

Forum

Health Law Institute: news, insights and discussion

September 2007

Jean Macchiaroli Eggen is Professor of Law at Widener's Delaware campus. Recent publications include Toxic Torts in a Nutshell (Nutshell Series, West, 2005), Toxic Torts at Ground Zero, 39 Ariz. St. L.J. 383 (2007), and The Normalization of Product Preemption Doctrine, 57 Alabama L.Rev. 725 (2005).

Punitive Damages and the Tobacco Industry

NEW GUIDELINES FROM THE U.S. SUPREME COURT

*Jean Macchiaroli Eggen
Professor of Law*

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Over the past decade, the United States Supreme Court has addressed the due process parameters of punitive damages awards under state law on several occasions.¹ These decisions have encompassed both the minimum procedural

requirements of assessing punitive damages² and the broader substantive due process issues of excessiveness.³ One troubling issue that the Supreme Court had not addressed directly until this year was whether the Due Process Clause allows a jury to base an award of punitive damages in part on the harmful conduct of the defendant toward persons who are not parties to the action. This issue arose in *Philip Morris USA v. Williams*,⁴ in which the

Court ruled that a jury could consider such conduct only for very limited purposes. While not the beacon of clarity that would have been desirable on this issue, the *Williams* decision will still have a major impact on punitive damages awards in the area of health-related mass torts, such as tobacco, asbestos, and pharmaceuticals.

The Supreme Court cases addressing the procedural due process pa-

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Letter from the Directors

The Health Law Institute at Widener has unleashed several new initiatives that promise to usher in the most exciting and productive era in our almost-20-year history.

First, Widener and Thomas Jefferson University recently announced the founding of two joint programs: the Juris Doctor/Master of Public Health and the Master of Jurisprudence/Master of

Public Health dual degree programs. These programs link two highly regarded institutions in a collaborative effort to exploit the interconnectedness of law and the emerging field of public health. The launch of these programs has spurred great interest in both the legal and health fields, and several students have already stated their intentions of pursuing one of these joint programs, which will

position them well to assume leadership positions in public health policy.

The Institute's emerging focus on public health is also being realized by an ambitious project spearheaded by Michele Forzley, a global public health lawyer who will be a Visiting Distinguished Professor at the law school for the 2007-2008

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Letter from the Directors (*continued*)

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Andrew J. Fichter,
Executive Director,
Institutes; Associate
Professor of Law

The Health Law Institute at the Widener University School of Law has unleashed several new initiatives that promise to usher in the most exciting and productive era in our almost-20-year history.

year, and likely for years to come. Michele addresses an issue of global public health interest in this issue of **Forum**. Michele is currently starting up the International Public Health Law Information Project (I-PHLIP), whose goal is to collect and organize no less than the health law-related information of every nation on the planet. She chose Widener because of both our national reputation in health law and our collaboration with the National Library of Medicine and the Delaware Academy of Medicine on the domestic version of this project, known as the Public Health Legal Information Project, or “PHLIP.” PHLIP has been in process since 2005, and is using Delaware as the pilot state to test-run the collection and organization of public health law-related information from every state in the United States. The pilot is expected to finish by summer 2008.

Public health law will also be the topic of an important symposium the Institute is hosting on October 19. Entitled “Public Health Perspectives on Charged Legal Issues,” the symposium will feature prominent academics who will bring a public health perspective to bear on

a wide range of controversial political and legal topics, including domestic violence, gun policy, racism, the fight over marriage equality, abortion, euthanasia, and the role of civil law (namely, torts) and punitive damages in achieving good public health outcomes. Plans are underway to convert the presentations into a book, with a chapter dedicated to each of the symposium’s timely topics.

Additionally, public health concerns have been a central theme of a two-part conference that the Institute has sponsored on the topic of long-term care. The first part of this timely symposium took place last spring, and the second will be in the fall. Co-sponsored by the Health Law Division of the Delaware State Bar Association and the Philadelphia law firm of White & Williams, this symposium features attorneys from the public and private sector as well as Widener faculty members in discussions of topics ranging from litigation to regulation to criminal and civil enforcement and penalty issues.

In another joint undertaking, on October 9 the Health Law Institute will again host a lecture spon-

sored annually by the Philadelphia law firm of Raynes McCarty, this time featuring Professor Michele Goodwin, JD, LL.M. Professor Goodwin will speak on the subject of her recent book, *Black Markets: The Supply and Demand of Body Parts* (Cambridge).

In addition to public events such as the above, the health law faculty continues to engage in a wide spectrum of scholarly, teaching and service-related pursuits. To cite just a few from among a large number of examples:

- Professor Jean Eggen has added a new course, Science and the Law, to her health law-related courses that already include Toxic Torts and Tobacco and the Law. She continues to produce scholarly works at a daunting rate, with her most recent edition of the *Toxic Torts in a Nutshell* book being joined by a host of recent articles appearing in both scholarly and practicing-law journals.
- Professor Tom Reed’s relentless advocacy on behalf of veterans seeking health benefits has now taken the form of a Veterans Law Clinic, in which he and his students prepare for and present veterans’ cases

Letter from the Directors (*continued*)

before both administrative and judicial tribunals. In addition, Professor Reed's co-authored supplement to his book, *Will Contests*, was recently published by the West Group.

- Professor Nicholas Mirkay, a frequent guest speaker on tax issues, continues his impressive scholarship on tax-exempt organizations with *Is It "Charitable" To Discriminate?* 2007 WISC. L.REV. (forthcoming) and *Relinquish Control! Why the IRS Should Change Its Stance on Exempt Organizations in Ancillary Joint Ventures*, 6 NEV. L.J. 21 (Fall 2005).
- Andrew Fichter, recently appointed Executive Director of Widener's Health Law Institute and its Institute of Delaware Corporate and Business Law, continues his important work on the financial and transactional side of health care. Andrew has created a new skills-oriented course, Health Law Mergers & Acquisitions, in which students participate as lawyers in a simulated transaction. His most recent article on "lay" ownership of medical practices appeared in the *Journal of Health Law* in 2006.
- In addition to his duties as Director of the Health

Law Institute, John Culhane has recently completed two articles: *What Does Justice Require for the Victims of Katrina and September 11?*, 10 DEPAUL J. HEALTH CARE L. 177 (2007) (in Symposium: Shaping A New Direction for Law and Medicine: an International Debate on Culture, Disaster, Biotechnology and Public Health), and *Beyond Rights and Morality: The Overlooked Public Health Argument for Same-Sex Marriage*, 17 J. L. & SEXUALITY ____ (forthcoming 2008). He has been heard on National Public Radio, discussing both gay family issues and the New Jersey Supreme Court's recent decision requiring the state to extend equal rights to same-sex couples, and was recently interviewed for an upcoming documentary on Hurricane Katrina; the film is to be distributed to theaters by Fox Searchlight Pictures in 2008.

Although space constraints prevent a fuller accounting of the health law faculty's accomplishments, we can't go without mentioning the two visiting faculty who will be joining Michele Forzley this Fall. Thaddeus Pope joins us from the University of Memphis, where he has been teaching

and writing in the area of health law, with an emphasis on bioethics and end-of-life issues. Professor Pope holds both a J.D. and a Ph.D. in philosophy, and his influential work is informed by his deep theoretical background. He will teach courses in health law and business organizations.

Finally, KingJean Wu, a legal academic with a degree in dentistry from Taiwan, will also be at Widener during the 2007-08 academic year, researching the American formulation of the informed consent rule and sharing his work with full-time faculty.

We're only getting started. Within the next year, the Health Law Institute will be looking into expanding our successful externship program (perhaps to include sending law students on medical rotations with doctors), establishing a relationship with the Delaware legislature, offering a new certificate program in health-care compliance, and creating our own peer-reviewed health law journal. Stay tuned.

John G. Culhane

Andrew J. Fichter

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John G. Culhane,
Director, Health
Law Institute;
Professor of Law

Punitive Damages (*continued*)

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rameters of a punitive damages award have centered on the state-court mechanisms for assuring that an award is not excessive. In *Honda Motor Co. v. Oberg*,⁵ the Court made clear that the availability of post-verdict review of a punitive damages award is necessary to satisfy due process.⁶ The Court approved of the Alabama procedures at issue in *Pacific Mutual Life Insurance Co. v. Haslip*.⁷

Those procedures consisted of a two-tiered review – in the trial court and in the Alabama Supreme Court – to assure that the punitive damages award was not excessively disproportionate to the reprehensible character of the defendant’s conduct.⁸ The factors to be examined were the culpability and duration of the conduct, the existence of similar conduct in the past, the degree to which the defendant profited from its conduct, the defendant’s financial position, and the amount of any criminal or other civil sanctions that could be imposed for the same wrongful conduct.⁹ In a later case, *TXO Produc-*

tion Corp. v. Alliance Resources Corp.,¹⁰ the Court made clear that the state procedures to review a punitive damages award need not be identical to the Alabama procedures, provided that the same general due process concerns were addressed.¹¹

The Supreme Court has also addressed, in a string of cases, the substantive due process parameters of an award of punitive damages. In *Haslip*, the Court stated that the key factor in this determination was whether a reasonable relationship existed between the punitive damages award and the harm to the plaintiff, but emphasized that a bright line was impossible to establish.¹² In *TXO*, the Court stated that in setting the amount of punitive damages, it was appropriate for the jury to consider “the magnitude of the potential harm that the defendant’s conduct would have caused to its intended victim if the wrongful plan had succeeded, as well as the possible harm to other victims” if the defendant’s conduct had not been stopped.¹³ This latter statement was clarified

somewhat in *BMW of North America, Inc. v. Gore*,¹⁴ where the Court said that the award should be analyzed in relation to the defendant’s conduct that occurred solely within Alabama, and not nationally.¹⁵ In the same case, the Court also established three factors that have become known as the “Gore Guideposts”: (1) the reprehensibility of the defendant’s conduct, (2) the reasonableness of the ratio between the amount of punitive damages and the amount of compensatory damages awarded in the case, and (3) a comparison of other criminal and civil sanctions available for the same conduct.¹⁶

On the matter of the ratio between punitive damages and compensatory damages, the Court has issued a number of ambiguous, if not conflicting, statements. In *Haslip*, the Court approved the award of punitive damages that was four times the compensatory damages, stating that while it “may be close to the [due process] line,” it “did not lack objective criteria.”¹⁷ In *TXO*, the



Jean Macchiaroli Eggen, Professor of Law, Widener University

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award that was approved was 526 times the compensatory damages.¹⁸ In *Gore*, however, the Court held that an award of punitive damages that was 500 times the compensatory damages violated due process because, among other things, few aggravating factors were present in the case, and the harm done was purely economic in nature.¹⁹

Language in the 2003 U.S. Supreme Court decision in *State Farm Mutual Automobile Insurance Co. v. Campbell*,²⁰ in which the Court held that a punitive damages award of 145 times the compensatory damages violated due process, moved perilously close to the “bright line” that the Court has continued to reject. The Court stated: “[I]n practice, few awards exceeding a single-digit ratio . . . will satisfy due process.”²¹ The Court also expressed concern that the court below may have impermissibly relied upon the defendant’s practice in other states to form the basis of the punitive damages award.²²

In *Philip Morris USA v. Williams*,²³ the Court

attempted to limit itself to the procedural parameters of due process. The action arose out of the death of the plaintiff’s decedent from smoking-related illness and involved claims based on negligence and deceit. On the deceit claim – the claim at issue in the U.S. Supreme Court’s decision – the jury had awarded \$821,000 in compensatory damages and \$79.5 million in punitive damages, almost 100 times the compensatory damages award.²⁴ The Court focused its discussion on whether the jury instruction on punitive damages given by the Oregon trial court satisfied due process requirements.

The jury instruction given by the trial court stated, in part, that “‘you may consider the extent of harm suffered by others in determining what [the] reasonable relationship is’” between the wrongful conduct of the defendant and the harm to the plaintiff’s decedent, but that “‘you are not to punish the defendant for the impact of its alleged misconduct on other persons, who may bring lawsuits of their own in which other juries can resolve the claims.’”²⁵ The

U.S. Supreme Court vacated the judgment that relied upon this instruction because the instruction lacked clarity on the manner in which the jury could consider harm to other persons not before the court in determining the amount of punitive damages in the particular case. Regarding this particular instruction, the Court stated:

“How can we know whether a jury, in taking account of harm caused others under the rubric of reprehensibility, also seeks to punish the defendant for having caused injury to others? Our answer is that state courts cannot authorize procedures that create an unreasonable and unnecessary risk of any such confusion occurring.”²⁶

The Court concluded that this instruction manifested just such confusion and created a significant risk of misinterpretation by the jury.²⁷

The Court’s discussion of the procedural protections necessitated by the Due Process Clause spilled into a broader exposition on the substantive due process limits of punitive damages awards. The Court stated: “In our view, the Constitution’s Due

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“One troubling issue that the Supreme Court had not addressed directly until this year was whether the Due Process Clause allows a jury to base an award of punitive damages in part on the harmful conduct of the defendant toward persons who are not parties to the action.”

Public Health Risks of International Concern

Michele Forzley, JD, MPH

In this issue of the Health Law Institute's *Forum*, Prof. John Culhane demonstrates how the public health system failed to stop Andrew Speaker, an Atlanta attorney, from crossing borders even though he was positively diagnosed with extremely drug-resistant tuberculosis (XDR-TB). Prof. Eggen looks at punitive damages and the tobacco industry. Both issues raise global public health concerns which this note will consider in light of two recent additions to international health law jurisprudence. These are the Framework Convention on Tobacco Control (FCTC) and the International Health Regu-

lations (IHR).

FCTC

Since the early 20th century science has known that exposure to tobacco—whether by smoking, second hand or chewing—increases one's risk of cancer of the lungs and diseases elsewhere in the body. The World Health Organization reports:

“Tobacco is the second major cause of death in the world. It is currently responsible for the death of one in ten adults worldwide (about 5 million deaths each year). If current smoking patterns continue, it will cause some 10 million deaths each year by 2020. Half the people that smoke today—that is about 650 million people—will eventually be killed by tobacco.”

On February 27, 2005, the

FCTC entered into force for the 148 of the 168 countries that had signed it. The US has signed but not ratified this treaty; thus, while it provides international normative guidance, it may not be binding on our courts, our state legislatures or Congress. The Senate's failure to act is regrettable as the FCTC is a prime example of solid scientific evidence-based legislation and an effective tool for tobacco control.

One of the reasons the treaty has not been ratified is that it raises the difficult question of how an international treaty affects state powers to protect public health, a subject that has historically been the exclusive purview of state legislatures. This is an example

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Michele Forzley joins the Widener Health Law Institute this year to manage its International Public Health Law Information Project (I-PHLIP), the goal of which is to collect and organize no less than the health law-related information of every nation on the planet.



 **Widener University
School of Law**
Health Law Institute

is pleased to announce the appointment of

Michele Forzley, JD, MPH
as
Visiting Distinguished Professor and
Project Director of Widener Law's International
Public Health Legal Information Project (IPHLIP)

The Public Health Legal Information Project

Imagine that you are a state public health official faced with what you suspect is an outbreak of "bird flu". In addition to contacting the federal Centers for Disease Control and Prevention, you need to know what your legal options are. Perhaps you have ready access to in-house legal counsel, perhaps not. Even if legal counsel is available, time is of the essence. Is there a way to obtain answers to vital questions quickly?

There soon will be. The Public Health Legal Information Project, initiated and funded by the National Library of Medicine (NLM, an organization within the National Institutes of Health), aims to deliver public health law information to public health professionals – and the general public – in an easily understood and useful form. Widener University School of Law's Health Law Institute is proud to have been chosen as the NLM's partner for the collection of this information from the state of Delaware, which has been designated as the pilot state for what is expected to be a model for other states to follow.

Professor John Culhane, Director of the Health Law Institute, is the Project Di-

rector from Widener. Also involved is a team of students, who conduct legal research and draft case law annotations for inclusion in the database. The students focus on stripping the language of legalese that would be hard for a layperson to comprehend. Once the Delaware law is fully entered into the database, users will be able to type in relevant keywords and obtain a list of statutes, regulations, and decisional law pertinent to their subject.

Library professionals are also vital to PHLIP. Widener's Sandra Sadow, a professional indexer, has been working with P.J. Grier of the Delaware Academy of Medicine to create a separate controlled vocabulary based on the NLM's standard Medical Subject Headings (MeSH), a medically robust vocabulary, but limited in legal terminology. Sadow thus has the challenge of coming up with new terms to describe the content of these medical/legal issues. As she states: "The intent of PJ's and my keywording is to tie similar concepts together regardless of their location in the database. This should complement the annotations and keywords provided by the students."

This ambitious project has been in process since late 2005 and is expected to be completed by 2008. Then it could "fan out" to ever-greater numbers of states. NLM's PHLIP project manager, Brent Bolin, explains that: "PHLIP in Delaware is a pilot program and proof of concept for a model that NLM and its partners think can be successful in any state. Should we succeed in Delaware, our goal is to package our program and lessons learned and offer the PHLIP as a model to other states."

But while PHLIP will be contained within the borders of the United States, its even more ambitious counterpart will not be. International PHLIP, anyone? This exponentially more challenging project is the brainchild of Michele Forzley, who, as mentioned in the Letter from the Directors herein, will be in residence at Widener Law during 2007-08 as Visiting Distinguished Professor of Law. Professor Forzley brings strength to the team of scholars at Widener intent on expanding our reach globally.

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Punitive Damages (*continued*)

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“Some juries may approach their task by first estimating an “overall” harm to the entire population injured, then discounting down to the amount represented by the plaintiff in the case....

This kind of mathematical division could underestimate the true value of punitive damages for the particular named plaintiff.”

Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon non-parties . . . , i.e. injury that it inflicts upon those who are, essentially, strangers to the litigation.”²⁸ The Court was primarily concerned that such an award would deny the defendant an opportunity to put forth a meaningful defense, as the other persons are not parties to the action.²⁹ Moreover, the Court observed, allowing punishment for actions against nonparties “would add a near standardless dimension to the punitive damages equation.”³⁰ It would be unlikely, the Court opined, that the particular trial would provide sufficient information for a jury to accurately assess the scope of the harm inflicted on others by the defendant.³¹

The respondent argued that harm to others from the same course of conduct that injured her decedent was an appropriate consideration on the matter of reprehensibility, the first Gore Guidepost. The Court agreed in theory, but

stated that constitutional limitations require special care when it comes to instructing the jury on this point:

“[G]iven the risks of arbitrariness, the concern for adequate notice, and the risk that punitive damages awards can, in practice, impose one State’s (or jury’s) policies (e.g., banning cigarettes) upon other states . . . it is particularly important that States avoid procedure that unnecessarily deprives juries of proper legal guidance. We therefore conclude that the Due Process Clause requires States to provide assurance that juries are not asking the wrong question, i.e., seeking, not simply to determine reprehensibility, but also to punish for harm caused strangers.”³²

Concluding that the Oregon Supreme Court had employed an incorrect due process standard in evaluating the instruction, the *Philip Morris* Court remanded the case for consideration of, among other things, the need for a new trial. The Court declined to proceed further and discuss the excessiveness question, including the ratio issues raised by the award.³³

Justice Breyer’s majority opinion was joined

by Chief Justice Roberts and Justices Kennedy, Souter, and Alito. The case generated three dissenting opinions. Justice Ginsburg’s position was that the record below contained nothing that would indicate either that the jury instruction was infirm in any way or that the jury mistook the instruction to mean something constitutionally improper.³⁴ Justices Thomas and Scalia joined Justice Ginsburg’s opinion, but Justice Thomas wrote separately to state also that the majority’s characterization of the scope of its decision as procedural was inaccurate. In his opinion, the Court’s rule fell into the category of substantive due process and was vague and difficult to apply.³⁵ Justice Stevens’s dissent similarly criticized the majority for attempting to fashion a rule that was too difficult to apply.³⁶

The rule announced by the Court in *Philip Morris USA v. Williams* is not especially groundbreaking. Although it makes constitutional a standard that the Court had already discussed in previous cases – that harm to others may be

Punitive Damages (*continued*)

considered in determining the reprehensibility of the conduct in question, but may not be used to punish the defendant directly for its conduct toward persons who are not parties to the lawsuit – the degree to which it will affect jury instructions or the amounts of punitive damages awards is uncertain. One of the key points in the opinion is the fact that the Court retained the validity of using harm to others as a factor in determining the reprehensibility of – and thus the amount of punishment appropriate to – the defendant’s conduct. Actual implementation of the Court’s rule is likely to be no easier after this case was decided than before.

Consider an example. Some juries may approach their task by first estimating an “overall” harm to the entire population injured, then discounting down to the amount represented by the plaintiff in the case. Thus, if there were 100 people harmed, the plaintiff would represent 1/100. Would the resulting amount – 1/100 of the overall harm – be an accurate reflection of the reprehensibility of the

defendant’s conduct?

This kind of mathematical division could underestimate the true value of punitive damages for the particular named plaintiff.

Another question that arises is whether the defendant’s conduct could ever be so reprehensible that it would support a large punitive damages award, well beyond the “single-digit” ratio that the Court recommended in *State Farm*. This is the question that the Court declined to address in *Philip Morris USA v. Williams*. But it is in crucial need of an answer, given the mixed messages the Court has sent in its line of cases addressing punitive damages ratios.

1 See, e.g., *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991).

2 See, e.g., *Honda Motor Co. v. Oberg*, 512 U.S. 415, 430-32 (1994); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 19-22 (1991).

3 See, e.g., *State Farm, Gore, TXO*, *supra* note 1.

4 127 S. Ct. 1057 (2007).

5 512 U.S. 415 (1994).

6 *Id.* at 434-35.

7 499 U.S. 1 (1991).

8 *Id.* at 20-21.

9 *Id.* at 20-22.

10 509 U.S. 443 (1993).

11 See *id.* at 462-66. In another case, the U.S. Supreme Court held that the appropriate standard for an appellate court reviewing an award of punitive damages is de novo review. *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 443 (2001).

12 *Haslip*, 499 U.S. at 18.

13 *TXO*, 509 U.S. at 460.

14 517 U.S. 559 (1996).

15 *Id.* at 572-73.

16 *Id.* at 575-85.

17 *Haslip*, 499 U.S. at 23.

18 *TXO*, 509 U.S. at 453, 462.

19 *Gore*, 517 U.S. at 576.

20 538 U.S. 408 (2003).

21 *Id.* at 425.

22 *Id.* at 422-23.

23 127 S. Ct. 1057 (2007).

24 *Id.* at 1060-61. The Oregon trial court had reduced the punitive damages award to \$32 million on excessiveness grounds. *Id.* at 1061. Upon an appeal by both sides, the Oregon Court of Appeals restored the original punitive damages award. Philip Morris unsuccessfully sought review in the Oregon Supreme Court. *Id.* The U.S. Supreme Court then remanded the case for consideration by the Oregon Court of Appeals in light of the U.S. Supreme Court decision in *State Farm*. The Oregon Court of Appeals did not change its decision, and the Oregon Supreme Court granted review, ultimately upholding the punitive damages award of \$79.5 million. *Id.*

25 *Id.* at 1064 (quoting App. 280a).

26 *Id.* at 1065.

27 *Id.*

28 *Id.* at 1063.

29 *Id.*

30 *Id.*

31 *Id.*

32 *Id.* at 1064.

33 *Id.* at 1065.

34 *Id.* at 1068-69 (Ginsburg, J., dissenting).

35 *Id.* at 1067-68 (Thomas, J., dissenting).

36 *Id.* at 1066-67 (Stevens, J., dissenting).

One of the key points in [Philip Morris USA v. Williams] is the fact that the Court retained the validity of using harm to others as a factor in determining the reprehensibility of – and thus the amount of punishment appropriate to – the defendant’s conduct.

Public Health Risks (*continued*)

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The 2005 draft of the International Health Regulations (IHR 2005) was adopted by the World Health Assembly, the policy and law-making arm of the WHO. The IHR are legally binding regulations on its member states once ratified under national law.

of how public health has been globalized and pressure placed on the US Constitutional division of power between States and the federal government.

The FCTC provides measures to reduce the supply and demand for tobacco and to protect the environment, calls for scientific and technical cooperation. It also includes provisions on the implementation of the treaty such as financing the IHR secretariat (the office tasked with treaty implementation). FCTC Article 19 covers liability but does not provide any guidance to US courts or legislatures on how to manage criminal and civil liability in relation to violations of the treaty or existing national law. Thus, even were the treaty to have been ratified by the US Senate, it would not have any effect on the issue of punitive damages Prof. Eggen discusses.

IHR

As of 15 June 2007 a new legal framework entered into force that provides measures better to manage acute public health risks that can spread internationally. The 2005 draft of the IHR (IHR 2005) was adopted by the World

Health Assembly, the policy and law-making arm of the WHO. The IHR are legally binding regulations on its member states once ratified under national law. The IHR 2005 update the IHR (1969), which addressed only four diseases: cholera, plague, yellow fever and smallpox (which has since been eradicated). The IHR 2005 now apply to old health disease threats and new ones that may rapidly spread from one country to another. Such diseases include emerging infections like severe acute respiratory syndrome (SARS), or a new human influenza virus. Beyond contagious diseases, the IHR also cover other public health emergencies that may affect populations across borders, such as chemical spills, leaks and dumping or nuclear melt-downs.

The IHR 2005 are a treaty that defines the rights and obligations of member states and establishes procedures whereby states can ensure international health security without unnecessary interference in international traffic and trade. It is well recognized that international human and cargo traffic facilitates the movement of infectious diseases across borders, as was the case with Mr. Speaker. He was engaged in

short term travel and had been diagnosed with XDR-TB, an extremely dangerous infectious disease because it is resistant to three or more of the six classes of second-line drugs.

Had they been in effect in the US at the time of Mr. Speaker's travel, would the IHR have aided the Georgia public health officials and the Centers for Disease Control in managing this case? As a framework convention, the IHR establishes normative guidance and minimum standards on how member states may regulate regarding control of infectious diseases. It does so in terms of individuals and with respect to baggage, cargo, containers, conveyances, goods and postal parcels.

Regarding individuals such as Mr. Speaker, signatories to the IHR may:

- review travel history in affected areas;
- review proof of medical examination and any laboratory analysis;
- require medical examinations;
- review proof of vaccination or other prophylaxis;
- require vaccination or other prophylaxis;
- place suspect persons

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- under observation;
- implement quarantine or other health measures for suspect persons;
- implement isolation and treatment where necessary of affected persons;
- implement tracing of contacts of suspect or affected persons;
- refuse entry of suspect and affected persons;
- refuse entry of unaffected persons to affected areas; and
- implement exit screening and/or restrictions on persons from affected areas.

The IHR obligate signatories to designate a national focal point, conduct surveillance, notify the WHO of an “event”, defined as a manifestation of a disease or occurrence that creates a potential for disease, share information during unusual

public health events, permit verification of reports by State Parties, develop a capacity to respond to public health emergencies, and among other responsibilities develop appropriate national legislation to implement the IHR. This is because under treaty law, execution and ratification still requires that national laws are conformed to treaty terms. These steps are all designed to strengthen national and global response capacity in the event of an infectious disease of international concern.

Despite the IHR treaty and its clarification of public health powers in the case of an infectious disease of international concern, Mr. Speaker traveled to France, Greece, Italy, Canada and the Czech Republic, all of which have signed the treaty

(although only Canada and France have ratified it to date), but none of which applied any of its provisions to him. Without any concern for adverse legal action, clearly both Canada and France could have applied all of the permissible measures. Had they done so, perhaps the sad chronology of events detailed in Prof. Culhane’s sidebar article could have been avoided.

It is this author’s view that under both Georgia and US federal law, existing basic public health powers would have been sufficient for any public health authority of Georgia to quarantine Mr. Speaker and for the CDC and to prevent his departure from the US or re-entry via Canada. In this case in which it was clear he had a highly infectious disease it is unlikely that the IHR would

have been necessary to defend public health officials acting within existing powers. One can say that in this case there was no negative consequence of their failure to act as there has been no outbreak of XDR-TB. This is cold comfort as this “good” public health outcome may not be repeated in the future. One only has to look at dengue hemorrhagic fever and West Nile virus to realize that there has been an incidence, in other words new cases, of infectious diseases which previously have not been the cause of mortality or morbidity in the US. These have entered the US only by infected persons and cargo carrying disease vectors. The failure of public health officials in the Speaker case is no insurance that in the future the outcome will be as minimal.

Spotlight on Prof. Thaddeus Pope

Widener welcomes Thaddeus Mason Pope, J.D., Ph.D., as Visiting Assistant Professor of Law.

Thad Pope comes to Widener from the University of Memphis, where he is an Assistant Professor of Law. Prior to that, Thad was an attorney with Arnold & Porter after clerking for the U.S. Court of Appeals for the Seventh Circuit. At Widener, he will concentrate his teaching and scholarship on healthcare and business organization matters.

Thad’s current focus is on end-of-life issues. In that connection, his scholarly work in progress is tentatively titled *Hospital Ethics Committees as a Forum of Last Resort under the Texas Advance Directives Act: A Violation of Procedural Due Process*. He recently presented on this topic at the 2007 ASLME Health Law Professor’s Conference, and plans further presentations both for Texas Junior Legal Scholars and for Kaiser Permanente San Diego.

Forthcoming scholarship includes *Reassessing the Judicial Treatment of Medical Futility Cases: 1983 to 2008*, 10 MARQUETTER ELDER’S ADVISOR; *Medical Futility Statutes: No Safe Harbor to Unilaterally Stop Life-Sustaining Treatment*, 75 TENN. L. REV.; and *Mediation at the End-of-Life: Getting Beyond the Limits of the Talking Cure*, 22 OHIO ST. J. ON DISP. RESOL. (forthcoming).



Thaddeus M. Pope



Chronology of a Public Health Failure

Professor John G. Culhane

Andrew Speaker, the Atlanta attorney infected with extremely drug-resistant tuberculosis, was able to elude local, federal, and international public health and security authorities as he made his way through six countries, beginning and ending here in the U.S. A brief capsule description of the sequence of his movements is set forth in the Chronology below:

- Speaker meets with officials from Fulton County Georgia Department of Public Health, who either ask or tell him not to travel. Speaker, who was planning on getting married in Greece, and then honeymooning in Italy, disregards the DPH.
- After Speaker had left Greece to fly to Rome, the CDC's concern was magnified by tests confirming that his strain of TB was not merely drug-resistant (MDR), but extremely drug-resistant (XDR).
- CDC contacts the World Health Organization in accordance with then-pending requirements (see Professor Forzley's accompanying article), but again not until Speaker is on his way to Montreal.
- Speaker rents a car and drives across the Canadian/U.S. border. By this time, U.S. Customs and Border Protection had electronically keyed Speaker's passport with notice that he had a contagious disease, but the customs official at the U.S./Canadian border nonetheless waves him through.
- These officials deliver the message to the Centers for Disease Control and Prevention, but by the time the CDC attempts to reach Speaker to instruct him not to travel, he has boarded a plane that then travels through Paris on its way to Greece.
- CDC does not appear to have notified the Italian government, but they did communicate their concern to a former employee who happened to be working for the Italian Health Ministry. By the time this person reached Speaker's hotel, he was already on a plane traveling to Canada.
- At about the same time, CDC contacts both the Department of Homeland Security and one of its divisions (U.S. Customs and Border Protection), but Homeland Security, unsure of its authority to issue a "no fly" order to a non-terrorist, delays doing so until after Speaker is back in the U.S.!
- Finally, CDC makes contact with Speaker back in the U.S., and then flies him to Denver for treatment.

Calendar

October	October	October	May-June
9 Raynes McCarty Lecture: Michele Goodwin, "The Body Business: Markets, Morality, and the Politics of Choice"	19 Symposium, Wilmington: "Public Health Perspectives on Charged Legal Issues"	30 Symposium, Wilmington Campus: "Long Term Care, Part II: Risk Management in Light of Enhanced Whistleblower Attention"	Summer Program in Geneva (dates and courses to be determined)