than minimal risk" — a major departure from current human subject protections. It is not clear who gets to determine whether a given trial of a new drug poses "minimal risk."

Embedded in the language of the 21st Century Cures Act are some good ideas that could streamline the development and evaluation of new drugs and devices; its call for increased NIH funding may prove to be its most useful component. But political forces have also introduced other provisions that could lead to the approval of drugs and devices that are less safe or effective than existing criteria would permit.

An audio interview with Dr. Avorn is available at NEJM.org

Over the past 80 years, this country's regulatory approach has embraced steadily improving criteria for accurately assessing therapeutic efficacy and risk. Patients and physicians would not benefit from legislation that instead of catapulting us into the future, could actually bring back some of the problems we thought we had left behind in the 20th century.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston.

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Medical Facts versus Value Judgments — Toward Preference-Sensitive Guidelines

Peter A. Ubel, M.D.

The radiation oncologists apologetically informed us that they would not be able to offer my wife Paula a sixth week of treatment — a "boost" therapy aimed at the place where her breast cancer had resided before she received her lumpectomy. This tumor bed was no longer localizable, because Paula had received immediate reconstruction that had obscured its location. I was aghast. Although Paula would receive 5 weeks of whole-breast irradiation, she would not receive the benefits of that final week of treatment, the boost therapy that, according to National Comprehensive Cancer Network (NCCN) guidelines, is "recommended" for women like Paula, whose breast cancer is diagnosed before they are 50 years of age and who have axillary involvement.[1]

After the radiation oncology appointment, I obtained the main clinical trial that had established the value of boost therapy[2] and looked for the survival curves that corresponded to the size and location of Paula's tumor. I could see how much boost therapy would have reduced her chance of local recurrence. But I could also see the downside of this treatment, which increased the risk of breast fibrosis. It made me wonder: how did the NCCN come to so definitively recommend boost therapy for women like my wife?

A couple of years later, I stood in front of an audience of radiation oncologists, presenting a lecture on shared decision making. I asked them to imagine that they faced a choice between two types of radiation therapy for early-stage breast cancer. The first treatment would leave them with a 15% chance of local recurrence and a 10% chance of moderate or severe breast fibrosis. The second treatment would leave them with only an 8% chance of local recurrence but a 30% chance of moderate or severe fibrosis. The radiation oncologists raised their hands in almost equal numbers for the two treatments. Some believed the higher risk of fibrosis was unacceptable, given the treatability of most local recurrences, whereas others believed the trauma of recurrence outweighed the discomfort of fibrosis.

This division of opinion was not completely surprising. Often medical facts — such as data on rates of cancer recurrence versus rates of fibrosis — don't point toward an objectively superior

treatment but instead reveal trade-offs, whereby the best choice for an individual patient depends on her preferences, on how she weighs the relative pros and cons of her alternatives.

Yet in one respect, the divided opinion was unexpected, because I had presented these specialists with an estimate of the outcomes my wife faced when she received radiation treatment for breast cancer. The first set of outcomes captured her prognosis if she were to receive 5 weeks of whole-breast radiation. The second captured the impact of receiving boost therapy. Half the audience had rejected the "recommended" therapy. The NCCN, in crafting its treatment guidelines, had stepped beyond assessing medical facts to making a questionable value judgment, that the positive effect boost therapy has on local recurrence outweighs its negative effect on breast fibrosis.

This distinction between facts and value judgments has long been emphasized by experts on decision making, and not just in the medical domain. In the mid-1970s, amid substantial public debate about the proper role of scientific advisors in the government, Kenneth Hammond and Leonard Adelman wrote an article explaining that the integration of facts and values cannot be accomplished using science alone but also requires value judgments.[3] They described a 1974 controversy that was mishandled in part because the community turned a problem over to scientists without recognizing that there was no purely scientific answer to the question at hand. The Denver Police Department had begun using hollow-point bullets, because of their superior stopping power. The American Civil Liberties Union challenged this decision, contending that the greater lethality of the bullets would result in greater harm to innocent bystanders. Ballistic experts were asked to provide their scientific opinion about which bullet was "best." If the new bullets had been both safer and more effective than the old ones, scientists could have answered this question by pointing out those facts. But the new bullets presented a trade-off between lethality for criminals and safety for the public. Science on its own cannot determine which is the right choice in such circumstances. That choice depended on the relative importance the community placed on the two goals. Ballistics experts were in no better position than laypeople to make this judgment.

Like ballistics experts, physicians hold mastery over scientific facts that are relevant to important decisions and often assume the role of advisors to laypeople facing difficult choices. In this advisory capacity, physicians must recognize that their medical recommendations sometimes involve value judgments and that reasonable people may disagree on the best course of therapy.

The American Urological Association recognized this distinction in its guidelines for treatment of early-stage prostate cancer and wrote that patient preferences "should be considered in decision-making."[4] By contrast, NCCN guidelines do not include active surveillance as an available treatment for men with tumors with a Gleason score of 7 (the threshold for a high-grade tumor) who have a life expectancy of more than 10 years.[5] This guideline effectively treats patients' preferences as irrelevant to treatment choices for men with such tumors. In the process, it ignores the possibility that a 62-year-old man who can't afford to miss work might want to pursue active surveillance so he doesn't lose his job, or that a newly married 65-year-old man might not want to have erectile dysfunction as a result of surgical or radiation therapy. Given that such choices seem quite reasonable, I believe the NCCN overstepped its professional expertise when it implicitly recommended that physicians take this option off the table.

The same holds true for the NCCN guidelines regarding boost therapy for women with certain types of breast cancer. Physicians crafting the guidelines went beyond the medical facts and made the value judgment that women should accept the increased risk of breast fibrosis in order to reduce their chance of a local recurrence.

In some cases, I expect that the value judgments physicians and professional societies make are shared by their patients. But sometimes physicians' values differ in important ways from those of many patients. When such value judgments are incorporated into professional treatment guidelines, without any explicit acknowledgment that a reasonable patient might choose an alternative course of treatment, they take potential choices away from patients.

Good decision making requires familiarity with decision-relevant facts and recognition of the values relevant to weighing the pros and cons of the alternatives. If physicians or medical societies — in presenting treatment alternatives to patients or devel-

oping guidelines laying out the standard of care — fail to recognize when they have gone beyond the medical facts to make value judgments, they will harm patients by taking viable choices away from them.

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From the School of Medicine, the Fuqua School of Business, and the Sanford School of Public Policy, Duke University, Durham, NC.

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BECOMING A PHYSICIAN

Breaking the Silence of the Switch — Increasing Transparency about Trainee Participation in Surgery

Chryssa McAlister, M.D.

We stand and swap operating-room chairs, soundless in our socked feet. The room is silent as I run through the steps at the microscope: corneal incisions, viscoelastics, capsulorhexis — the tearing with forceps of a small circular hole in the anterior capsule to gain access to the lens. I breathe shallowly, trying to avoid making a sound with each inhale and exhale; the casual chit-chat common in operating rooms is conspicuously absent. I am relieved to hear the ding and musical crescendos of the phacoemulsification machine as it uses fluid and ultrasound to remove the cataract fragments. Silence returns as I insert the new lens and complete the final steps of the procedure. Then Dr. X nudges me aside to remove the speculum that holds open the eyelids and she pulls off the sterile drape covering the patient's face, which also prevents him from seeing.

"All done," says Dr. X. "Everything went well." She smiles, placing a shield over the patient's left eye, and he is wheeled out.

Dr. X turns to me. "Well done," she says. She gives me a few tips on how to "chop" the lens more efficiently and grabs the next chart.

Not all attending eye surgeons expect trainees to operate in silence, but many ophthalmology residents experience some variation on this scenario. Some surgeons speak openly as residents operate, and others even berate trainees for their technique, with little regard for patients' perceptions. I never minded such tongue lashings; rather, I always dreaded the silent switch. The miming, soundless communication over the top of a fully alert patient is clearly deceptive and seems directly at odds with the trust required in a good physician–patient relationship.

The problem of undisclosed trainee participation in care is not unique to ophthalmology — it is relevant to physicians training to perform procedures of all kinds. A qualitative study of Canadian surgeons in multiple specialties revealed a lack of disclosure to patients of the details of intraoperative participation by residents,[1] and surgery residents express moral angst over patients' lack of awareness of their role. It's relatively easy to keep the concept of resident participation abstract if a patient will be asleep or sedated during a procedure or if it must be performed by a team rather than an individual surgeon. The resident's role is more evident, however, in single-operator procedures such as cataract surgery, as an alert patient lies on the table waiting for someone to cut open his or her eye. The minimal sedation used forces the surgeon to either fully disclose the trainee's involvement or overtly deceive the patient to some de-