Patient Complaints and Risk of Being Sued

To the Editor: Dr Hickson and colleagues[1] found that physicians who had received more complaints from patients were also more likely to be sued for malpractice. I wish to report another scenario that is related to billing and may generate complaints and lawsuits.

It is not uncommon, particularly for patients with Medicare and a secondary insurer, for 3 to 6 months to pass before they receive the first bill from the physician's office. The patients may then be dismayed to find that they are said to be 90 to 150 days in arrears on payment. This common practice cannot help but add a significant degree of annoyance and irritation and, if there are other areas of dissatisfaction, may well trigger a lawsuit.

Billing is frequently outsourced or computerized. These programs should be changed to avoid presenting patients with late-payment bills. Given our present system, a bill's due date should begin with the first billing to the patient, not the date of care.

Garth K. Graham, MD
West Chester, Pa

1. Hickson GB, Federspiel CF, Pichert JW, Miller CS, Gauld-Jaeger J, Bost P. Patient complaints and malpractice risk. *JAMA*. 2002;287:2951-2957.

To the Editor: Dr Hickson and colleagues[1] found that malpractice risk is correlated with the number of patient complaints. This result agrees with those of earlier studies that show malpractice risk is associated with shorter office visits and patients' feelings of being rushed and ignored.[2,3] Hickson et al suggest that teaching physicians interpersonal skills will mitigate the risk of lawsuits. Unfortunately, short office visits, rushing of patients, and high levels of clinical activity are not due primarily to insensitive physicians. Rather, they are often deliberate products of the managed care system.

Managed care is supposed to reduce medical waste by limiting physician activity to financially measurable care. Unfortunately, good patient communication and rapport are not reimbursable. Managed care organizations maximize profit by increasing physician case load, creating a mass production–like mentality. Physicians who spend time communicating with patients are punished with reduced compensation, although physicians who do not are faced with unhappy patients and the risk of lawsuits. Managed care organizations have little reason to worry about the costs of malpractice litigation, since they are effectively shielded from liability.

Michael W. Itagaki, BA
University of Illinois College of Medicine
Urbana

1. Hickson GB, Federspiel CF, Pichert JW, Miller CS, Gauld-Jaeger J, Bost P. Patient complaints and malpractice risk. *JAMA*. 2002;287:2951-2957.
2. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. *JAMA*. 1997;277:553-559.
3. Hickson GB, Clayton EW, Entman SS, et al. Obstetricians' prior malpractice experience and patients' satisfaction with care. *JAMA*. 1994;272:1583-1587.

To the Editor: Dr Hickson and colleagues[1] present evidence that patient dissatisfaction can lead to lawsuits. However, this study is flawed because it did not consider that some physicians are quick to identify and eliminate from their practices those patients who they think have a low threshold for starting lawsuits. For example, some physicians with few patient complaints may have simply minimized their exposure and subsequently minimized their risk of being sued.

It is also unclear how often other family members' anger can instigate a lawsuit that otherwise would not have been set in motion. When an unexpected complication occurs, a distant relative who has not been involved in the case or who has not seen the patient in years may suddenly become involved and influence the momentum of the case. In my experience, they are quick to question the physician's ability and the quality of the hospital and nursing staff—in short, they create discord. The "concerned" relative has done nothing but create difficulties for everyone involved and has unknowingly facilitated a potential lawsuit. It would be interesting to have some data on this phenomenon.

Edward Volpintesta, MD
Bethel, Conn

1. Hickson GB, Federspiel CF, Pichert JW, Miller CS, Gauld-Jaeger J, Bost P. Patient complaints and malpractice risks. *JAMA*. 2002;287:2951-2957.

In Reply: We agree with Dr Graham that billing and collection processes are often complex, untimely, and incomprehensible. They may precipitate patient complaints and, sometimes, lawsuits. In a previous study, 24% of families who filed malpractice claims said they did so only after receiving a large bill or collection notice.[1] Medical groups should appreciate that patient dissatisfaction with care and outcomes may boil over when the bill arrives. Not surprisingly, then, one element of risk management involves careful attention to whatever control physicians may have over their billing processes.

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Letters Section Editor: Stephen J. Lurie, MD, PhD, Senior Editor.

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Mr Itagaki also correctly identifies another source of dissatisfaction—patients' sense that office visits are too brief. These perceptions may be due to insensitive staff or harried physicians, reimbursement-related pressures, seasonal variations in patient loads (eg, flu season), or failures to create appropriate, realistic expectations of visit lengths. Good doctoring requires time to involve patients, ask open-ended questions, identify needs, and respond appropriately. Within our study, some physicians with large patient volumes handled the task without generating complaints. Others did not. We need to learn from the former and be concerned for the latter, who may need training in how and why to establish and maintain rapport across a range of circumstances. They may also need to restructure their management systems. Armed with an understanding of dissatisfaction's consequences, medical professionals may be better equipped to make wise practice choices, including how many patients they can treat and how to promote reasonable expectations.

Dr Volpintesta asserts the reasonable hypothesis that certain patients have low thresholds for filing a lawsuit. The argument seems to follow that if such patients could be identified, they might be treated more carefully or dismissed from a practice, perhaps lessening that physician's malpractice risk. One study identified a few patient characteristics associated with somewhat increased risk of lawsuits, including higher education and affluence.[2] We cannot envision, however, how such factors could reliably and validly serve as the basis for identifying high-risk patients.

On the other hand, our data suggest that much might be done to proactively reduce individual physicians' risk of being sued. Some physicians, whether because of interpersonal or systems failures, attract disproportionate numbers of suits[3,4] and, as we have shown, patient complaints. If patients can be encouraged to offer specific observations and their complaints can be captured, reliably coded, and aggregated, the resulting complaint profiles may help identify health professionals and practices[5] at highest risk and suggest the reasons why. We do not know how to reliably identify high-risk patients, but our data suggest that, with patients' help, we can reliably identify high-risk physicians and practices.

Gerald B. Hickson, MD
Department of Pediatrics
James W. Pichert, PhD
Department of Medicine
Cynthia S. Miller, MSSW
Department of Social Work
Jean Gauld-Jaeger, MS
Department of Patient Affairs
Vanderbilt School of Medicine
Charles F. Federspiel, PhD
Department of Preventive Medicine
Vanderbilt School of Medicine
Nashville, Tenn
Preston Bost, PhD
Department of Pediatric Psychiatry
Wabash College
Wabash, Ind

1. Hickson GB, Clayton EW, Githens PB, Sloan FA. Factors that prompted families to file malpractice claims following perinatal injuries. *JAMA*. 1992;267:1359-1363.
2. Burstin HR, Johnson WG, Lipsitz SR, Brennan TA. Do the poor sue more? a case-control study of malpractice claims and socioeconomic status. *JAMA*. 1993; 270:1697-1701.
3. Sloan F, Mergenhagen EM, Burfield B, Bovbjerg RR, Hassan M. Medical malpractice experience of physicians: predictable or haphazard? *JAMA*. 1989;262: 3291-3297.
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Tobacco Advertising and Freedom of Speech

To the Editor: In response to repeated US Supreme Court decisions that have struck down attempts to regulate tobacco advertising, Dr Bayer and colleagues[1] advocate a strategy of counteradvertising coordinated by the Centers for Disease Control and Prevention. They suggest that this campaign could be funded by an excise tax that would raise approximately 20% each year of what the tobacco industry spends to promote its products.[2] They also propose that 50% of each print advertisement be composed of health warnings and that all cigarette packs contain a graphic picture of pathology caused by smoking.

While Bayer et al discuss this reactive role for Congress (eg, sponsoring counteradvertising), they do not describe what Congress should do to eradicate tobacco from American society. Such measures might include banning all advertising, creating "adults only" retail outlets, or stigmatizing smoking through countermarketing and restrictions on smoking in public places.

For Congress to initiate such policies, there must be a shift from treating tobacco products as products that can be legally made, promoted, and sold everywhere by private corporations to those that cannot. Clearly, corporations, which are not mentioned in the US Constitution, do not have an inherent right to produce and promote toxic products. In apparent agreement with this view, a former Food and Drug Administration (FDA) Commissioner has now concluded that the public health would be better served if Congress were to charter a not-for-profit corporation to manufacture and sell tobacco products.[3] To accomplish this goal, I have proposed a Toxic-Tobacco Law.[4] Although litigious and regulatory battles against the tobacco industry have been important elements in the war to reduce the morbidity and mortality caused by tobacco, I believe that it is now time to establish legislative strategy to eradicate tobacco use.

Terence A. Gerace, EdM, MA, PhD
Toxic-Tobacco Law Coalition
Washington, DC

1. Bayer R, Gostin LO, Javitt GH, Brandt A. Tobacco advertising in the United States: a proposal for a constitutionally acceptable form of regulation. *JAMA*. 2002;287: 2990-2995.
2. Federal Trade Commission Cigarette Report for 2000. Available at: http://www.ftc.gov/os/2002/05/2002cigrpt.pdf. Accessibility verified June 24, 2002.
3. Kessler DA. *A Question of Intent: A Great American Battle With a Deadly Industry*. New York, NY: PublicAffairs; 2001.
4. Gerace TA. The Toxic-Tobacco Law: "appropriate remedial action." *J Public Health Policy*. 1999;20:394-407.

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To the Editor: In their review of tobacco advertising and the First Amendment, Dr Bayer and colleagues[1] omit what may be the most constitutionally plausible type of regulation—the restriction of advertising to a "text-only" format, as recommended by the Institute of Medicine's 1994 report entitled *Growing Up Tobacco Free*[2] and subsequently embraced by the FDA in its 1996 Tobacco Rule.[3] Although this portion of the FDA regulation was invalidated by the federal district court[4] and never took effect, it was struck down because it exceeded the authority conferred on the FDA by Congress, not because it violated the First Amendment.

The text-only approach allows information (eg, price and product characteristics) to be communicated while banning images and messages designed to portray tobacco use as attractive and beneficial. These images and messages tend to encourage children and young people to have favorable attitudes toward tobacco use and thereby to encourage initiation. The distinction between informational advertising and image (or lifestyle) advertising is constitutionally significant for 2 reasons. First, a total ban on advertising in any medium (billboards, print, etc) is overly broad in relation to its most compelling objective—discouraging youthful initiation of tobacco use. Second, the advertising restrictions recently invalidated by the Supreme Court have all banned informational advertising. As Morrison[5] points out, the Supreme Court's increasingly protective approach toward commercial expression is rooted in skepticism about the legitimacy of any governmental effort to suppress truthful communication. A carefully drafted regulation that suppresses only images while leaving undisturbed truthful and nonmisleading information is very likely, in my opinion, to survive First Amendment scrutiny.

Bayer et al recommend that 50% of the space in all advertisements and one side of every cigarette package be used for counteradvertising and corrective messages. The 1994 Institute of Medicine report also urged Congress to "increase the salience and effectiveness of health warnings on both advertising and packaging," noting that this could be accomplished by regulating the amount of the package surface devoted to the warning, as well as by prescribing the content and format of the message. The report further encouraged consideration of so-called plain packaging (in black and white text).[2(p245)] Aggressive package regulation is a new frontier of tobacco control. Although the governing constitutional principles are currently unclear, it is likely that a company's First Amendment interests in the product package as a medium of communication are attenuated compared with ordinary communications media, and that the government's regulatory authority is correspondingly enhanced, especially when the regulation does no more than require warnings and other information concerning the product. The government probably has the authority to require large portions of the package to display warnings and product characteristics to increase their saliency and impact on consumers.

I am less certain, however, about the constitutionality of the additional step, taken in Canada, of requiring the package to display antismoking images. As a tactical matter, I would discourage tobacco control advocates from seeking any such regulation in the United States until the text-only approach (salient warnings and product information occupying large portions of the package) has been fully utilized and constitutionally validated.

Richard J. Bonnie, LLB
Schools of Law and Medicine
University of Virginia
Charlottesville

1. Bayer R, Gostin LO, Javitt GH, Brandt A. Tobacco advertising in the United States: a proposal for a constitutionally acceptable form of regulation. *JAMA*. 2002;287:2990-2995.
2. Institute of Medicine. *Growing Up Tobacco Free*. Washington, DC: National Academy Press; 1994.
3. 61 *Federal Register* 44396-45318 (1996) (codified at 21 CFR §801).
4. *Coyne Breahm, Inc v US Food and Drug Administration*, 966 FSupp 1374 (MDNC 1997).
5. Morrison A. Counteracting cigarette advertising. *JAMA*. 2002;287:3001-3003.

In Reply: The ultimate challenge for public health tobacco policy is to radically reduce the prevalence of smoking. In the next years, doing so in a way that affects cigarette consumption across all social strata will be critical, since over the past several decades a steep social gradient—those with greater resources smoke less, those with fewer resources smoke more—has emerged in the United States. To that end the denormalization of smoking will be essential. It was to foster such a process that we proposed our set of counteradvertising measures designed to have a fundamental impact on attitudes toward smoking.

Whether, as Dr Gerace suggests, a government corporation will serve the end of public health remains an open question. The experience in Japan, France, and other nations, including the former communist nations where state monopolies controlled the production and distribution of cigarettes, should provide a cautionary note. Nevertheless, a government monopoly created when smoking had already been denormalized and consumption radically reduced could function very differently.

Mr Bonnie may be right that the Supreme Court would accept a ban on all but "tombstone" advertising (ie, black and white, text-only format). But there are some reasons to believe that such limitations could face resistance given the Court's current posture. Redish, a proponent of commercial speech protections, testified before Congress in 1998 that, "Tombstone limitations should be deemed to be as harmful to free speech values as are any viewpoint-based regulations. [They] may actually be even more pernicious than a total ban because they give the illusion of allowing communication while in reality significantly interfering with the message conveyed by that communication."[1]

It is precisely because of our concerns about how the Court would react to restrictions of any kind that we placed such emphasis on aggressive counteradvertising—including the use of pictorials and evocative images on packages and in portions of print advertisements. Bonnie worries that the Court might reject such graphic materials. That could be the case, but we will not know until we try. Were the Court to strike down such counteradvertising, it would be possible to retreat to reliance on the printed word.

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We agree with both Gerace and Bonnie that the human suffering imposed by cigarette consumption in the United States (and, we hasten to add, in poorer nations) demands that cigarettes be viewed as something very different from other products that are bought, sold, and promoted in the marketplace. Any innovative attempts to reduce tobacco consumption will necessarily occur in a context of legal and social constraints that policy makers and public health officials must confront.

Ronald Bayer, PhD
Mailman School of Public Health
Columbia University
New York, NY
Lawrence Gostin, JD
Center for Law and the Public's Health
Georgetown University Law Center
Washington, DC
Allan Brandt, PhD
Department of Social Medicine
Harvard University
Boston, Mass
Gail Javitt, JD, MPH
University of Maryland School of Law
Baltimore

1. Testimony of Martin H. Redish before the Senate Judiciary Committee, February 10, 1998.

RESEARCH LETTER

Rates of Spontaneous Reporting of Adverse Drug Reactions in France

To the Editor: Spontaneous reporting remains the most used and efficient method of identifying new adverse drug reactions (ADRs) in the postmarketing phase.[1] We assessed the magnitude of underreporting for serious ADRs in France by using data from 3 field pharmacoepidemiological studies.

Methods. The 3 studies we selected for analysis[2-4] were published in peer-reviewed journals, conducted in France in 1997 through 1998, and based on a representative sample of the source population. Each study was intended to estimate the number of hospitalizations caused by drugs. Therefore, estimating the magnitude of underreporting was possible by comparing the reported ADRs to the number of cases spontaneously reported to the French pharmacovigilance system during the same period and within the same territory.

Results. In 1997, Lacoste-Roussillon et al[2] studied the incidence of serious ADRs observed by a representative random sample of 200 general practitioners in the Aquitaine Region (southwestern France). In this prospective study, the estimated number of ADRs leading to hospital admission in this area was 6236 a year (95% confidence interval [CI], 3319-10663). During the same year, 328 ADRs that were the cause of hospitalizations were spontaneously reported to the Regional Pharmacovigilance Center for the same source population. Therefore, the average percentage of serious ADRs that were actually reported is estimated to be 5.26% (95% CI, 3.08%-9.88%). Extrapolation of these data to the whole country gave an estimate of 103937 (95% CI, 51874-185953) ADR-caused hospitalizations per year.

The second study[3] was conducted in 1997 in a representative sample of inpatients in French public hospitals (departments of medicine, surgery, and geriatrics). According to this cross-sectional study, ADRs were the cause of 143624 hospitalizations (95% CI, 44042-247184). In 1997, 5973 similar cases were reported to the French pharmacovigilance system. Therefore, the percentage of reported cases was 4.16% (95% CI, 2.42%-13.56%).

According to the third study, a prospective multicenter study conducted in 1998[4] in a nationwide representative sample of medical departments in French teaching and general hospitals, the number of hospitalizations attributable to ADRs was 134159 (95% CI, 85263-182637). In 1998, 6371 cases of hospitalization caused by drugs were reported to the French pharmacovigilance system, which suggests a reporting rate of 4.75% (95% CI, 3.49%-7.47%).

Comment. Although the 3 studies are based on different approaches, their concordance is striking: the estimate of the annual number of hospital admissions caused by drugs in France was 103937 for Lacoste-Roussillon et al,[2] 143624 for Imbs et al,[3] and 134159 for Pouyanne et al.[4] The estimates of the reporting rate also appear to be relatively stable: 5.26%, 4.16%, and 4.75%, respectively. We conclude that, on average, no more than 5% of serious ADRs were actually reported, a striking figure, since the French pharmacovigilance system has been reported to be particularly efficient[5] and in many aspects comparable to the US system; both systems are based on voluntary reporting and have a roughly similar number of reports per million inhabitants.[6]

Bernard Bégaud, MD, PhD
Karin Martin, PharmD, MPH
Françoise Haramburu, MD, MPH
Nicholas Moore, MD, PhD
Département de Pharmacologie
Université Victor Segalen
Bordeaux, France

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