By Padraic B. Deighan, JD, PhD

Informed Consent

The informed consent process involves more than just sharing risks.

Informed consent is the process by which a treating healthcare provider discloses appropriate information to a patient in order for the patient to make a voluntary choice whether to accept or refuse the proposed treatment. It originates from the legal and ethical rights of the patient to direct what happens to his or her body as well as from the ethical duty of the physician to involve the patient in the healthcare decision-making process.

The most important goal of informed consent is to make sure that the patient is given an opportunity to act as an informed participant in his or her healthcare decisions. It is generally accepted that informed consent includes a discussion of the following elements:

- The nature of the procedure and expected outcomes;
- Reasonable alternatives to the proposed procedure;
- The relevant risks, benefits and uncertainties related to each procedure;
- An assessment of the patient's understanding of the above elements;
- The patient's acceptance of the intervention.

If the recommended procedure involves an "off-label" use of a product or device, the informed consent must include a disclosure that the product is being used in an off-label manner and that the patient understands what the term means (i.e., this is a non-FDA-approved indication).

In order for the patient's consent to be valid, he or she must be legally and mentally competent to make the decision, and the consent must be voluntary. It is true that most aesthetic physicians are not psychiatrists or psychologists; however, objective and prudent judgment should always be utilized and maintained throughout the decision-making process.

It is easy for inherently coercive situations to arise in aesthetic medicine. Patients are often in a position of vulnerability: They do not know the relevant risks versus potential rewards of a particular procedure. A friend who advised them that the surgeon and procedure yielded wonderful results may have referred the patient, meaning that the patient has entered the practice with unrealistic expectations. The patient may have body dysmorphic disorder or other emotional or mental conditions that make informed consent a challenging proposition. These patients are considered vulnerable because the overwhelming desire for self-improvement outweighs their own personal judgment. Therefore, the physician must act as gatekeeper, screening such patients. (In these cases, the decision not to treat a particular patient may be a prudent one.)

EDUCATING THE PATIENT

When presenting information in the informed consent form, the physician should make clear to the patient that they are participating in a decision-making process and not merely signing a necessary form as a matter of procedure. The process should be viewed as an invitation for the patient to ask questions and actively participate in his or her medical aesthetic care.

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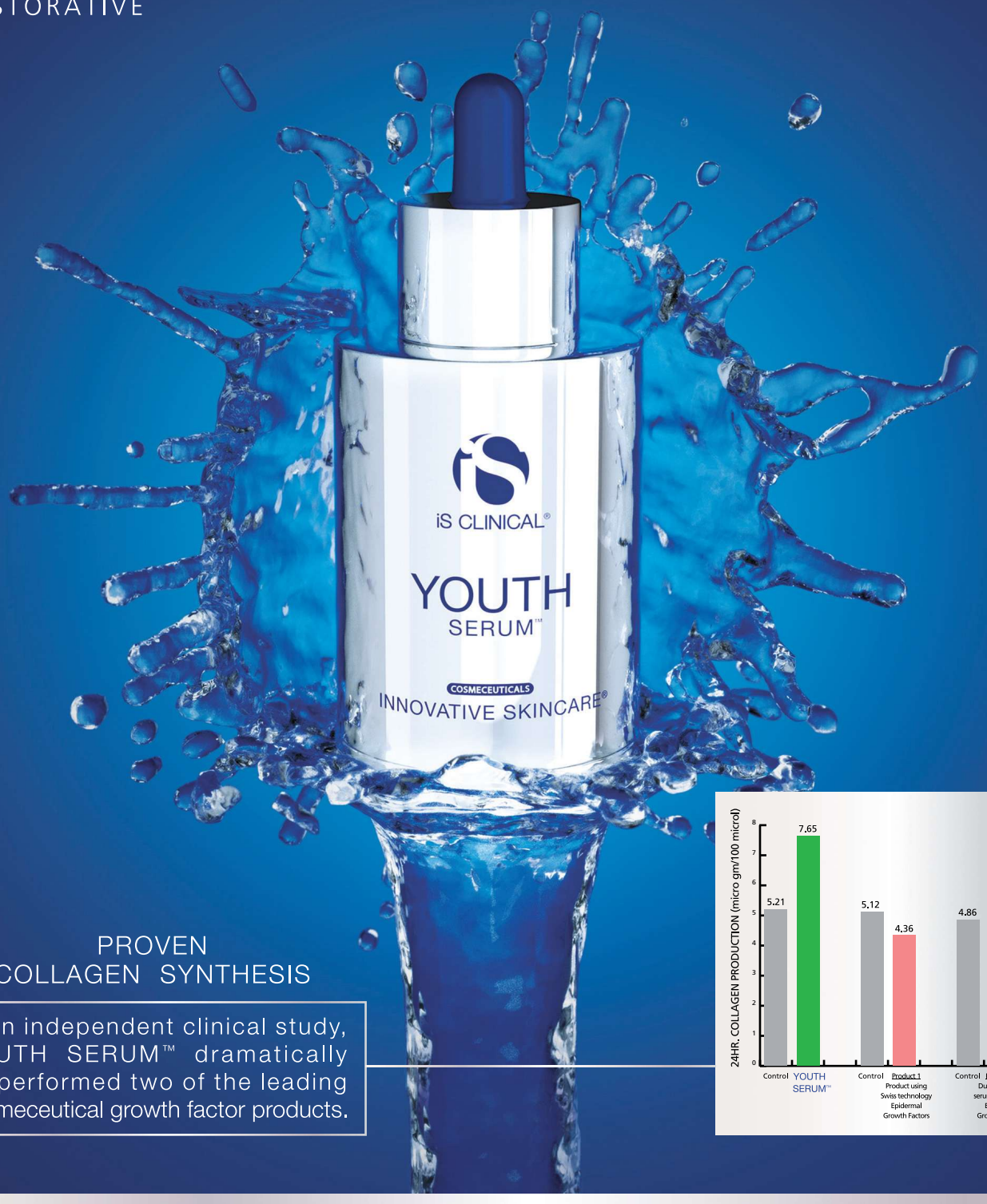

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During this process, the physician provides a treatment recommendation and shares the reasoning behind the recommendation with the patient. Comprehension on the part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in nonmedical terms as much as possible to ensure complete and thorough understanding. The physician should stop to assess the patient's understanding throughout the process.

The type of information included in the informed consent process is relative to the procedure recommended by the physician. An abdominoplasty, for instance, requires a higher level of informed consent than a mild glycolic acid peel, due to the increased risk and recovery period. Keep in mind that informed consent may also apply to procedures performed by nonmedical providers in your facility. This is certainly true of all laser procedures regardless of who—and what scope of license—is performing the treatment.

Noninvasive or minimally invasive treatments, for which there is a consensus that the procedure is the best option (e.g., neurotoxin for glabella lines) or that the procedure is relatively low risk, require only basic informed consent with a low level of patient involvement. If a patient does not consent under the paradigm of basic consent, then a fuller informed consent discussion is warranted.

Minors and Informed Consent

If a procedure is being performed on a minor, the patient's parent must provide informed consent. Unfortunately, there are cases in cosmetic medicine where the parent wants an aesthetic treatment performed on the child more than the child actually wants to have the procedure performed. Therefore, it is sound policy to require additional informed consent when performing a treatment on a minor. This may include an interview with the minor patient absent the parent's presence as well as further discussion and a review of the patient's healthcare records, especially if the minor has received emotional or mental health counseling services.

WHAT TO INCLUDE?

Given the wide range of treatment options and modalities in cosmetic medicine, practices are best served by creating multiple informed consent forms and processes based on the type of procedure performed. There are three basic approaches to determining the amount of information required for informed consent:

1. **Reasonable physician standard**: This standard allows the physician to determine what information is appropriate to disclose based on what a typical aesthetic physician would share in regard to a particular procedure. This standard may be inadequate for most procedures for two reasons: First, it is generally considered inconsistent with the goals of informed consent, as the focus is on the physician rather than on what the patient needs to know. Second, there is little standardization of care in aesthetic medicine. For example, protocols for liposuction vary widely, making it difficult to assess a "reasonable physician standard" for a liposuction procedure. Most aesthetic physicians utilize some variation of this standard, though it may not be sufficient or appropriate in today's medical, legal and ethical environment.

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2. **Reasonable patient standard**: This standard focuses on what a typical patient would need to know in order to understand the decision at hand. It involves stepping into the patient's shoes and considering what the average patient would want or need to know in order to make an informed decision regarding the procedure.

3. **Subjective standard**: This standard is the most challenging to incorporate into practice, since it requires customization of information to each patient. In this case, the physician must determine what this *particular* patient needs to know and understand in order to make an informed decision. Based on the wide range of treatment options available, the many variations in the delivery of a particular treatment and the subjective nature of patient satisfaction with outcomes, this may be the best option for most aesthetic medical practices today.

Informed consent has evolved over the years, and it is important for aesthetic physicians to review their consent guidelines regularly. This involves more than a review of the forms presented to the patient for signature. Physicians should review their entire education and information exchange process, including a review of any patient coordinator functions and any new procedures that have been introduced into the practice since the last informed consent review.

Always keep in mind that true, informed consent involves a consideration of the risk, benefits and alternatives to treatment; legal and financial considerations; and current ethical guidelines. ME

Padraic B. Deighan, JD, PhD, is president of Aston McLaren, a medical and spa consulting firm, and the former president and CEO of DermAmerica, the nation's largest network of dermatology and plastic surgery centers. Contact him at 877.557.9669, medicalandspaconsulting.com.