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A Letter from the Chair of the Board

PROMISES, PROMISES...

Famous Quotes:

"We're gonna win the pennant this year!"

"Expect sunny skies this weekend!"

"And, if elected..."

Do any of these sound familiar? Have you ever made a promise you just couldn't keep, or guaranteed something that later turned out not to be the case? Many of us have done this in our personal lives and under certain circumstances, grandiose promises made and not kept are no big deal, but how about in a clinical context? Making unrealistic promises may not only be problematic for Physicians, but can damage the Patient-Doctor relationship and make unhappy patients more inclined to bring a lawsuit.

Promising more than he could deliver created a problem in the following case:

An adult female sustained a left hand injury while working at home. Her hand immediately became

Continued on next page

Elizabeth A. Svoysky
Assistant Vice President - Risk Management

Dear Colleague:

There probably isn't a day that goes by that you don't hear about promises being made and broken. Some of these broken promises carry consequences, some do not.

Promises made by Physicians and other health care providers can be an issue if your patients have relied on them and been disappointed or even injured as a result. This issue of the newsletter looks at two cases which illustrate how promises made in the clinical setting led to medical malpractice litigation and informed consent issues.

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Chair of the Board

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swollen and discolored. She was seen at the local hospital where she was given Ibuprofen and Flexeril and the injured hand placed in a splint. X-rays taken at the hospital showed no evidence of a bone, joint or soft tissue injury. Two days after the injury, she was seen by our Insured hand surgeon for further evaluation. He diagnosed a sprain, advised contrast baths and placed her in a wrist splint. At the follow-up visit, the patient still complained about discomfort. A repeat x-ray again showed no evidence of fracture. Our Insured prescribed an anti-inflammatory and continuation of the contrast baths.

Two weeks later, the patient was still complaining of discomfort and our Insured recommended surgical excision of an organized hematoma. According to the patient's later deposition testimony, she recalled our Insured advising her that it would be a simple procedure, a fast recovery, and that everything would turn out just fine. She further stated that when she asked him if this was definitely going to take care of the problem, he responded, "yes, it will take care of it." The patient agreed to have the surgery expecting to be pain-free as a result. Subsequently, the patient still complained of discomfort as well as numbness over the fourth and fifth fingers. Our Insured felt that this was



all part of the healing process and that the problems would diminish with time. When this didn't happen, the patient sought a second opinion.

Additional surgery was ultimately performed by another surgeon with some improvement. It was alleged in the resulting lawsuit that our Insured had apparently cut a nerve during the excision of the hematoma. An informed consent count was added which alleged that our Insured had failed to provide information regarding possible risks of going ahead with the excision.

What initially got this Physician into trouble with this patient were his assurances about an end result that ultimately did not occur. In his deposition testimony, the Insured stated that he provided the patient with positive reinforcement about going ahead with the surgery and that once the hematoma had been removed, the source of discomfort and, therefore, the discomfort in her hand would be better. The Insured did not document his verbal discussion with the patient regarding risks of the surgery, and did not include nerve injury as one of those possible risks.

Here's another example of how guaranteeing a perfect result only encouraged a lawsuit:



An adult female patient was referred to our Insured surgical group for treatment of gallstones confirmed by sonogram. A laparoscopic cholecystectomy was performed by our Insured. Three days after surgery, the patient was seen by another member of the group for complaints of abdominal pain and vomiting. Diagnostic and lab tests were ordered to check for a bile duct injury or leakage. The patient was seen again in follow-up. Because she was miserable from continued abdominal and flank pain, she was readmitted. She was scheduled for an exploratory laparoscopic procedure following a positive scan for bile leakage.

An ERCP was not ordered because this was not available on the weekend when the patient was readmitted. Surgery revealed that the two clips which had been placed on the cystic duct stump during the prior procedure were not completely covering the entire cystic duct stump. Other sources of leakage were found in the biliary tree.

Repair to the cystic duct stump was performed and a cholangiogram indicated no further leakage. The Insured did not place drains as she did not feel they were necessary since she felt she had fully cleaned out the abdomen and fixed the leakage problem. The patient was followed by the group for several weeks with continued complaints of pain and lack of appetite. Eventually, a CT scan indicated a large biloma.

The patient did not follow up with our Insured but self-referred to another Physician. In a conversation with the new surgeon, our Insured advised against his plan for an ERCP given the normal cholangiogram following her repair. The ERCP was subsequently cancelled and the patient treated with percutaneous drainage instead. Since the patient's condition did not improve, the new Physician performed an ERCP, which revealed additional bile leakage. Surgery was performed with good results and a full recovery. The patient had no further medical care for any problems related to the bile leakage.

The patient's medical course, though not preferred, was certainly not outside of the realm of possible





CME Evaluation Form

Statement of Educational Purpose

"Doctors RX" is a newsletter sent twice each year to the Insured Physicians of MEDICAL MUTUAL/Professionals Advocate®. Its mission and educational purpose is to identify current health care related risk management issues and provide Physicians with educational information that will enable them to reduce their malpractice liability risk.

Readers of the newsletter should be able to obtain the following educational objectives:

- 1) Gain information on topics of particular importance to them as Physicians,
- 2) Assess the newsletter's value to them as practicing Physicians, and
- 3) Assess how this information may influence their own practices.

CME Objectives for "Promises, Promises..."

Educational Objectives: Participants should be able to:

- 1) Understand the ramifications of making promises to patients regarding treatment outcomes,
- 2) Describe the concept of informed consent, and
- 3) Address unrealistic expectations in patient care.

	Strongly Agree		Strongly Disagree
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Part 1. Educational Value:

5 4 3 2 1

I learned something new that was important.

I verified some important information.

I plan to seek more information on this topic.

This information is likely to have an impact on my practice.

Part 2. Commitment to Change: What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

Part 3. Statement of Completion: I attest to having completed the CME activity.

Signature: _____ Date: _____

Part 4. Identifying Information: Please PRINT legibly or type the following:

Name: _____ Telephone Number: _____

Address: _____



CME Test Questions

Instructions for CME Participation

CME Accreditation Statement — MEDICAL MUTUAL Liability Insurance Society of Maryland, which is affiliated with the Professionals Advocate® Insurance Company, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for Physicians. MEDICAL MUTUAL designates this educational activity for a maximum of 1.0 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Instructions—to receive credit, please follow these steps:

1. Read the articles contained in the newsletter and then answer the test questions.
2. Mail or fax your completed answers for grading:

Med•Lantic Management Services, Inc.	Fax: 410-785-2631
225 International Circle	
P.O. Box 8016	
Hunt Valley, Maryland 21030	
Attention: Risk Management Services Dept.	

3. One of our goals is to assess the continuing educational needs of our readers so we may enhance the educational effectiveness of the Doctors RX. To achieve this goal, we need your help. You must complete the CME evaluation form to receive credit.
4. Completion Deadline: October 10, 2008
5. Upon completion of the test and evaluation form, a certificate of credit will be mailed to you.

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1. The doctrine of medical informed consent is based on the intentional tort of assault.</p> <p style="text-align: center;">A. True B. False</p> | <p>6. Once you have completed your verbal discussion of the risks and benefits of a procedure, you are effectively finished with the informed consent process.</p> <p style="text-align: center;">A. True B. False</p> |
| <p>2. Maryland law requires Physicians to advise their patients of all possible risks.</p> <p style="text-align: center;">A. True B. False</p> | <p>7. Making unrealistic promises to patients raises the failure bar.</p> <p style="text-align: center;">A. True B. False</p> |
| <p>3. The purpose of informed consent is to tell patients what to do.</p> <p style="text-align: center;">A. True B. False</p> | <p>8. A Physician cannot be sued if his/her intentions are good.</p> <p style="text-align: center;">A. True B. False</p> |
| <p>4. Patients need to know that an expectation of a particular result is not a guarantee of success.</p> <p style="text-align: center;">A. True B. False</p> | <p>9. Language barriers make the informed consent process more challenging.</p> <p style="text-align: center;">A. True B. False</p> |
| <p>5. The amount of information that must be disclosed depends on the nature of the procedure.</p> <p style="text-align: center;">A. True B. False</p> | <p>10. If disclosure of all material risks would not have changed the patient's decision about going ahead, then there is no causative connection between the nondisclosure and the patient's damages.</p> <p style="text-align: center;">A. True B. False</p> |

complications. and, if only considering the medicine, could have been defensible if the following promise had not been given by the Physician regarding the repair. In her deposition, the patient stated that, not only was she upset about having multiple leaks, but that our Insured had guaranteed 100% success with the repair of the leak, which obviously didn't happen. Once again, as in the first case scenario, the patient based her decision regarding whether to have additional treatment on the "sure thing" promised by our Insured.

What both of these cases have in common are promises of a result made by the treating Physician that did not materialize. What they also have are angry patients that took their anger and desire for information to an attorney. The attorney then put together an informed consent allegation out of the promises that were made and subsequently broken.



There are many aspects of practice that can create problems for Physicians when promises are made and not kept. Sometimes very dependent patients can lead a Physician into promising that he/she will always be available for them, that they won't have to see some partner (or staff member) they don't like, or that the patient can always get their preferred Physician seven days a week, 365 days a year. No Physician can always be that available. Promising and not delivering can only lead to disappointment and disillusionment on the part of the patient. Another example that sometimes arises is promising to call a patient after surgery to see how he/she is doing and being unable to honor that promise because of situations out of a Physician's control. This otherwise good intention leads to patient dissatisfaction and a feeling that the Physician **just doesn't care** – the opposite of what was desired. Never promise what you can't deliver!

Problems of perception can also arise in the clinical setting. If a Physician tells a patient that he/she expects the patient to be home in a couple of days without pain or other problems, the expectation verbalized by the Physician is perceived as a promise on the part of the patient. The Physician needs to make clear that an **expectation** of a particular result is not a guarantee of its success. It is always better to exceed the expectation than to raise it and disappoint.

Failing to meet patient expectations based on promises made and not kept in the health care setting can lead to



anger and, ultimately, to a plaintiff's attorney. The plaintiff's attorney takes the patient's anger at the broken promise (and unexpected injury) and often molds it into an **informed consent** allegation in the resultant medical malpractice lawsuit.

Where does the concept of informed consent come from? Medical informed consent law as we know it today developed from the intentional tort of "battery," which provides protection to individuals from unwanted physical touching of the body without either their express or implied consent. Battery occurs in a medical setting when a Physician performs a procedure without the consent of the patient; performs a different procedure than the one consented to; or has someone else perform the procedure without the patient's knowledge or consent. The "informed" part of informed consent comes into play when the patient's decision (consent) is based on the knowledge of his/her condition, the available options for treatment, known risks, etc.

Virtually all states recognize, either by statute or by case law, the concept of informed consent. Over the years, medical informed consent issues have revolved around what the Physician disclosed to the patient about a recommended treatment or procedure. The doctrine of informed consent imposes on a **Physician**, before he subjects his patient to medical treatment, the following **duty**:

1. To explain the procedure to the patient; and
2. To warn the patient of any material risks or dangers inherent in or collateral to the therapy,

...so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment.

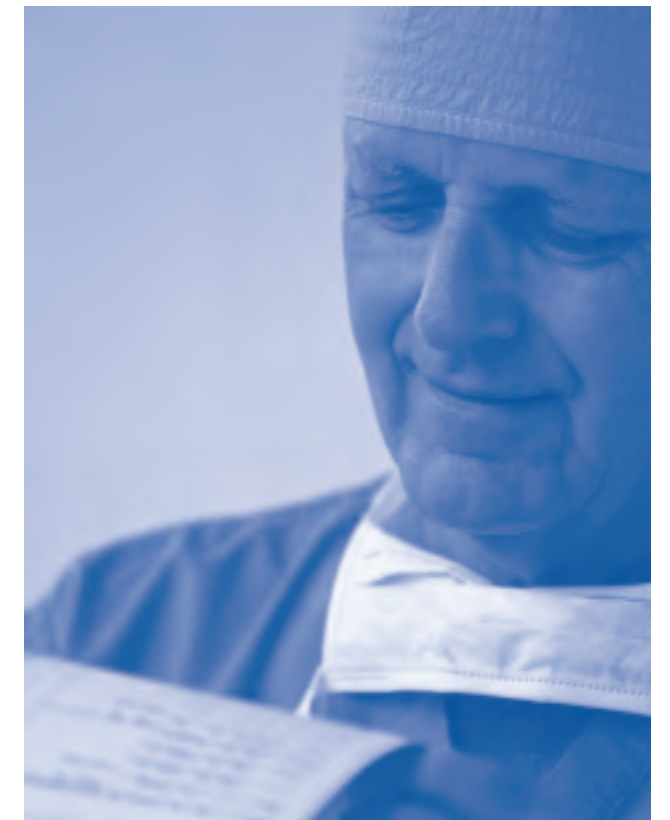
This duty to disclose requires a Physician to provide the patient with the following information:

1. The nature of the ailment
2. The nature of the proposed treatment
3. The probability of success of the contemplated therapy
4. The probability of success of its alternatives
5. The risk of unfortunate consequences associated with such treatment

In other words, it is **not** the duty of the patient to ask. It is, however, the duty of the Physician to disclose.¹

There is no state statute in **Maryland** regarding informed consent; only case law that has evolved over the years. It is an objective standard not requiring expert testimony except to the extent that the jury needs to know medically what the potential risks of a procedure or treatment are. The scope of the Physician's duty to inform is measured by the **materiality** of the information to the decision-making process of the patient (i.e. material risks). A material risk is one which a Physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure.

Whether or not a Physician has fulfilled his/her duty to disclose is determined by reference to a general standard of reasonable conduct and is not measured by a professional standard of care. Physicians frequently inquire about the amount of information necessary to have a true informed consent (i.e. how much is enough?). Maryland courts have provided a series of limitations on the duty to disclose such that Physicians are not obligated to deliver a dissertation on the





subject, but rather should inform the patient of only those risks which are material to the intelligent decision of a reasonably prudent patient.

Maryland law also provides that Physicians do not have to disclose information where the risk is either known to the patient or is so obvious as to be presumed. The Physician is under no duty to discuss **rare or remote** risks where it is common knowledge that risks inherent in the procedure have a very low incidence of occurring. However, Maryland courts have not yet defined what constitutes a rare risk. Other states have attempted to do so (e.g. less than 1% chance of occurring).

When an informed consent allegation is part of a medical malpractice claim, the plaintiff will be required to prove that a reasonable person in the patient's position would have withheld consent if all **material** risks had been disclosed. If disclosure of all material risks would **not** have changed the decision of a reasonable person in the patient's position, there is then **no** causative connection between the nondisclosure and the patient's damage and the lack of informed consent count fails.



Virginia case law on informed consent favors a two-pronged approach. First, "what would a reasonable Physician disclose" or the reasonable Physician standard.

In an informed consent situation, the patient must show by expert testimony that "prevailing medical practice requires disclosure of certain information, that the information is material to an informed decision on treatment, and that disclosure would not pose an unreasonable threat of detriment to the patient's well-being or to his ability to make a rational decision." Second, "if informed of the risks, benefits and alternatives, what would a reasonable patient do under the same circumstances?"² Many jurisdictions require expert testimony as to what a reasonable patient would do. The Supreme Court of Virginia has not discussed this issue. Presumably it would use the reasonable patient standard (what would the **average** patient need to know in order to be an informed participant in the decision?), in contrast to the **District of Columbia** which uses a subjective patient standard (what would **this** patient need to know and understand in order to make an informed decision?). The Supreme Court of Virginia has expressly rejected the subjective standard.

The amount of information that must be disclosed to a patient ranges based on the procedure being performed. A Physician in Virginia does not need to communicate information that a patient already knows or of which any reasonably intelligent person should be aware.

There may be additional barriers during the informed consent process that Physicians must work through. These can include physical problems or issues of limited proficiency in English that make communication of information difficult. The Physician who has worked through these barriers understands that he/she has given the patient (or the patient's surrogate) the knowledge



necessary to make an informed decision regarding appropriate medical care.

Summary:

The informed consent discussion is your best (and possibly last) chance to detect unrealistic expectations prior to going ahead with a treatment plan or procedure. Don't guarantee results. Make your patient a part of the process and **document** your discussions. The purpose of informed consent is to give patients the opportunity to participate in the health care decisions that ultimately affect them. This includes understanding the associated risks and complications of the recommended treatment/procedure. The patient who has assumed responsibility for a treatment decision may be less likely to blame you if the outcome is less than what was hoped for.

Promises in and of themselves are not always a bad thing. Promising more than you can deliver as a Physician can be. Basic medical consent law involves letting the patient know what you would like to do and asking if that's okay. In conversations with your patients about proposed treatments or procedures, it is important to help them understand that while you always strive for a good result, every patient is uniquely different and the outcome is not guaranteed. The goal is to create reasonable expectations so that your patient does not feel like the victim of a broken promise.



References

1. Sard V Hardy, 281 Md. 432, 379a.2d 1014, 1020 (1977)
2. Virginia Medical Malpractice Act, VA Code 8.01-581.1 et seq

Doctors RX

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