and take it as a sign the patient will survive.

“Another way to look at the situation may be to say, ‘Depending on the goals of care and whether dialysis would be of benefit, it may, or may not, be indicated,’” says Firn.

In a time-sensitive situation, says Firn, “it’s easy to just do the next indicated thing.” She says clinicians must be clear about the following things:

- the time period in which improvement can be expected after an intervention is started,
- whether a time-limited trial of a specific intervention makes sense, and
- what the plan will be if the intervention is not helping to improve or reverse the situation.

“To soften bad news, we may say the patient is not strong enough to be a candidate for a specific treatment at this time,” notes Firn. Surrogates may assume the patient will be a candidate in the future when he or she is stronger, when it is unlikely the patient will ever recover enough to receive the treatment.

Another barrier to effective communication is the sheer number of providers speaking with the family in complex cases. “Providers may essentially be communicating the same information, but using different words,” explains Firn. This could give the impression that they are not in agreement about the patient’s status. One provider may say, “The creatinine is stable today,” and another may say, “The patient still has kidney failure.”

Clinicians may default to medical terminology if they’re uncomfortable delivering bad news. “Talking more rather than less can overwhelm the surrogate with details,” says Firn. “The message we’re trying to convey could get lost.” She recommends the following practices to reduce conflicts involving prognosis:

- **Make family meetings a routine part of practice.**

  If the team has periodic meetings with the family not only when death is imminent, but also to discuss what is good care, “that makes it less intimidating,” says Firn.

- **Round informally in the ICU.**

  This is a good time for ethicists to ask some “bigger picture” questions of the clinical team, says Firn, such as, “What are we hoping for out of this? What is the family hoping for?”

  The continual monitoring in medicine can itself be misleading. “There are so many things we are monitoring and paying attention to,” says Firn. “The numbers may be better, but have no meaningful difference in the outcome.”

  The challenge is tying it all together to explain what it means for the patient’s prognosis. Bioethicists can help by asking clinicians, “What does that actually mean for the patient? Do you think it will get them off the ventilator? Do you think it will change the overall outcome?”

- **Pinpoint what the family actually has to decide.**

  In an effort to promote autonomy, clinicians may present the situation to families as making a decision as to whether someone lives or dies. “Oftentimes it’s more about how and where,” says Firn. “We could do a better job at talking about, ‘What’s the real question here?’”

  With proactive education of clinicians, fewer consultations with ethicists and the palliative care team are needed. “They will still consult ethics for serious ethical concerns,” says Firn. “But they will stop needing us for routine issues if they have a bigger toolbox to address issues upfront.”

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EXECUTIVE SUMMARY
A new palliative care policy statement from a leading heart and stroke organization aims to reduce barriers that prevent many patients from receiving palliative care.1

“Ethicists play a central role in addressing distributive justice and equitable access to the highest-quality and evidence-based care,” says Diane E. Meier, MD, director of the Center to Advance Palliative Care in New York City.

Meier says ethicists should advocate for standardized access to palliative care, with the use of “trigger” tools and screening to identify high-need patients who will benefit from these services. “That would be a powerful and needed lever to get our health system to match the care we deliver with what seriously ill patients and their families say is most important to them,” she says.

The statement, issued by the American Heart Association/American Stroke Association, makes the following recommendations:
• federal and state agencies should reimburse for palliative care services,
• payers and providers should share data to identify patients in need of palliative care,
• healthcare systems should develop policies for palliative care during hospitalizations, and
• training should be improved to expand the number of healthcare providers who can deliver high-quality palliative care.

Few hospital palliative care programs meet national staffing recommendations, according to a recent study.2 The findings reflect the fact that palliative care is a relatively new field and clinical service, according to Meier, one of the study’s authors. “As with any transformation, adoption and implementation are variable across the country,” she says.

There are currently no requirements from The Joint Commission, the nation’s dominant accrediting body for hospitals, either to provide palliative care, or to ensure that palliative care provided meets national quality guidelines.

“Given the strong evidence of benefit to seriously ill patients and their families, this needs to change,” says Meier.

The quality of care received by seriously ill patients should not depend on where they live, or whether their doctor understands the value of palliative care, says Meier. “The ethical principles of beneficence, self-determination, and distributive justice are, in palliative care — as in so many other elements of our healthcare system — not honored,” she says.

Joanne Spetz, PhD, FAAN, the study’s lead author and professor at the Philip R. Lee Institute for Health Policy Studies at University of California, San Francisco, expected to find that many programs did not meet national staffing guidelines. “But we were surprised at the degree
to which this was true,” she says.

The researchers were also surprised by how many programs that participate in the National Palliative Care Registry are led by nurses. “We know that nurses are an integral part of nearly every palliative care program,” says Spetz. “But we were surprised to find many without a paid physician, NP, or PA on the team.”

(For more information on the registry, visit: https://registry.capc.org.)

Few Patients Get Consult

Palliative care is known to lead to better patient outcomes and lower costs.1 “But more importantly, it is an approach to care that focuses on the overall well-being of the patient,” says Spetz. This is true regardless of whether the patient is aggressively pursuing treatment and expected to recover, or approaching the end of life, she says.

A small minority of hospitalized patients ever receives a palliative care consultation, however. This is the case even in hospitals with defined palliative care programs.

“Stretching the workforce this thin clearly means that patients in need are not getting the guidance they need,” says Spetz. Patients end up being “overtreated” for some things and “undertreated” for others.

Because of understaffing, “providers in palliative care also face important burnout issues, with rates being relatively high,” says Spetz.

Salimah H. Meghani, PhD, MBE, RN, FAAN, an associate professor at University of Pennsylvania, believes the success of many palliative care policy recommendations hinges on “both the buy-in and the uptake by clinicians and other stakeholders.”

Even clarifying basic differences between hospice and palliative care to clinicians remains challenging, notes Meghani. “Ethicists can work with administrators and clinicians to develop interventions for the uptake of palliative care at the institutional or community levels,” she suggests.

Bioethicists can also advocate for the integration of comprehensive palliative care as part of the emerging value-based healthcare delivery models. “It is important to do it right at the level of conceptualizing and designing these value-based programs,” Meghani says. ■

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Provide High-Quality Ethics Education on a Limited Budget

Ethics sometimes shortchanged with resources

Medical institutions didn’t always understand the importance of ethics to physician training, notes Timothy Lahey, MD, MMSc, chair of the clinical ethics committee at Lebanon, NH-based Dartmouth-Hitchcock Medical Center, and associate professor at Dartmouth’s Geisel School of Medicine.

“We valued physiology and histology and other canonical topics, and paid to teach them,” he says. This failure to recognize the importance of ethics training has left many departments underfunded.

“Upon realizing ethics training was important, those negotiating for funding to teach it often were late to the table, and at risk of getting the scraps of educational funding,” Lahey explains.

Administrative obstacles are another complicating factor. If funding for medical education flows through
leaders in medical education need to ask first what students need to learn, then pay for teaching that addresses that need. “There is little argument physicians confront ethics issues on a regular basis, and thus, that ethics training is a core skill whose teaching should be funded,” says Lahey.

One way to make ethics training more cost-efficient is to integrate it into sessions that address other “bedrock” topics. “For instance, students can learn about the ethics of end-of-life care decision-making in a session about respiratory failure and ventilator physiology,” says Lahey.

Ethics education faces some similar challenges in the hospital setting. “High-quality ethics education can only be provided by clinical ethicists,” says Katrina A. Bramstedt, PhD, a clinical ethicist and adjunct professor at Bond University School of Medicine in Australia, and former faculty in the Department of Bioethics at Cleveland (OH) Clinic Foundation.

“These professionals have advanced training and applied skills in inpatient and outpatient medical ethics,” she explains. Not all hospitals have a fellowship-trained clinical ethicist on staff, however.

“In my experience, hospitals in this situation have reached out to me, essentially borrowing me from my primary institution, to provide their on-site education,” says Bramstedt. She created monthly and quarterly Bioethics Grand Rounds for many hospitals. The sessions are open to doctors, nurses, allied health staff, and students.

“These sessions are video or audiotaped to create a local educational archive. They are sometimes live-streamed to remote in-network hospitals,” says Bramstedt.

She recommends that hospitals first conduct a needs assessment to identify which topics are most appropriate to the setting. For example, a session on transplant ethics would not be appropriate for a hospital that doesn’t perform organ transplants, but a session on organ donation ethics is appropriate for any hospital.

“Hospitals might have specific needs based on recent events such as a serious medical error, media relations fiasco, or complex clinical trial,” says Bramstedt. To increase attendance at ethics education sessions, she suggests the following:

• Align funding with students’ educational needs.
• Integrate ethics into multidisciplinary teaching.
• Conduct a needs assessment to determine which topics are most relevant to the setting.

Executive Summary

Ethics education is often underfunded, both in the hospital and medical school settings, due to lack of importance being placed on it historically, and administrative obstacles. Possible approaches include the following:

• Align funding with students’ educational needs.
• Integrate ethics into sessions covering scientific topics.
• Conduct a needs assessment to determine which topics are most relevant to the setting.

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Physicians Paid to Refer Patients: ‘Fundamental and Clear’ Ethical Violation

Improper financial relationships led to lawsuits and indictments

The nonprofit hospital system Broward Health in Florida recently agreed to pay $70 million to settle allegations that it engaged in “improper financial relationships” under laws prohibiting kickbacks for patient referrals.¹

In a separate incident, federal prosecutors indicted a hospital administrator and surgeons in a kickback scheme netting nearly $600 million in fraudulent claims for spinal surgeries at Pacific Hospital in California.² Some patients lived hundreds of miles away from the hospital, and closer to other qualified medical facilities, and were not informed that medical professionals had been offered kickbacks to refer the surgeries to the hospital.

“You can't pay someone to refer patients — it’s illegal. There is no one in medicine that doesn’t know that a kickback for a referral is not allowed,” says Charles D. Rosen, MD, professor of the department of orthopaedic surgery at University of California, Irvine, School of Medicine, and president of the Monarch Beach, CA-based Association for Medical Ethics.

‘Very Dubious Ethically’

Paul T. Menzel, PhD, professor of philosophy emeritus at Pacific Lutheran University in Tacoma, WA, wasn’t surprised the incidents occurred — “only by their volume, and how brazen they were.”

While the well-publicized incidents were particularly egregious, it’s possible that many other physicians and hospitals, as yet undetected, are engaging in similar practices. “It’s likely that lesser, more disguised versions happen whenever something like this occurs, where we can understand the strong financial incentives behind it,” says Menzel.

Menzel says that regardless of whether a hospital actually put physicians on payroll, or whether it only had a contractual agreement with them in a network, “it is very dubious ethically. The reason is fundamental and clear.”

This is because the hospital has created a financial incentive to physicians that is not based on what is the best care for the patient. “Incentives for referrals is one of the worst violations of the fundamental patient/physician relationship,” says Menzel.

Declining revenue for hospitals and physicians is likely a contributing factor to the recent kickback incidents. “Reimbursement has been reduced significantly, and continues to be,” says Rosen. “Hospitals are struggling to make revenue. Doctors that want to ignore the law are resorting to this.”

In Rosen’s view, a disproportionate amount of money in medicine goes to medical device makers and pharmaceutical companies, as opposed to physicians. “For example, for a total hip replacement, the device rep makes almost as much as the surgeon putting them in,” he says.

Menzel says, “We’ve got a number of forces coming together in how healthcare is paid for. Competing insurers, and even Medicare, are trying to hold down costs. They don’t want to pay providers any more than they have to.”

The use of physician networks is becoming more prevalent. “The increasing size of integrative delivery organizations and additional mergers may push the emphasis on networks,” adds Menzel.

Physicians may insist they will only do what’s best for patients, regardless of payment for referrals. “But if they’re getting paid for referrals to a hospital or specialist, can we really believe that the incentive won’t warp their decision-making?” asks Menzel.

Rosen doesn’t think it’s realistic to expect patients to ask physicians if they have a financial incentive to refer...
them to a specialist, or for surgery. He points out that few patients ask physicians if they have a financial incentive to prescribe a particular medication.

Menzel says that before the kickback incidents were widely reported, most patients probably never even considered their physician might get some type of incentive for a referral. “Even now, not all that many think of it,” says Menzel. “If you ask them whether they would like to know, of course they say yes. But without asking them, few think of it.”

A 2008 survey showed that most (64%) Americans believe it’s important to know their physician’s ties to pharmaceutical companies. However, most (55%) said they would be unlikely to directly ask their physicians about it.

The Physician Payments Sunshine Act requires that financial relationships between physicians and industry be made public. “My hope is that the public is more aware now, and will want to check,” says Rosen. “Ninety percent of doctors want to do the right thing, but you have 5 or 10% that have sold their souls to industry. They’re going to promote what they’re paid to promote.”

Rosen thinks that while it’s unlikely patients will directly ask their doctors, they will seek out available information. “Our website has a doctor search function where you can pull up all payments listed for past 10 years for any physician,” he says. (For more information, visit: www.ethicaldoctor.org.)

Menzel says ethically conscious hospital administrators with a strong “moral compass” are sorely needed. “Hospital administrators have financial obligations, but they have moral obligations, too,” he says.

If hospitals feel competitive pressure to participate in unethical practices, a joint approach might be called for. “Maybe what they should do is go to all hospital networks in the area and say, ‘We won’t make these bargains,’” says Menzel. “Get an agreement that levels the playing field and relieves them of the temptation.”

Hospital administrators might otherwise turn to kickbacks in order to get a leg up on the competition, or simply survive. On the other hand, if these trials yield convictions, hospital CEOs are likely to stand up and take notice — thus, the practice may decrease. “But if the penalties to those found guilty are just to pay back no more than what they gained, there will still be temptation,” says Menzel.

The bottom line is that patients should not have to depend on the threat of fines and convictions to ensure physicians put their best interests first, says Menzel. “We expect our physicians and hospitals not to be in these conflicts,” he says. “If they want patients to trust them, they can’t be in these kinds of relationships.”

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New Report Examines Ethics of Gene Drive Research

A recent report from the National Academies of Sciences, Engineering, and Medicine examines the ethics of gene drive research.¹ Developing gene drives would allow scientists to engineer genetic changes in sexually reproducing organisms, and quickly spread them throughout an entire species. (The report can be downloaded at: http://bit.ly/2d9eywQ.)

“This is a promising approach to limiting vector-borne diseases and addressing some very complicated human health and environmental problems, and it warrants careful investigation,” says Elizabeth Heitman, PhD, a co-chair of the committee that wrote the report. Heitman is an associate professor of medical ethics at Vanderbilt University Medical Center’s Center
Gene drive techniques hold promise for addressing public health threats such as dengue, malaria, and Zika by modifying the organisms that carry these diseases. “Rather than try to make humans immune to malaria, it might be possible to make mosquitoes immune to malaria,” explains Heitman. Likewise, if mice can be made immune to the pathogen that causes Lyme disease, ticks that bite the mice won’t be able to transmit the disease to humans.\(^2\)

By creating gene drives, researchers can introduce a dominant trait and “drive” it into an entire population. “Current research is exploring how to eliminate both human health threats and ecological problems caused by invasive species,” says Heitman.

**Answers Needed on Safety**

Heitman says, “The science is intriguing, but there is much we don’t know about the safety of gene drive-modified organisms.”

A central concern is the possibility of introducing irreversible changes to the environment by changing one or more genetic traits in a given species. It’s unclear how researchers will know it’s safe to release gene drive-modified mosquitoes, how to predict “off-target” effects, and longer-term ecological changes. Some have suggested using “reverse drives” to restore modified species to their earlier state, if unexpected harms arise. However, “the committee was not content with using the same technology to address unanticipated consequences of gene drives,” says Heitman. “There need to be other mechanisms for prevention and remediation of unwanted effects as well.”

“**THE SCIENCE IS INTRIGUING, BUT THERE IS MUCH WE DON’T KNOW ABOUT THE SAFETY OF GENE DRIVE-MODIFIED ORGANISMS.”**

The committee recommended using a “phased testing” approach similar to that used by the World Health Organization, where researchers are required to show a high level of evidence of safety at each stage before proceeding to the next step. “As gene drive safety is evaluated, we need to think about how the public understands their possible harms and benefits,” says Heitman. How best to do this is unclear. “We don’t have good strategies for doing public engagement on that wide a scale,” says Heitman. “And international public engagement across many cultures, with potentially different perspectives, will be a real challenge.”

**Regulatory Questions**

How gene drive techniques will be regulated is another challenge. “Neither the U.S. nor the international regulatory structures are designed for the kind of questions that the technology raises,” says Heitman. The traditional regulation of genetically modified organisms through containment is a poor fit because gene drives are intended to spread.

Because the first research on gene drives was published at the same time as stories about human genome editing, many people associate these separate and distinct techniques. How to explain the science behind gene drives in a way that honestly conveys its potential harms and benefits will be an important question for ethicists and policymakers, as well as researchers.

“The science involves so many disciplines that it was often difficult even for our expert committee members, who are senior scientists in their individual fields, to get a handle on all the pieces of the big picture,” says Heitman.

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**EXECUTIVE SUMMARY**

Gene drive techniques hold promise for addressing public health threats such as dengue, malaria, and Zika, but important ethical questions remain.

- Scientists can quickly spread genetic changes throughout a species.
- A central concern is the possibility of introducing irreversible changes.
- The current regulatory structure is not designed for the kind of questions that the technology raises.
A new business model is emerging in which pharmaceutical companies buy the rights to a drug, then raise the price dramatically. Often, the drugs are produced by one manufacturer, with few or no alternatives.

“It is one thing to charge high prices in order to recoup costs associated with the research and development of a drug,” says Jonathan D. Alpern, MD, co-author of a recent paper on the topic. Alpern is an infectious disease fellow at University of Minnesota.

Companies are not recouping research and development costs, however, because the drugs already exist on the market. Craig M. Klugman, PhD, a professor in the Department of Health Sciences at Chicago-based DePaul University, says, “They are very simply trying to maximize the profit on their purchase of these drugs. The motivation is nothing more or less than greed.”

Excessive Profit

Klugman calls charging excessive prices for drugs needed by people who are suffering “unethical and immoral. Certainly, these companies have a right to make a profit on their investment. But they are not entitled to make an excessive profit.”

Alpern notes the activity has been especially prominent in markets dominated by economically disadvantaged patient populations. Thus, access to life-saving drugs is being limited for patients who can’t afford them. “This has now become a common scenario, with outcomes that I think are unacceptable,” Alpern says.

Patients are going without treatment, receiving second-line therapy, or acquiring the drug from overseas or the internet. “This places clinicians in ethically difficult positions,” says Alpern. “Do you allow your patient to go without therapy, or support them in acquiring the drug from an unregulated source?”

Many companies with this business model have promoted their patient assistance programs. These can be very difficult to access for patients that are in the most need, says Alpern.

Alpern doesn’t expect to see this problem solved anytime soon. “Meanwhile, it would be encouraging to see examples in the pharmaceutical industry of a new model — one that shows how fair pricing can occur while still making a reasonable profit,” he says.

Klugman notes that stories of drug companies buying patents of investment firms, then raising the cost dramatically are becoming “more and more frequent.” The following are some recent examples:

• Turing Pharmaceuticals raised the cost of a toxoplasmosis drug by 5,500% after the company bought the patent.
• Company leaders recently appeared before Congress to explain why the price of EpiPen increased 791% after being acquired by Mylan Pharmaceuticals.
• Novum Pharma, after purchasing several drugs from Primus Pharmaceuticals, raised the price of drugs used to treat eczema and skin infections over 4,000%.

Lower-cost alternatives exist for some of the drugs, but not all. “Charging excessive costs, well above and beyond the cost of manufacture, marketing, and selling, is a gross violation of justice,” says Klugman.

Klugman suggests that perhaps the answer is to make all of healthcare nonprofit. “There is something askew with the idea that we profit off the illness of others. Medical care does not follow the free market very well,” he says.

Patients do not choose their drugs and cannot shop around for options and alternatives — they must take the drug that a physician prescribes. “Doctors control prescriptions, and only licensed pharmacies can dispense them,” notes Klugman.

Klugman believes that applying profit motive principles to a controlled market violates equity and fairness.
“If I do not buy a widget, then I don’t have a widget. But if I do not buy my medication, then I suffer and may imperil my health further,” he says. Klugman concludes, “Not only must we understand the ethical problems these charges represent, but we must consider whether legislation needs to be introduced to make such price gouging illegal.”

Klugman says bioethicists should encourage Congress to regulate the drug industry, and require review of all corporate sales of drug licenses and patents to ensure that the new owners will not seek excessive profits and high charges.

“Utilities and insurers already have to submit requests for price increases for government approval,” notes Klugman. Similarly, insurance companies and large corporations need to be reviewed by the FTC to be sure that changes do not cause monopolies or impose a price burden on consumers.

“Drug companies should have to do the same — whether the entire company is being acquired, or merely a few drugs are being sold,” says Klugman.

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<td>September 2016</td>
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<th>c. Total Paid and/or Requested Circulation</th>
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<th>17. Total Paid/Requested Outside the USA (Sum of 15b. and 15c)</th>
<th>18. Average No. Copies Each Issue During Preceding 12 Months</th>
<th>19. No. Copies of Single Issue Published Nearest to Filing Date</th>
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<th>20. Publication of Ownership</th>
<th>21. Publication required. Publication must be printed in the November 2016 issue of this publication.</th>
<th>22. Publisher and CEO</th>
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**9/12/2016**

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