Leonard Berlin, MD, FCR, is Professor of Radiology at Rush Medical College and the University of Illinois College of Medicine. He has been a contributor to more than 430 medical journal articles, presenter of 385 lectures, and author of the book Malpractice Issues in Radiology. But it was his role as a participant in the Society to Improve Diagnosis in Medicine’s listserv discussion that we noticed his work on an intriguing notion, “incidentalomas.” While not yet linked to a high volume of MPL claims, it is likely that their numbers will increase, as imaging and other testing modalities become ever more powerful.

Inside Medical Liability: For anyone unfamiliar with the term, what is an “incidentaloma”? Berlin: “Incidentaloma” is a colloquial term for incidental findings. It is defined as an incidentally discovered mass or lesion detected by a CT or other imaging modality that was performed for an unrelated reason.

Two examples: incidentally discovered benign thyroid nodules, now common on ultrasound studies of the neck, and false-positive findings suggesting Alzheimer’s and related neurodegenerative diseases that cause dementia are increasing in amyloid PET studies.

There are numerous reports in the radiology literature about clinically incidental CNS findings in patients who undergo procedures like MR scanning, whole-body MR screening, and MR research studies.

But the major cause of the increase in incidentalomas is the rapid expansion in CT scanning—which is accessible, quick, and relatively inexpensive.

In 1980, fewer than 3 million CT scans were done. But since then, the volume of CT scans has increased by 10% each year. By 2009, the number had increased to 80 million per year.

IML: What is the estimated incidence of these incidentalomas, per year?

Berlin: Here are data from several recent studies:

- Among patients undergoing aortoiliac CT angiography, 49%
- In patients being imaged by CT for staging of prostate cancer, 82%
- Among patients undergoing research imaging exams at the Mayo Clinic, 67%.

But in fact, the consequences of these discoveries are minimal: one study by Welch and colleagues published in 2011 revealed that less than 1% of lung nodules, and less than 1% of incidentalomas elsewhere, evolves into a lethal carcinoma.

IML: Why have they emerged as a bigger problem in recent years—more powerful imaging tools, for sure, but are there other developments involved as well?

Berlin: Well, there is also the massive increase in the utilization of every sort of high-tech imaging modalities, not just in CT scans. There is also ultrasound, positron emission tomography, and magnetic resonance imaging.

IML: What is the fundamental ethical dilemma for radiologists in regard to incidentalomas?

Berlin: If the radiologist believes that there is a reasonable likelihood that the incidentaloma is of no clinical significance, then reporting it, will no doubt lead to a battery of high-priced tests—and some of these may, ironically, result in very real iatrogenic complications.

But if the radiologist does not report the incidentaloma, and while improbable, it does turn out to have been a carcinoma or other serious disease, the patient may be harmed, and medical professional litigation may well follow.

IML: Are radiologists required to report all findings to patients?

Berlin: Over the years, U.S. Appeals courts have increasingly stressed what is termed a “patient’s rights of self-determination,” under which physicians must reveal to their patients all of the relevant medical information. In 2004, in (Stanley v McCarver), the court stated that: “A doctor who undertakes to read x-rays, on which he observes abnormalities, must act reasonably in reading the x-rays and reporting the results.” Who decides about this? The court in this case said, “What constitutes reasonable reporting must be determined by a jury.”

IML: Has the American Medical Association weighed in on a physician’s duty with incidental findings?

Berlin: Yes. In 2015, the AMA’s Council on Ethical and Judicial Affairs stated: “The physician’s obligation is to present the
medical facts accurately...and disclose all relevant information to patients.”

IML: But are those statements of much practical use to a radiologist who discerns an incidental finding?

Berlin: No. Fundamental questions remain. For example, can an incidentaloma be considered “relevant medical information”?

IML: Are there applicable standards of care for incidentalomas?

Berlin: Well, the established standard of care, overall, is this: “Use of the same degree of knowledge, skill, and ability as any careful physician would exercise under similar circumstances” (Advincula v United Blood Services 1996).

But what is considered “usual and customary conduct” in confronting the enigma of an incidentaloma? If every radiologist managed incidentalomas in the same way, the standard of care would be clear. But studies of what they do indicate a marked lack of consistency: some radiologists report them; others ignore them.

The American College of Radiology published a “white paper” that specified guidelines that they hoped would help radiologists become more consistent in deciding whether to report an incidental finding, based on specific characteristics. But in a survey of 14,200 radiologists, wherein 20% (2,865) responded, only 34% said that they adhered to these guidelines.

IML: So what, in practice, do radiologists do with incidentalomas, when considering their response to an incidental finding?

Berlin: One study, by Berland et al. (2014) found that 76% of them recommended additional imaging studies—because they worry about being sued.

IML: Can you give me an example of how that affects clinical practice?

Berlin: A notable expert in obstetrical ultrasound, Dr. Roy Filly, says that fully 10% of sonograms contain apparent abnormalities that can be interpreted as markers of Down syndrome. Most of these are clinically unimportant, since Down syndrome is in fact very rare.

Dr. Filly struggled with the question of whether he should tell his patients about these findings. He asked himself, “Should I have the courage of my convictions and ignore these features?” He concluded that he did not—because in today’s medicolegal climate, it is simply not possible to ignore incidentalomas.

IML: What happens in the courtroom when an incidentaloma—against all probability turns out to be something dangerous?

Berlin: It can be a hard case to defend. This is what happened to a radiologist who was sued because she decided not to report an incidentaloma because it was almost certainly benign. But it later turned out to be a carcinoma.

The plaintiff’s attorney asked if the incidentaloma “could have represented an early cancer.”

The defendant radiologists responded, “Yes, but probably no more than a 1% chance.

And then the plaintiff’s attorney said, “Well, doctor, in this case, it was 100%.” He added, “Shouldn’t you have let the patient and his private physician decide whether further testing was indicated?”

The radiologist had to say “yes,” and the jury found in favor of the patient.

IML: Do you have any advice for physicians in considering whether to disclose incidentalomas to a patient?

Berlin: If a radiologist does decide to report an incidental finding, I would suggest that the following caveat be included: “An incidental density (or lesion) measuring xx mm is noted in the liver (or the kidney, lungs, etc.). The likelihood that this represents a malignancy is highly remote.”

With that said, the decision about whether to undertake follow-up studies, and if so, which ones, is handed off to the referring physician and the patient.