A recent increase in legislative initiatives involving specific aspects of the practice of medicine is challenging traditional doctor–patient relationships. A Florida state law prohibiting physicians from asking patients about the presence of guns in the home could potentially result in real harm because of the risk of childhood injuries, domestic violence, suicide, and homicide. A number of states have specific language physicians are supposed to use when obtaining consent for pregnancy terminations. Some of these items required by law to be contained in the informed consent are not based on science, but instead on political beliefs. Other legislative initiatives involve issues as varied as hysterectomy consents, glomerular filtration rates, family planning, and palliative care. Laws that prohibit physicians from asking patients certain questions may be violating doctors’ First Amendment rights. Laws mandating what information is contained in procedural consent forms and requiring certain scripts to be utilized may interfere with patients’ ability to have accurate, unbiased, objective information to assist in their decision making. Physicians may be caught in the untenable position of balancing their professional and ethical obligations to their patients with their duty to obey the law as citizens. Physicians should be involved in legislative advocacy to try to prevent policy makers from legislating the practice of medicine. The American Congress of Obstetricians and Gynecologists’ Committee on Ethics should consider review of this evolving issue.

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The doctor–patient relationship long has been held sacrosanct among physicians, and rightly so. In 2009 Goold and Lipkin noted, “The relationship between doctors and their patients has received philosophical, sociological, and literary attention since Hippocrates, and is the subject of some 8,000 articles, monographs, chapters, and books in the modern medical literature.”1 The American College of Emergency Physicians’ Code of Ethics specifically notes, “The physician-patient relationship has been and remains the moral center of medicine and the major defining element in biomedical ethics.”2 Physicians should interact with their patients in the context of that special relationship guided by their ethical and professional standards, not by local legislative or political processes. A troubling trend of legislative interference in this process has become evident over time in this country. This article will review a number of these issues, including legislative policies regarding informed consents in abortions and hysterectomies, family planning services, glomerular filtration rates, domestic violence screening, firearm safety, and palliative care. Given the depth and breadth of these legislative maneuverings, this list does not portend to be exhaustive.

THE “GAG RULE”
The gag rule first was announced in a 1984 conference in Mexico City. This policy restricted nongovernmental organizations in developing countries that received funding from the U.S. Agency for International Development from engaging in most abortion-related services, even with their own funds.3 Physicians in these locations were not permitted to discuss many family planning options, or to provide family planning services, owing to the potential for jeopardizing international aid. Although the focus of this article is not international health policy, the gag rule’s prohibitions prevented physicians from discussing health care options with their patients. This
policy has been rescinded and reinstated with changes in administrations.

As a result, 430 foreign organizations in more than 50 countries agreed to stop performing abortions, or even discussing abortion, to continue to qualify for U.S. Agency for International Development family planning funds. This law eventually was repealed, but, according to *Time* magazine, not before Planned Parenthood of Zambia had lost nearly a quarter of its funding and almost 40% of its staff. There is still some discussion among Congressional leaders of reinstating this bill that is, according to one activist, “... a life sentence for the world’s poorest women.”

**ABORTION SCRIPTS**

In 2008, after surviving 3 years of legal challenges to a South Dakota law, the legislation regarding “informed consent” for abortions took effect in that state. This law, according to Attorney Zita Lazzarini, dictates that any abortion provider in South Dakota must tell any patient seeking pregnancy termination that she is aborting the life of “… a whole separate, unique, living human being” with whom she has an “existing relationship.” It further details how the physicians must give the patient, in writing, a detailed description of the medical and “statistically significant” risk of depression, including psychological diseases, suicide, risks to future pregnancies, and death. The physician must also review the gestational age of the fetus and describe its stage of development. The patient must then sign each page of the document. The physician must subsequently, “… answer all of the woman’s questions in writing and enter them into her medical record” and also state in the record that the patient has understood all that was discussed. Failure of physicians in this state to comply with this law may result in their loss of licensure, license suspension, or a class 2 misdemeanor charge.

Regardless of whether one is “prochoice” or “prolife,” this intrusion by the government in the informed consent process for a legal procedure is troubling. A thoughtful review regarding this bill in *The Journal of Contemporary Health Law and Policy* argues this law has to be considered as a potential violation of both the physician’s First Amendment right and a woman’s due process rights.

A 2006 *Guttmacher Policy Review* noted that, “… states have been enacting ‘informed consent’ mandates specific to abortion for decades, and 32 states currently have mandates in effect.” In July of 2006 they conducted an analysis of all 50 states’ laws regarding patient materials, and determined 22 states’ health departments had developed written materials, required for distribution by providers, as mandated by the legislature. What was most alarming regarding their analysis was, “... that although most of the information in the materials about abortion comports with recent scientific findings and the principles of informed consent, some content—specifically that which is related to breast cancer, psychological impact, fetal pain, and referrals for additional care is either misleading or altogether incorrect.”

So not only can one object to the fact the government is requiring physicians to hand out specific written materials before getting consent for a surgical procedure, this material is often scientifically flawed. This potentially seriously undermines the ethics and professionalism of the physicians who are compelled, by law, to distribute these materials. Kramener and Gostin eloquently stated the potential dangerous overlap of various considerations, stating, “A wall of separation is needed between science, norms, and politics. Science should inform normative discussion and provide evidentiary base for political choices. Likewise, values will always be important in deciding how science is applied for human benefit. But neither should be permitted to distort the other; limits on the outer boundaries of what questions each can answer must be respected when making public policy. Medical science, and the health of patients who depend on it, are too important to be subjected to political ideologies.”

**HYSTERECTOMY CONSENTS**

In 2010 two bills were introduced in the Indiana legislature governing hysterectomy practice. One would involve in a study of hysterectomy practices in the state, and the other would specifically outline what the physician should say to the patient, both verbally and in writing, regarding the informed consent process. Specific features of the informed consent for hysterectomy are outlined, including the “… estimated financial cost to the patient for the physician’s and surgeon’s fees.” The bill establishing the study commission notes, “... many of the women having hysterectomies were not given the information necessary to make an informed consent decision regarding what would or would not be done to their bodies.” Some advocacy groups, such as the Hysterectomy Educational Resources and Services foundation, are lobbying representatives to mandate physicians to provide a DVD of hysterectomy risks as part of their consent processes. As physicians, we should work hard to ensure our patients are informed of all of their therapeutic options without bias or pressure and
commit to the informed consent process as being essential to our commitment to our patients. Some might argue past inadequacies in this arena by medical professionals have prompted some bills. Are advocacy groups going to try to compel legislators to enact legislation regarding other surgical procedures are well? There is a lot of political debate about circumcisions, tubal ligations, and vasectomies. Is there an argument to be made the legislature should be involved in any of these informed consents of patients at the bedside? Where would this slippery slope end?

PALLIATIVE CARE SCRIPTS

On February 9, 2011 the New York Palliative Care Information Act was enacted. According to this law, “… if a patient is diagnosed with a terminal illness or condition, the patients’ attending health care practitioner shall offer to provide the patient with information and counseling regarding palliative care and end-of-life options appropriate to the patient, including… prognosis, risks and benefits of the various options; and the patient’s legal rights to comprehensive pain and symptom management.” California has a similar law. Physicians found to be in violation of this law may be fined up to $5,000 or they may even be incarcerated for up to 1 year. As Drs. Astrow and Popp outlined in a recent editorial, the legislature did not define what a “terminal illness” is. They also further noted that for some conditions that are eventually fatal, such as heart disease, the duration of illness is not always clear, and having a discussion about palliative care at the onset of that diagnosis may not be appropriate. The legislature has attempted to help patients be aware of options for end of life care, but by forcing providers to discuss end of life issues with all patients who might potentially eventually be terminal, the sensitivity of these discussions, and nuances regarding their timing have been ignored.

PROHIBITION OF FIREARM QUESTIONS

Of all of these examples, state laws prohibiting physicians from asking patients about whether there are firearms in their homes are probably the most dangerous. As of May 17, 2011, three states were considering bills that would penalize health care providers for asking patients about whether they have guns in their homes. Indeed, one of these bills recently was adopted by the Florida state legislature and signed into law by Governor Rick Scott on June 1, 2011. The National Rifle Association-Institute for Legislative Action’s recent press release lauding the adoption of the Privacy of Firearms Owners law summarized that this will, “Stop pediatricians from invading privacy rights of gun owners and bringing antigun politics into medical examining rooms.” This new law, however, may be in direct violation of the physician’s First Amendment rights. It is not the role of the legislature to prohibit its citizens from asking certain questions, regardless of political affiliations. In this case, however, such prohibitions could result in an increase in significant harm to the population.

There are many studies in the literature highlighting the importance of ascertaining a history of firearms in the home as a risk factor for mortality. One large population-based case-control study of women’s violent deaths in their homes, evaluating three counties (from Washington, Tennessee, and Ohio) revealed that firearms were involved in 46% of the homicides and 42% of the suicides. Indeed, having one or more gun in the home resulted in an odds ratio for suicide of 4.6 (95% confidence interval 1.2–17.5) and an odds ratio for homicide of 3.4 (95% confidence interval 1.6–7.1.) This is particularly an issue in the United States, which, as George Comerci reports, “… leads by far other developed countries in firearm homicides in males aged 15 to 24 years. The total number of homicides of this age group was 4,223 for the United States (3,187 by firearms), 62 for Canada (17 by firearms), and 48 for England and Wales (3 by firearms).” The Centers for Disease Control and Prevention conducted an analysis of homicides from 1981–1998 and concluded that 50% of intimate partner homicides were committed by legal spouses, and 33% by boyfriends or girlfriends. Firearms were the weapon most commonly utilized in these homicides. According to another study, when firearms are the weapons used, the fatality rate is three times higher than when knives or other sharp instruments are used, and 23 times higher than when other types of weapons are involved.

Screening for domestic violence in pregnancy is particularly important. A 1999 analysis revealed that the injury-related death rate for all women of reproductive age was the third highest cause of mortality in that population. The authors further commented, “… homicide is a leading cause of death during pregnancy and the postpartum period.” The risk of firearm related injury is particularly high for victims of domestic violence. Kellermann and Heron highlighted this, stating, “Over the past two decades, firearms have been used to kill more than 33,500 victims of intimate partner violence.” Patients who purchase handguns themselves for domestic use may in fact be more vulnerable to injury. One study assessing 28,181 female handgun purchasers in Cali-
fornia found for these women there was a 50% increase in homicide risk, which was, “… attributable entirely to a doubling of the handgun purchasers’ risk for firearm homicide.”²² Another national randomized telephone survey done by Azrael and Hemenway concluded “… it is more likely that a gun used in the home will be used against a family member than to protect a family member.”²³

As obstetrician–gynecologists we focus on domestic violence in ascertaining the risk of firearms in the home, but pediatric providers need to inquire about guns in the home to try protect children’s safety. One study surveying 604 patients revealed that 47% of homes with both children and firearms had at least one gun that was stored unlocked and 26% had at least one loaded firearm.²⁴ There is evidence that office-based patient education interventions regarding safe firearm storage resulted in a statistically significant improvement in safe practices at 6 months of follow-up comparing the study group with controls.²⁵

OTHER LEGISLATIVE FORAYS INTO MEDICINE

Although some of the aforementioned issues might be more politically charged, there are other seemingly more innocuous laws involving the legislature’s direct involvement in medical care. A recently adopted New Jersey law mandates the “… calculation and reporting by clinical laboratories of the estimated glomerular filtration rate whenever a serum creatinine test is performed.”²⁶ The Breast Density and Mammography Reporting Act of 2010, a Congressional Bill, specifically outlines what should be contained in the breast imaging reports women with dense breasts receive.²⁷ In 2006 a New Jersey law was enacted that mandates postpartum depression screening by obstetricians in office settings.²⁸ The motivations for all of these laws are commendable. Few could dispute the importance of screening for renal disease, or patient counseling about breast cancer risk factors, or provider involvement in diagnosing and treating women with postpartum depression—a potentially fatal disease. Health care providers, not legislative bodies have to remain at the forefront of identifying appropriate clinical tests and treatments.

CONCLUSION

Despite any local or national legislative initiatives to refine or direct the practice of medicine, physicians must remain advocates for their patients. When considering the laws addressing procedural informed consents, obstetrician–gynecologists should consider the American College of Obstetricians and Gynecologists Committee Opinion stating, “Informed consent should be looked on as a process rather than a signature on a form. This process includes a mutual sharing of information over time between the clinician and the patient to facilitate the patient’s autonomy in the process of making ongoing choices.”²⁹

Physicians should adhere to ethical principles of the profession, recognizing the ultimate responsibilities to their patients. The America Medical Association recently noted, “… its ethical guidelines are not binding by law, although courts have used ethical obligations as the basis for imposing legal obligations… A physician’s legal obligations are defined by the US Constitution, by federal and state laws and regulations, and by the courts.”³⁰ Physicians, as citizens, need to adhere to the law or risk civil or criminal penalties. Perhaps American College of Obstetricians and Gynecologists’s Committee on Ethics could further review this issue, to help physicians struggling with the balance between professional and ethical obligations and legal mandates that may not be entirely congruent with those principles.

Physicians should get involved in legislative advocacy through organized medicine. The websites of both the American Medical Association (www.ama-assn.org) and the American Congress of Obstetricians and Gynecologists (www.acog.org) have active legislative advocacy sites in addition to updates regarding national and regional initiatives. Membership support of these organizations and of their political action committees are other ways physicians can positively influence health policy. State medical societies usually have legislative updates and mechanisms for local advocacy as well.

Many of the aforementioned legislative efforts are clear violations of providers’ professional responsibilities to provide patients with the most current, evidence-based information and to assist patients with their decision making, free from value judgments or political influences. Many of these legislative intrusions into the critically important doctor–patient relationship are driven solely by political agendas, without a clear understanding of the need for both the art and the science of medicine. Some of these bills were, I suspect, written by policy makers with the best of intentions to improve the health of the population, but without the understanding that one truly cannot and should not legislate the practice of medicine. Some of the provisions probably constitute violations to physicians’ First Amendment rights as citizens. More important than all of these considerations, however, is real harm may come to patients if these
laws continue to interfere with patients’ ability to be safe, and have access to the most current medical information available. Our ethical and professional obligation to our patients should not be compromised by political forces. We must advocate on behalf of our patients with legislative bodies trying to take on these issues, by being active participants in the process as citizens and utilizing organized medicine’s myriad of tools. We must never lose sight of the oath we took at our medical school commencements: *primum non nocere*. There were no asterisks after that quote about having our bedside care of the patient being subject to the changing tides of political forces. The doctor–patient relationship, the rock on which all of clinical medicine is built, should be protected and restored.

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