

Einer Elhauge

The faculty director of the newly established bioethics center at Harvard Law School believes that law is the framework for looking at all the issues relevant to the delivery of healthcare, from malpractice to insurance to patents.

If there's a current area of legal practice that cries out for more scholarship and new ideas, it is healthcare. And although healthcare consumes 15% of the US gross domestic product and probably an even greater share of legal practice given its regulatory nature, it is also less than 1% of the focus of legal scholarship in the US. That's the belief of the sponsors of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, launched in November 2005. Its name comes from New York lawyer Joseph Flom, a Harvard graduate, and the Carroll and Milton Petrie Foundation who together endowed the Center with \$10 million.

"The leading law schools don't have much of a presence in health law," says Einer Elhauge, Carroll and Milton Petrie Professor of Law at Harvard Law School and the faculty director of the new center. He adds, "In some ways, biotechnology is one of the main causes of current health law issues. It creates wonderful miracles, but also costs."

The focus on efficiencies, incentives and the fair allocation of costs is central to Elhauge's health policy world view. Laws are an essential determinant of how healthcare is delivered in other ways, too. "The delegation to the medical profession itself is structured by laws," he contends, including malpractice, insurance contracts that cover medically necessary care, and managed care efforts to restrict delivery of services.

Born of Argentinean parents, Elhauge was an undergraduate in biochemical sciences and spent one year in medical school before taking a leave of absence to go to law school. After graduation, he became interested in antitrust, which also drew him toward healthcare policy.

At that time, in the 1980s, the antitrust effects of hospital mergers were coming under review for the first time. Since then, of course, biotech has had an increasingly profound influence on health policy.

"New technologies for the future are likely to raise all sorts of deep, fundamental questions about the extent to which you should be able to modify genes and select for attributes," he says. Elhauge foresees genetic engineering technology providing some of the low-hanging fruit for the Center's endeavors—and not just whether techniques should be outlawed or allowed. Access to genetic information versus an individual's privacy rights is already being discussed in legal circles. Down the road will be questions around whether there's an affirmative duty to fix an unborn child that will inherit a genetic disease. Should people be given tests to determine if they should have children, due to their underlying medical genetic makeup?

Other significant health policy questions arise around economic incentives. "Some people think it's a problem that you can't get devices and drugs in developing countries," explains Elhauge, that a different cost structure is needed. "From an economic perspective, there's poor dissemination of whatever technology you create," he suggests. "Right now, there's incentive to make something marginally better than what's out there, and reap the profits from that. These are problems for the economy at large, but it's inevitable with medical technology since everyone pays such a big share of it. The profits may exceed the actual benefits."

It's also clear to Elhauge that the law frames all of these questions—Fellows at the Petrie-Flom Center could conduct empirical studies and economic analyses to determine what actually happens under current

healthcare funding mechanisms, to ascertain whether the incentive structures they create seem desirable, he says. Conversely, laws are shaped by funding systems. "You can't understand malpractice and quality of care without understanding financing," he says. "Financing creates a lot of the levers." Unlike other industries, in healthcare "it's not simple like 'I'm paying my dollars, I know how valuable the service I'm getting is to me. There's also a decision maker involved.'"

Elhauge is careful to say that he brings no preconceptions to the Center's studies and wants the fellows to find their own way.

Indeed, as a fellowship program, Petrie-Flom may be able to shed light on a broader range of issues than many other schools' bioethics tracks. By way of contrast, most current bioethics programs are for graduate students, who are more focused on their next career option.

One area is international law. Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania in Philadelphia, points out that in those relatively few places where health law policy is taught, it tends to be within a narrow framework. "Law schools tend to be very America-oriented," he explains. "But that's not the world of biotechnology today. Bioethics is really international human rights. Students tend to leave not knowing that."

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George Annas, chair of the Department of Health Law, Bioethics and Human Rights at Boston University's School of Public Health, agrees that to most students, international law means international commercial law—intellectual property, drug pricing, the availability of AIDS drugs and the like. "They understand there's public international law, but they're more focused on banking and multinational contracts."

Whether professional standards for the medical profession arise from state, federal, or international law is an issue Annas thinks merits much greater attention. "Mostly it's state law, but that makes no sense." Similarly, the issue of whether industry bears some special responsibility given the necessity of the products and services it delivers should go well beyond state or even federal law. So long as companies felt their competitors would act in a similar way, Annas believes companies would operate according to a higher ethic. "You need a level playing field, but that would take an international treaty process," he says.

Petrie-Flom did not arise from a concerted internal effort at Harvard to extend its health policy scholarship. Rather, a donor decided to earmark a contribution for that specific purpose. Nonetheless, the opening of an interdisciplinary fellowship program at such a leading university is telling. "What's new is not the field that Harvard's joining, but that Harvard's joining it," says Annas. "I'm confident they'll figure out how to make a meaningful contribution."

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