SCRIPTDOCTOR: MEDICINE IN THE MEDIA

I Want My Med TV

By Andrew Holtz, MPH

“Enjoy the stories and don’t get too worked up over each medical faux pas or dramatic exaggeration—and maybe pick up a few insights about how medicine looks to those on the outside, including your patients.”

“Congress has prohibited general access to experimental drugs and has prescribed in detail how they may be studied and used by the scientific and medical communities.” In other words, the law is the law.

The Alliance claimed self-defense principles to support its argument, saying that terminally ill people are in immediate danger of harm from cancer. Thus they should be able to use whatever medical means are necessary to defend themselves. Judge Griffith, though, said this analogy fails because it is “not about using reasonable force to defend oneself, nor is it about access to life-saving medical treatment. Rather, it is about whether there is a constitutional right to assume enormous risks in pursuit of potentially life-saving drugs.” This case involves risk from drugs with no proven therapeutic effect and thus cannot be supported by the doctrine of self-defense, he said.

The Dissent: ‘A Stunning Misunderstanding of the Stakes’

Chief Judge Douglas Ginsburg and Judge Judith Rogers, however, dissented. The latter wrote the dissent, calling the majority opinion a “stunning misunderstanding of the stakes.” She added that the court did not come to grips with American history and tradition, which reflect deep respect and protection for the right to preserve life.

She accused the majority of “addressing regulations to prevent fraud in the sale of misbranded and adulterated medications or safety restrictions applicable to all medicines—which says little about the historic importance of a right of a person to save her own life.”

In addition to the self-defense “error,” Judge Rogers said that denying a terminally ill patient the only chance to survive is a “dangerous brand of paternalism. Such intervention is directly at odds with this Nation’s history and traditions giving recognition to individual self-determination and autonomy where one’s own life is at stake.”

Reactions from the Principals

Frank Burroughs said that the Alliance is “dubiously” — that most of the judges tragically missed the merits of the case. He said it will be difficult for FDA and its supporters to put a positive spin on the court’s decision.

Asked by OT what he meant by that, Mr. Burroughs said that he found it shocking that the eight judges didn’t understand the issues they were deciding. “But there might be a silver lining in this,” he said. “We’re getting lots of media attention, and hundreds of people have called in support.”

From the other side of the aisle, ASCO EVP and CEO Allen S. Lichter, MD, said in a statement that ASCO is pleased that the court decided in favor of ensuring that drugs are safe and effective before they are used in patients. “We are sympathetic to the desire of patients to access experimental drugs when they have no other treatment option or when they are legitimately ineligible for a clinical trial, and we have advocated that FDA expand and clarify its expanded access program,” he said.

“But the court made the right decision in this case,” Dr. Lichter said. “Phase I studies are not designed to determine either safety or efficacy, so had this suit prevailed, cancer patients could receive treatments that do not work or are actually harmful. In addition, allowing access to unproved therapies could harm the ability to develop effective new drugs for all cancer patients by deterring participation in clinical trials.”

Next Step: Supreme Court

The next step is the Supreme Court. Paul Kamenar, Esq., Washington Legal Foundation, pro bono counsel to the Abigail Alliance, said that it has 90 days to make the appeal. Then the Department of Justice, arguing for FDA, has 30 days to respond. After that, the Court meets in secret session to decide if it will hear the case. “So it would be well into Spring 2008 before we have a decision—if the court decides to hear it.”

Does he think the court will decide to hear the case? “There’s a better than 50-50 chance,” Mr. Kamenar replied. “The case raises important issues, and it’s getting a lot of media coverage.”

“This is a landmark civil rights issue,” Mr. Burroughs added.

Abigail

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Majority Opinion

The 8-2 to 2 decision for that en banc hearing was handed down last month, written by Judge Thomas Griffith. Among his points were the following:

• Such rights are not set forth in the Constitution, and the Supreme Court has cautioned against expanding rights protected by the Due Process Clause because guideposts for responsible decision-making in this uncharted area are scarce and open ended….We must exercise the utmost care whenever we are asked to break new ground, lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of others.” In other words, due process should not be used for that which was not intended.

• The Abigail Alliance argued that the right it claimed can be found in US history and legal traditions because government never interfered with physicians’ judgment about medical efficacy of a drug until 1962 (when major amendments were made to the Food, Drug and Cosmetic Act). Judge Griffith countered by saying, “The Alliance ignores one simple fact: It is unlawful to procure experimental drugs not only because they have not been proven effective, but because they have not been proven safe.”

• “Congress has prohibited general access to experimental drugs and has prescribed in detail how they may be studied and used by the scientific and medical communities.” In other words, the law is the law.

• The Alliance claimed self-defense principles to support its argument, saying that terminally ill people are in immediate danger of harm from cancer. Thus they should be able to use whatever medical means are necessary to defend themselves. Judge Griffith, though, said this analogy fails because it is “not about using reasonable force to defend oneself, nor is it about access to life-saving medical treatment. Rather, it is about whether there is a constitutional right to assume enormous risks in pursuit of potentially life-saving drugs.” This case involves risk from drugs with no proven therapeutic effect and thus cannot be supported by the doctrine of self-defense, he said.

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Saving My Self

By Wendy S. Harpham, MD

My white coat and stethoscope lay draped over my chair, as if I’d slipped out of my office for a moment. Meanwhile, in another office, a surgeon was about to utter two words that would change my world forever: “It’s back.”

Soon after beginning treatment for this first cancer recurrence, I sat in a circle on the floor of my bedroom with a few girlfriends and my seven-year-old daughter. Chatting and laughing, we might have been mistaken for playing a child’s game if it weren’t for the stacks of “Dear Patient” letters announcing the closing of my medical practice.

While stuffing envelopes, one friend started to tell a story. “Since Wendy is a doctor…” My daughter interrupted, “Mom used to be a doctor.” As often happens when a child exposes the elephant in the room, an awkward twitter spread through my little party, and the topic quickly changed. But I was left wondering, “If I’m not a doctor, who am I?”

Over the next few weeks, my patients’ charts scattered to doctors throughout the metropolis like feathers in the wind. At home, I fielded phone calls and read greeting cards from well-wishers expressing pity or sadness about my having cancer.

My insistence on resuming my cancer exercise routine and plowing through my New England Journals of Medicine were transparent attempts to pretend I had cancer exercise routine and plowing through my New England Journals of Medicine were transparent attempts to prettify my world and escape what was happening.

“Addressing each patient as a unique individual dignifies the person with the disease.”

When your words and actions say, “You are you, no matter what is happening medically,” you help patients let go of their “old normal” and recreate themselves in a “new normal” that integrates the changes and challenges accompanying their illness. In essence, addressing each patient as a unique individual dignifies the person with the disease.

Last week, someone asked my now 22-year-old daughter what I do. I was curious what she’d say. She answered, “She’s a survivor. She used to be a doctor.”

I suppose that’s why I keep my white coat and stethoscope hanging just inside my closet door. They remind me of the doctor I used to be and the person I am today.

“It is a heavy load, but my wife is still a resident in internal medicine, so she still works more hours than I do,” he points out.

The radio show gives him a venue for discussing all sorts of popular issues, including those raised in medical TV shows.

“The ethical dilemma of the week is usually the highest volume of calls for the entire week. People love having these discussions. And that’s why they love Grey’s Anatomy and that’s why they love ER, because these ethical dilemmas are interesting,” Dr. Mazzarelli says.

“End-of-life issues are incredibly under-discussed by patients and their families. These dilemmas arise all the time in almost all the medical shows and can serve as a starting point for discussions that are necessary and important for family members to understand each others wishes. You want them to think about it ahead of time, so it’s an issue they’ve thought about before they actually are faced with a situation in their real life.”

A few years ago, an article in the medical student edition of JAMA ran an article noting that regular viewing of ER throughout medical school would add up to about as many hours as a typical emergency medicine rotation at most schools (Michael M. O’Connor, “The Role of the Television Drama ER in Medical Student Life: Entertainment or Socialization?” JAMA 1998;280: 854-855).

The author went on to speculate about the cumulative effect on medical students: “The popularity of ER among students raises interesting questions about the role of the media in shaping aspiring doctors’ perceptions about their chosen profession. Does the show cultivate the development of spurious attitudes toward various medical specialties? Do ER physicians set the contemporary standard for the ideal physician? Although most will agree that ER provides a captivating escape from one’s studies, a latent socialization force may also operate in tandem with its entertaining storylines.”

Dr. Mazzarelli said he doesn’t worry too much about it.

“I think sometimes we overanalyze these fictional shows and we watch them a little too seriously,” he says. “The bottom line is that after a while you don’t watch these shows for the medicine, you watch them for the characters. Both Grey’s Anatomy and ER are character-driven shows. Maybe in the beginning you watch the shows because you have an interest in medicine, but that’s not what keeps you watching.”