American Board of Genetic Counseling, Inc.
ABGC

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American College of Medical Genetics
Medical Genetics: Translating Genes Into Health™

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VIA FEDERAL EXPRESS

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125 Paterson Street, Clinical Academic Bldg Room 2117
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Re: Opposition to Potential Amendments to Assembly Bill 269

Dear Elena:

The undersigned, on behalf of the organizations which they lead and the thousands of members whom they serve, support Assembly Bill No. 269 (AB269) (and any corresponding Senate bill) and the State of New Jersey's progress toward achieving licensure of genetic counselors. We are greatly troubled, however, by suggestions that this important legislation may be distorted by the inclusion of language that is contrary to a genetic counselor's obligation to respect each patient's right to full disclosure of all appropriate medical options regarding reproductive testing and management of genetic diseases and birth defects. As discussed more fully below, while the enactment of AB269 as it is currently written would have the laudable effect of protecting New Jersey citizens by providing requirements for the licensure of genetic counselors, the addition of any so-called "conscience clause" language would do a great disserve to those citizens by abrogating their legally-protected rights to informed consent and medical self-determination. See Canesi v. Wilson, 158 N.J. 490, 503-04 (N.J. 1999).

DISCUSSION

A. Interests of the Undersigned

1. The American Board of Genetic Counseling, Inc. ("ABGC") is the national credentialing body for the genetic counseling profession. The ABGC defines professional standards and competencies for the practice of genetic counseling through (a) accreditation of educational programs at colleges and universities that have met predetermined and standardized national training criteria, and (2) certification of genetic counselors who have

met predetermined national standards in their training, clinical experiences, and performance on ABGC's National Certification Examination.

ABGC is the only recognized national credentialing body that certifies master's level genetic counselors and accredits genetic counseling programs. The standards for practice and quality of care set by the ABGC have been established and accepted by the profession. Over 2,000 genetic counselors have been awarded ABGC certification – the highest professional credential that can be obtained by a genetic counselor. Thirty genetic counseling graduate programs have obtained ABGC accreditation. ABGC credentials are recognized as the gold standard in the healthcare industry. Genetic counselors with ABGC certification and genetic counseling programs with ABGC accreditation can attest to the profession – and to the public – that this standard has been achieved.

2. <u>The American Board of Medical Genetics</u> ("ABMG") is the national credentialing body for doctoral level medical geneticists. The ABMG defines professional standards and competencies for the education of clinical and laboratory geneticists through (1) the accreditation of post doctoral educational programs that have met predetermined and standardized national training criteria, and (2) certification of M.D.'s and Ph.D.'s who have met predetermined national standards in their training, clinical experiences, and performance on ABMG's National Certification Examination in five specialties and 2 subspecialties of medical genetics.

Up until 1990, ABMG was also certifying master's level genetic counselors. In 1991, the ABMG was invited to become the 24th member board of the American Board of Medical Specialties. At that time, the ABGC established its own board for certification of genetic counselors and accreditation of graduate level genetic counselor training programs. Over 2,700 certificates have been issued by the ABMG.

3. <u>The American College of Medical Genetics</u> ("ACMG") is a private, non-profit, voluntary organization of clinical and laboratory geneticists. The Fellows of the ACMG are doctoral level medical geneticists and other physicians involved in the practice of medical genetics, which includes genetic counseling. The 1,300 members of the ACMG practice in all states. The ACMG promotes the development and implementation of methods to diagnose, treat and prevent genetic disease. In order to fulfill this mission, the ACMG strives to (a) advance the art and sciences of medical genetics by maintaining high standards in education, practice and research; (b) increase access to medical genetic services and improve public health; (c) develop clinical practice guidelines; and (d) establish uniform laboratory standards, quality assurance and proficiency testing. The position of the ACMG is that informed consent is an essential element of all medical decision-making, and that medical geneticists and other genetic counselors may not impose their personal moral values, or substitute their moral judgment, for that of their patients.

B. <u>The Right to Informed Medical and Reproductive Decision-making</u>

Since the time of Hippocrates, a basic tenet of medical ethics has been the patient's right to make decisions regarding his or her medical care. This right can be effectively exercised only if the patient possesses enough information to enable an informed choice. As a corollary to this principle, it has long been recognized that the healthcare provider's obligation – medical, ethical, and legal obligation – is to present the medical facts and options available to the patient, in accordance with applicable standards of medical care, in order to enable the patient's informed decision-making and consent. American Medical Association ("AMA"), Policy E-8.08 *Informed Consent*.

Under New Jersey law, the doctrine of informed consent imposes a duty on a physician "to disclose to the patient all medical information that a reasonably prudent patient would find material before deciding whether to undergo a medical procedure." Acuna v. Turkish, 192 N.J. 399, 415 (N.J. 2007). The doctrine is rooted in the principle that every person has a right to determine what shall be done with his own body. Canesi v. Wilson, 158 N.J. 490, 504 (N.J. 1999) (citing Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972)). Physicians may not substitute their own judgment for that of the patient. See Matthies v. Mastromonaco, 160 N.J. 26, 34 (N.J. 1999) (noting that "the ultimate decision is for the patient"). "The foundation for the physician's duty to disclose in the first place is found in the idea that 'it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie.'" Largey v. Rothman, 110 N.J. 204, 214 (N.J. 1988) (quoting Canterbury, 464 F.2d at 781).

Accordingly, informed consent requires the physician to provide "the patient with adequate information regarding the risks of a given treatment or with adequate information regarding the availability of alternative treatments and the comparative risks and benefits of each." Eagel v. Newman, 325 N.J. Super. 467, 474-75 (App. Div. 1999). Under New Jersey jurisprudence, the precise scope of a physician's communications for the purposes of informed consent depends upon "what a reasonable patient needs to know – that is, what a reasonable patient would likely find significant given the risks – to make an informed decision in foregoing or assenting to a medical procedure." Acuna, 192 N.J. at 415 (italics omitted). Generally, the doctrine of informed consent requires physicians to inform patients of the available medical options, the risks associated with those options, and the nature of the intended procedure. Howard v. Univ. of Med. & Dentistry of N.J., 172 N.J. 537, 548 (N.J. 2002).

Genetic counselors, medical geneticists, and other providers of genetic counseling services are not exempt from this obligation merely because their practice may involve *reproductive* decision-making. Indeed, the right to independent and informed reproductive decision-making is at the very heart of genetic counseling. AMA policy provides that:

> "Physicians engaged in genetic counseling are ethically obligated to provide prospective parents with the basis for an informed decision for childbearing. . . . When counseling prospective parents, physicians should avoid the imposition of their personal moral values and the substitution of their own moral judgment for that of the prospective parents. The

> physician should be aware that where a genetic defect is found in the fetus, prospective parents may request or refuse an abortion. Physicians who consider the legal and ethical requirements applicable to genetic counseling to be in conflict with their moral values and conscience may choose to limit their services to preconception diagnosis and advice or not provide any genetic services. However, the physician who is so disposed is nevertheless obligated to alert prospective parents when a potential genetic problem does exist, so that the patient may decide whether to seek further genetic counseling from another qualified specialist."

AMA Policy E-2.12 *Genetic Counseling* (1994) (emphasis added).

Similarly, the National Society of Genetic Counselors ("NSGC") supports:

> "an individual's right to full disclosure of all appropriate medical options regarding reproductive testing and management of genetic diseases and birth defects. It is the care provider's responsibility to provide effective communication of all available options and to obtain informed consent for procedures involving risk to the individual or fetus."

NSGC Position Statement on *Disclosure and Informed Consent* (1991). In accord is the position of the ACMG:

> "It is inherent in the standard of care for all medical genetics service delivery that patients and families have the right to receive all applicable information that will inform their decision-making."

ACMG Policy Statement on the *Relationship Between the Delivery of Genetic Services and Provider Conscience* (2006).

Genetic counselors and other providers of genetic counseling services are not, of course, required to deliver particular medical genetic services; however, they are required to at least *inform* patients that such services are available and to refer them as appropriate. By imposing their own moral positions, rather than acting in the best interests of their patients, providers limit the range of options available and the breadth of information necessary for the patient's fully informed decision-making. This is completely contrary to the value neutrality of providers which has been a philosophical underpinning of medical genetic services for over a half a century. As a result, the failure to provide all reproductive options available to a couple who have, for example, received a prenatal diagnosis of a severely-affected fetus, is an actionable breach of the standard of care for genetic counselors. See, e.g., Acuna v. Turkish, supra.

In fact, virtually every court in the nation that has addressed such an action – a "wrongful birth" action – has recognized it. In particiular, New Jersey law is clear. "Because the patient's protectable interest is the personal right of self-determination, the doctor's duty of disclosure must be sufficient to enable her to make an informed and meaningful decision concerning whether or not to continue the pregnancy." Canesi, 158 N.J. at 502 (recognizing wrongful birth actions under New Jersey law).

C. Assembly Bill 269

The undersigned and the national organizations and thousands of members they represent all recognize the value of establishing standards for the licensure of genetic counselors. However, if a so-called "conscience clause" is amended to AB269, the core elements of the licensure requirements will have been eviscerated to the point of providing no value to the citizens of New Jersey. Indeed, it would instead poses a serious *threat* to the ability of New Jersey citizens to make informed and meaningful medical decisions.

Among the essential practice-based competencies that define the role of the genetic counselor is the ability to inform, educate and counsel patients, in a non-directive manner, on the total spectrum of options available to them when facing the diagnosis of a genetic disorder, *including the option of pregnancy termination*. Accordingly, this competency must be, and will always be, a required element of genetic counseling training in ABGC and ABMG accredited training programs and a required competency tested by the ABGC/ABMG National Certification Examinations. Accordingly, any attempt to nullify New Jersey medical malpractice law, to deprive the citizens of New Jersey of the benefits of the established standards of care for practicing genetic counselors (as well as other medical geneticists and all other medical professionals), would deny those citizens their Constitutionally-protected right to informed consent in reproductive decision-making.

Moreover, any such attempt would represent nothing more than a very thinly veiled attempt to contort AB269 into an anti-abortion vehicle. It is particularly distasteful in light of the fact that AB269 is a bill that otherwise attempts to ensure that the citizens of New Jersey receive genetic counseling services from individuals who, by virtue of their graduation from a nationally-accredited training program, and their successful completion of national certifying examinations are well-qualified to provide those services according to a nationally established and recognized standard of care. A so-called "conscious clause" amendment would do just the opposite.

Any language that would allow genetic counselors, or any person providing medical or genetic counseling, to substitute their moral values and judgment for that of their patients would completely eviscerate the entire concept of "informed" consent. By shielding such persons from the threat of, inter alia, a malpractice action, such language would deny pregnant women and couples their constitutionally-protected right to freedom of reproductive choice. Griswold v. Connecticut, 381 U.S. 479, 85 S. Ct. 1678, 14 L. Ed. 2d 510 (1965); Eisenstadt v. Baird, 405 U.S. 438, 92 S. Ct. 1029, 31 L. Ed. 2d 349 (1972); Roe v. Wade, 410 U.S. 113, 93 S. Ct. 705, 35 L. Ed. 2d 147 (1973); and Casey, 505 U.S. 833, 112 S. Ct. 2791, 120 L. Ed. 2d 674.

Nor is it sufficient for proponents of such language to say that these patients – who have received intentionally incomplete medical advice – will still have access to information about pregnancy termination from other sources. “[A] provider’s failure to mention abortion as a legal option, in the context of an otherwise neutral medical consultation, could well cause the woman to conclude that abortion is not a legal or medical option for her under the circumstances. Planned Parenthood v. Sullivan, 913 F.2d 1492 (10th Cir. 1990). A patient will not seek further information if she has no reason to believe it available or could be helpful. By permitting genetic counselors to refuse – without fear of consequence – to mention abortion, discuss abortion as a medical option, or provide professional referrals to others who will counsel about *all* medical options, including abortion, such language would deny New Jersey patients their right to reproductive freedom and informed medical decision-making.

* * *

For all of the reasons set forth above, we hereby request that you inform us immediately should you be advised of any proposed amendment to AB269 that includes a so-called “conscience clause”. In that event, we will assure that our position on this critical issue is made clear to the legislators and the citizens of New Jersey.

Should you wish to discuss this matter, please do not hesitate to call any of the undersigned.

Sincerely yours,

AMERICAN BOARD OF GENETIC COUNSELING
By: Robin E. Grubs, PhD, CGC
Title: President
Robin E. Grubs

AMERICAN BOARD OF MEDICAL GENETICS
By: Karla J. Matteson, PhD, FACMG
Title: Executive Director
Karla Matteson

AMERICAN COLLEGE OF MEDICAL GENETICS
By: Joe Leigh Simpson
Title: President
Joe L. Simpson

cc: Michael S. Watson, PhD, FACMG
Lynn D. Fleisher, PhD, JD, FACMG