To Dr. David B. Nash, Editor-in-Chief

I just read your editorial on adverse drug events (ADEs) and ambulatory care [in the May 2004 issue of P&T]. Thanks for highlighting this most critical area. As you noted, it is easier to identify and do something about ADEs in the acute care setting, but the incidence and prevalence is huge and may even become a more extensive issue with reimportation. Thanks again.

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Medical Malpractice: When Is It a Crime?

Dear P&T:

I feel I must comment on the section on malpractice litigation referenced in “The new federal fetal protection law: implications for health policy.”1 The author states that medical malpractice is “not a crime.” I must disagree in the current state of affairs in our country.

It is becoming more commonplace for physicians to be arrested and tried for criminal offenses that offhand should be malpractice. This “criminalization of medical errors” is a rising trend.2 Physicians are beginning to face a litany of charges including negligence, reckless endangerment, and even manslaughter, to name a few. We find examples of these cases almost every month in our news media.

The article must be clarified. Medical malpractice is usually not a crime, but sometimes it becomes one. I fear under this new federal law, we added a new charge to the list.

References

Sincerely,

Jonathan D. Block, MD, PhD
Mohawk Valley Urology, PC, Utica, New York

Author’s Response

Dr. Block is correct in noting that acts of medical malpractice can form the basis for criminal prosecution, although the instances in which this has occurred are extremely rare. His observation raises the question of whether treating malpractice as a crime rather than as a civil matter could more readily bring into play the Unborn Victims of Violence Act, which makes it a separate and distinct crime to end the life of a fetus during a violent attack on the mother.

It is unlikely that the Act would affect malpractice prosecutions directly. The kinds of crimes that prosecutors can allege in such cases are almost all at the state level, and the Act applies only when a limited number of violent federal crimes are involved. However, the criminalization of malpractice presents an additional route through which the reasoning behind the Act could indirectly influence state courts and legislatures. If an act of malpractice is treated as a crime rather than an unintended civil wrong, then harm to a fetus could more readily be characterized as a separate criminal offense against an additional victim. Dr. Block’s observation, therefore, raises a new avenue for speculation concerning the Act’s possible effects.

Sincerely,

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Associate Professor of Health Policy
University of the Sciences
Philadelphia, Pennsylvania

ED Drugs: The Need for Apples-to-Apples Comparisons

Dear P&T:

In the article by Williams et al.1 [in the May 2004 issue of P&T], the study by Govier et al.2 comparing tadalafil 20 mg versus sildenafil 50 mg is referenced. The key point of the Govier article is noted that 66.3% of the 190 patients preferred tadalafil 20 mg to 33.7% for sildenafil 50 mg. However, we must couch these results with great care, since it was not an “apples to apples” comparison, which the review by Williams did not adequately critique. While tadalafil 20 mg represents the maximum dosing with its inherent maximal results, the maximum dosing of sildenafil is 100 mg.

A more accurate and truer comparison for that study would have been tadalafil 20 mg versus sildenafil 100 mg: a maximum dose to maximum dose comparison to compare maximal efficacies. This was not done, and to miss this salient point is critical. A truer study to have referenced, though not without its own difficulties, is from Stroberg et al.3 in which tadalafil 20 mg was compared to multiple dosings of sildenafil 25, 50, and 100 mg. That study showed a 9:1 preference of tadalafil over sildenafil. However, that study also is open to harsh criticism for several reasons, including a lack of randomness with regard to lack of appropriate treatment arms or dosing levels and having no treatment-naive patients trialed. These study

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errors can cause severe bias in the results. It is extremely important to adequately critique studies presented in review articles for potential errors to prevent presentation bias—this was not done in the Williams article. With careful review, bias and error can be detected and properly presented to maintain review article integrity.

References


Sincerely,

Jonathan D. Block, MD, PhD
Mohawk Valley Urology, PC, Utica, New York

Author’s Response

Our article regarding tadalafil provided only reference literature that was appropriately conducted. Although the comparison of tadalafil 20 mg to sildenafil 100 mg, as seen in the study by Stroberg et al., ultimately evaluates maximal doses, it has been under obvious scrutiny because of the open-labeled research techniques applied. The study by Govier et al. provides the reader with clear, concise information that has been properly tested and, ultimately, lacks bias. Even though the trial compares tadalafil 20 mg with sildenafil 50 mg, the results are authentic and meaningful because it was a randomized, double-blind, crossover study. Moreover, regardless of reviewing Govier et al. or Stroberg et al., both trials provided the same conclusion: subsequent to comparison, patients preferred tadalafil.

We are in agreement with [the need for] providing the reader with review articles that maintain literature integrity, but I must also stress the need to incorporate primary literature that lacks bias, therefore allowing the clinician to make informed decisions based upon legitimate clinical trials. This will ensure that our patients receive the highest quality of medical and pharmaceutical care.

References


Sincerely,

Tarrah Williams, PharmD Candidate
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