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COURT OF APPEALS, DIVISION II  
OF THE STATE OF WASHINGTON

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KENNETH FLYTE, as Personal Representative of THE ESTATE OF  
KATHRYN FLYTE, on behalf of their son JACOB FLYTE, and as personal  
representative of THE ESTATE OF ABIGAIL FLYTE,

Appellants,

v.

SUMMIT VIEW CLINIC, a Washington corporation,

Respondent.

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APPELLANTS' REPLY BRIEF

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ORIGINAL

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## I. INTRODUCTION

The Flyte family submits this Reply memorandum to the Clinic's opposition briefing. This medial malpractice case proceeded to trial premised many key evidentiary rulings having been rendered based upon now overturned case law pertaining to the admission of settlement evidence in the form of a \$3.5 million settlement with a non-party, the Franciscan Health System. The corresponding "limiting instruction" was actually a comment on the evidence and compounded the prejudicial impact of the already inflammatory evidence. Adding fuel to the prejudicial flames was the fact that an employee of the Franciscan Health System was a participant on the jury. During deliberations, that same juror turned out to be the foreperson. In addition to these abnormalities, the jury was improperly instructed that the Flyte family had to establish a negligent diagnosis claim as a condition precedent to prevailing on an informed consent claim. The corresponding instruction was not consistent with Washington law, the trends in modern medicine, and eviscerated a key portion of the Flyte family's case. Based upon these assorted errors of

law, individually and/or cumulatively,<sup>1</sup> the Flyte family did not receive a fair trial and this matter should be reversed and remanded.

## II. ARGUMENT

**Issue 1: This Court should grant a new trial premised upon the fact that the Flyte family's case was judged by a jury which included a juror foreperson that worked in management for an entity that had settled with the Flyte family for \$3.5 million thereby causing harmful error to include providing a prejudicial jury instruction.**

The Flyte family contends that the settlement evidence in this case was inherently prejudicial and its admission warrants granting a new trial. In that regard, the Clinic contends that the "*jury was informed that plaintiff had settled with St. Joseph Hospital, not Franciscan Health Systems.*"<sup>2</sup> The Clinic's assertion is incorrect. During the trial, the jury was repeatedly read Instruction No. 15 which informed them that Ms. Knight's employer, the **Franciscan Medical Group**, had already paid out \$3.5 million to the Flyte family: "*You have heard evidence that St. Joseph Medical Center/Franciscan Medical Group entered into a settlement with the plaintiff, agreeing to pay the plaintiff \$3,500,000...*"<sup>3</sup> This repeated occurrence was highly prejudicial and likely caused the Flyte family to lose the case.

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<sup>1</sup> See *In re Morris*, 288 P.3d 1140 (2012) (cumulative errors warrant new trial even when single error alone would not).

<sup>2</sup> Response Brief, Page 12

<sup>3</sup> CP 21

Additionally, that same instruction also commented directly upon the evidence by suggesting that the Flyte family was already fully compensated: “*The evidence is admissible for the limited purpose of demonstrating that the plaintiff may have already been compensated for the injury complained of from another source.*” The entirety of Instruction No. 15 is misleading and confusing and gives the aura that the trial judge was telling the jury that the Flyte family already got enough money from another non-party.

According to *Heitfel v. Benev. Prot. Order of Keglers*, 36 Wn.2d 685, 220 P.2d 655 (1950), on issue of judicial comment upon the evidence, “each case must be determined on its own peculiar facts and circumstances...” *Id.* In this instance, how can the trial court telling the jury about a \$3.5 million settlement coupled with the comment that the Flyte family had “*already been compensated from another source*” possibly *not* qualify as a comment on the evidence? The trial court was telling the jury that the Flyte family had already been properly compensated.<sup>4</sup> The combination of (1) the introduction of this inherently

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<sup>4</sup> The Clinic suggests that Instruction No. 14 regarding the potentiality of multiple proximate causes remedies the misleading nature of Instruction No. 15. However, it is virtually impossible to reconcile Instruction No. 14 with Instruction No. 15 in that the latter clearly leads the jury into believing that the Flyte family was already fully compensated. Under these peculiar facts and circumstances, it cannot be said that Instruction No. 14 cured the problem.

prejudicial evidence and (2) the misleading nature of the instruction justifies a new trial.

Contrary to the Clinic's contention, Washington courts have noted that "an additional reason supporting the inadmissibility of settlements is a justifiable fear that a juror with such knowledge may conclude the plaintiff has already received sufficient satisfaction for his or her injuries and further compensation from a remaining defendant is unwarranted." *Byerly v. Madsen M.D., et al*, 41 Wash. App. 495, 704 P.2d 1236 (1985). In this instance, Instruction No. 15 ran afoul of exactly the concern noted in *Byerly* in that it instructed the jury about a multi-million dollar settlement and suggested, without clarity, that another party may have been fully responsible for the injury that occurred. Importantly, the *Byerly* Court ruled that referencing evidence of settlement in the context of a medical malpractice case warranted granting the plaintiff a new trial. *Id.*

As noted in the opening brief, in this context, there was no way to capture that shock in the eyes of the members of the jury when they first heard about the \$3.5 million settlement with Ms. Knight's employer. Court reporters cannot transcribe the images of jurors' faces nor emotions. A transcript will never be able to capture the inherent bias on the part of some jurors once they learned that the Flyte family were already multi-millionaires. And there is no feasible way to "make a record" about the

manner in which settlement evidence biases a veneer at a conscious or subconscious level, but it absolutely does so, *See* ER 408. By contrast, it is safe to assume that any member of *this* Court would recuse from hearing this case if the Flyte family had already successfully sued and settled with Division II the Court of Appeals for \$3.5 million based upon facts or circumstances related to these proceedings. According to Rule 2.11 of the Canons of Judicial Conduct, a “judge shall disqualify himself or herself in any proceeding in which the judge’s impartiality might reasonably be questioned...” Should the standard be different for a juror foreperson sitting on a medical malpractice lawsuit? Absolutely not.

The Flyte family did not get a fair trial. In *Diaz*, the Supreme Court ultimately held that settlement evidence of this nature is inherently prejudicial and inadmissible. At the time of trial, the trial court was constricted by what is now overturned *Diaz* precedent from Division I. Moreover, the entire *voir dire* process was muddled and confused as related to seating Ms. Knight stemming from confusion about how Division I’s *Diaz* opinion was even supposed to be applied during *voir dire* and/or at trial. If the Flyte family’s case was not adjudicated by a juror whose employer, the Franciscan Health System, had already settled and paid \$3.5 million, there is a strong possibility that the case would have come out differently. By contrast, in *Diaz*, when denying the request for a

new trial, the Supreme Court noted that the case had already been tried *twice* with one occasion resulting in a hung jury:

...Diaz asks us to do more than just recognize that the trial court erred. He asks us to reverse the jury verdict in this costly and lengthy trial **that has already been retried once before**. He asks us to do so despite the fact that the settlement evidence was mentioned only once in the trial (by Diaz, no less) and settlement evidence was never actually admitted into evidence.

*Diaz v. State*, 175 Wash.2d 457, 471-472, 285 P.3d 873, 881 (2012) (emphasis added). Based upon *this* very distinguishable record, and the inherent bias implicated by the introduction of settlement evidence as noted in *Diaz* and *Bylerly*, this Court should grant a new trial pursuant to CR 59(a)(1),(8) and (9).

**Issue 2: This Court should grant a new trial premised upon the fact that the trial court improperly relied upon post-verdict juror-declarations when denying the motion for a new trial:**

In relation to this appeal, the Clinic designated as Clerk's papers two juror declarations of Ms. Knight and Mr. Ichiyama (both health care employees) that were improperly considered by the trial court when denying the Flyte family's motion for a new trial.<sup>5</sup> By designating these juror declarations on appeal, the Clinic invites this Court to make the same error as did the trial court. Specifically, the Clinic designates these

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<sup>5</sup> See CP 344-50 and CP 351-52

Clerk's papers in the hope that this Court will take notice of Ms. Knight's characterization of her jury's thought process when delivering a defense verdict: "*Juror Knight also asserted in her declaration that the settlement evidence had not influenced her or figured in the jury's deliberations.*"<sup>6</sup> As a matter of law, a juror declaration such as that Ms. Knight's which purportedly describes the rationale underlying a verdict is never properly considered:

The mental process by which individual jurors reached their respective conclusions, their motives in arriving at their verdicts, the effect of the evidence may have had upon the jurors or weight particular jurors may have given to particular evidence, or jurors' intentions or beliefs...inhere in the verdict itself, and averments concerning them are inadmissible...

*Gardner v. Malone*, 60 Wash.2d 836, 376 P.2d 651 (1962).

If juror opinions and thought processes were admissible for such a purpose, the undersigned counsel would have obtained similar declarations capturing some of the noted conflicting opinions after trial from other jurors indicating that the \$3.5 million settlement evidence was confusing and led them to believe that only Ms. Knight's employer was properly held at fault. Other jurors expressed just that sentiment towards the undersigned counsel post-trial. When asked after trial, one confused

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<sup>6</sup> Appellee's Brief, Page 20

juror asked: “*why don't you sue that other hospital?*” Will this Court consider that information on appeal? Presumably not. And this Court should also not make the same mistake and consider the juror declarations that the Clinic obtained from its fellow health care industry workers. This is particularly important as relates to Ms. Knight – an employee of the Franciscan Health System which paid out \$3.5 million in settlement funds.

The Clinic questions the Flyte family’s taking issue with the juror’s declarations in relation to the trajectory of this appeal. In that regard, at the time that the Flyte family moved for a new trial, *Diaz* was still the law. It’s precedent which was set and then overruled in *Diaz* and the \$3.5 million settlement permeated *voir dire*, opening statements, closing arguments, and jury instructions. After receiving a verdict, the Flyte family moved for a new trial which the trial court ruled upon when *Diaz* was still the law of the land. It was fundamental error as a matter of law to consider the juror declarations, and the trial court rendered the ruling on the motion for a new trial based upon those impermissible declarations and what is now bad law.

If *Diaz* had been overruled prior to the trial court ruling on the motion for a new trial, the trial court may have granted the motion. This entire matter is complicated by the fact that the trial court relied upon what is now overturned case law. On top of that, the trial court improperly

considered juror declarations which relate specifically to one juror's description of how the jury purportedly considered the \$3.5 million settlement – which never should have been admitted. *Gardner, supra*. Because the trial court relied upon bad law, and also improperly considered juror declarations relating to the processes purportedly supporting the verdict, this Court should be more inclined to reverse the trial court's order denying the request for a new trial.

**Issue 3: This Court should grant a new trial premised upon the fact that the trial court improperly instructed the jury as the burden of proof for establishing a breach of informed consent:**

The jury was improperly guided as to the applicable legal standard when instructed as follows on the issue of informed consent:

*A physician has no duty to disclose treatments for a condition that may indicate a risk to the patient's health until the physician diagnoses that condition.*<sup>7</sup>

Washington Supreme Court precedent specifically provides the law is the opposite: no formal diagnosis is required in order to trigger full informed consent obligations. *Gates v. Jensen*, 92 Wn.2d 246, 250-51, 595 P.2d 919 (1979). (“The patient's right to know is not confined to the choice of treatment once a disease is present and has been conclusively diagnosed.”) Without reference to any authoritative source, the Clinic contends that

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<sup>7</sup> CP 146-76; Instruction No. 11

*Gates* was overruled for the principle upon which the Flyte family offers it and also argues that any informed consent claim was subsumed by the negligence theories. Both of the Clinic's propositions are in error.

It is true that *Gates* was decided in 1974 prior to the codification of the medical malpractice laws in 1979. See RCW 7.70.010. However, *Gates* is in no way inconsistent with the subsequent codification and has never been overruled by later Supreme Court precedent. *Id.* The express purpose of the codification of the medical malpractice laws under Chapter 7.70 did not include jettisoning all existing case law. *Id.* The Legislature made no assertions within RCW 7.70.010 disavowing the existing case law, to include *Gates*. *Id.* As to the issue of a doctor's obligation to inform a patient of risks associated with a certain clinical presentation even in the absence of a particular diagnosis, *Gates* remains the law of Washington. The Clinic cites *no* law demonstrating that *Gates* has been overturned or modified on the discrete informed consent issue before this Court. At best, the Clinic cites a sprinkle of lower court decisions that are not on point and distinguished herein. On that basis alone, the jury was misled on the issue of informed consent and a new trial should therefore be granted.

The Clinic's suggestion that any informed consent theory was "really" just a negligence claim is also incorrect as a matter of law. To be

clear, the Flyte family was *never* asserting a failure to diagnose claim.<sup>8</sup> The Flyte family maintained this position and theory from the very beginning of the trial and made a clear record before the trial court, and before the jury was ever seated:

MR. BEAUREGARD: ...So with that, there's a second component of our argument, Your Honor, and that's – and we are going to be trying to make very clear to this jury through this whole entire trial that under the health advisories and according to our experts, you don't have to diagnose influenza in order to offer Tamiflu. That was the point of the CDC's warnings; that was the point of the health alerts, is that pregnant women are at such risk, they are at such risk for complications that if a pregnant woman come in your office and you think she could just possibly have this, she's at risk of dying. Give her the medication and give it to her right away, and give it to her as close to the 48-hour window as you can, and you don't wait for and kind of confirmed test or anything along those lines for that precise reason. You can't screw around.<sup>9</sup>

At trial, the Flyte family deliberately did not present any evidence to advance a negligent diagnosis claim. Instead, the Flyte family presented the CDC warnings indicating that dire nature of exposure to H1N1 on the part of pregnant women and the need to have them treated prophylactically, without a confirmed diagnosis:

Antiviral treatment should be initiated as soon as possible after the onset of symptoms. Evidence indicates benefit

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<sup>8</sup> Verbatim Report of Proceedings July 9, 2012, Pages 6-7

<sup>9</sup> Verbatim Report of Proceedings July 9, 2012, Pages 6-7

from treatment in studies of seasonal influenza is strongest when treatment is started within 48 hours of illness onset...<sup>10</sup>

By mandating that which the CDC requirements did not require, a formal diagnosis of H1N1 prior to informing Mrs. Flyte about the associated risks, the viability of the Flyte family's informed consent claim was eviscerated by Instruction No. 11. In accord with Instruction No. 11, any doctor, such as Dr. Marsh, that fails to formally diagnose and dangerous condition has no legal obligation to inform the patient about the associated risks. This cannot possibly be the law.

The Clinic relies heavily upon *Gomez v. Sauerwein*, 172 Wn. App. 370, 289 P.2d 597, review denied, 119 Wn.2d 1020 (2012) for the proposition that "a physician's failure to diagnose a condition is a matter of medical negligence, not a violation of the duty to inform..." *Gates* is distinguishable. In *Gates*, the defending doctors had failed to diagnose a condition that would have prompted proper treatment. *Id.* And the medical malpractice claimant in *Gates* advanced a negligent diagnosis claim: "The estate's alternative claim for medical negligence, asserting misdiagnosis by Dr. Sauerwin, was rejected by a jury." *Id.* at 372. By contrast, in this case, even in the absence of a formal H1N1 diagnosis, the Clinic had an obligation to inform Mrs. Flyte, a pregnant woman at risk

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<sup>10</sup> Appendix of Exhibit P-5

for serious complications, of prophylactic measures as recommended by the Tacoma/Pierce County Health Department and the CDC:

Q. I want to ask you another question about informed consent, Doctor.

MR. BEAUREGARD: And I'd also like to publish and show to the jury Plaintiff's Exhibit 15.

THE COURT: You may publish.

MR. BEAUREGARD: Plaintiff's 5, excuse me.

[Whereupon, Exhibit No. 5 was published]

Q. (By Mr. Beauregard) Do you have a quick impression what this document is?

A. This is an advisory from the Tacoma Pierce County Health Department on swine flu or H1N1 novel influenza, which it was called technically, May 5<sup>th</sup>, I believe, of 2009. And it was both an advisory on the availability of medication and isolation techniques, namely masks, as well as information on the treatment of patients for the influenza pandemic that we were seeing begin at that time.

Specifically, I know that there has this – been this discussion about the timing of the administration of medication. And that statement here was that it would well be prescribed beyond the 48 hours that the package insert on Tamiflu showed. And so it would be incumbent on the physician to include that in their discussion with the patient.

You could certainly say, you know, the package insert, the FDA says that this might not be effective beyond 48 hours, because, again, that's the time during which the studies

were done. But when you look at the clinical application of this drug many, many authorities – and we draw upon many authorities to help us make these kind of decisions – have stated it is effective beyond that stated timeframe.

Q. Doctor, would it have been part of participatory medicine for Dr. Marsh and Summit View Clinic to have told Katie Flyte that as of June 26<sup>th</sup>, 2009, they had received some 10, 11, 12 of these health advisories?

A. Well, I don't know so much that he would have had to of told her that he received the health advisories as to the fact of what the health advisories contained.

Saying we have this drug to treat influenza, which is a Category C, explain that means, and that the package insert by the sanctity of the Food an Drug Administration has said that it may not work beyond 48 hours. It appears, perhaps, that your symptoms have been ongoing on for more than 48 hours. But the harm, the risk is minimal, and the benefit could be substantial. And I would like you to consider that in whether you would like me to prescribe this drug or not.

Again, patient has to be participating. I wouldn't say this is the drug you need. You must take it. I would offer it, and if the patient chose, understanding the risks and benefits, then she could fill the prescription.<sup>11</sup>

Moreover, it is not disputed that there was no reliable test available for expeditiously confirming a clinical Swine Flu diagnosis: “*Note that a negative test does not rule out influenza.*”<sup>12</sup> Under the informed consent law as interpreted by the Clinic, in the face of a pandemic, a front line

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<sup>11</sup> Hal Zimmer, M.D. Trial Transcript, Pages 11-13

<sup>12</sup> *Id.*

health care facility has no duty to inform an at-risk patient of prophylactic measures that might save her from the recognized risks, and save the life of her baby too. Upholding Instruction 11 could eventually lead to the death of more uninformed patients in the future.

Moreover, Instruction No. 11 is consistent with the trend in modern medicine towards treating the cause of an ailment versus the condition:

*Too many people in our country are not reaching their full potential for health because of preventable conditions. Moreover, Americans receive only about half of the preventative services that are recommended – a finding that highlights the national need for improved health promotion. The 2010 Affordable Care Act responds to this need with a vibrant emphasis on disease prevention...*

See Appendix: The New England Journal of Medicine: *Promoting Prevention through the Affordable Care Act*; see also The Patient Protection and Affordable Care Act: H.R. 3590. According to the Clinic, a patient that comes to the facility for outpatient care and notes drinking a six pack of Mountain Dew everyday does not have the right to be informed of medical research indicating the potential for diabetes until the condition has actually been diagnosed. A smoker with signs of a lung cancer has no right to be informed about the preventative measures that might be taken until the cancer has come to full fruition. An avid runner

with a heart murmur has no right to be informed and warned about risks of excessive exertion until after a heart attack has been confirmed months or years later.

The Clinic's interpretation of the law promotes treating the illness instead of the cause. This cannot be the law and is not consistent with the trend in modern medicine including recently enacted Patient Protection and Affordable Care Act:

*...Examples of covered services include screening for breast cancer, cervical cancer, and colorectal cancer; screening for human immune-deficiency virus (HIV) for persons at high risk; alcohol-misuse counseling, depression screening (when systems are in place to ensure accurate diagnosis, effective treatment, and follow-up); and immunizations.*

*Id.* As a matter of law and policy, Instruction No. 11 promotes treating the illness and not the cause and is inconsistent with the law and modern medicine. *Id.* Moreover, Instruction No. 11 is in direct conflict with *Gates*.

The Clinic also relies heavily upon *Thomas v. Wilfac, Inc.*, 65 Wn. App. 255, 828 P.2d 597, rev denied, 119 Wn.2d 1020 (1992). In *Thomas*, the case went to the jury on theories of both medical negligence and a lack of informed consent. *Id.* The jury returned a complete defense verdict. Ms. Thomas argued that "as a matter of law" the defending doctor violated

the obligations of informed consent. *Id.* at 259. The *Thomas* opinion does engage in a lengthy discussion about the principles associated with informed consent claims. However, the *Thomas* case did not involve a jury instruction that mirrored Instruction No. 11 in this case and is therefore of minimal relevance to these proceedings. *Thomas* offers nothing of precedential value in contrast to the Clinic's Instruction No. 11. Moreover, Division III's opinion in *Thomas* *did not* and *could not* overrule Supreme Court precedent set by *Gates*.

In sum, the jury was improperly instructed on the issue of informed consent. According to Instruction No. 11, the Flyte family could never prevail on an informed consent theory absent also proving a negligent diagnosis claim. Here, unlike the plaintiff in *Gomez*, the Flyte family was not even pursuing a negligent diagnosis claim so the informed consent claim was dead on arrival. In this context, the informed consent claim was a focal point in the case particularly in light of the warnings issued by the CDC and the Tacoma/Pierce County Health Departments. Also noteworthy is that fact that the St. Joe's Hospital medical records reflect that Mrs. Flyte was actively seeking the type of treatment being recommend: "*She was asking about antibiotics, and I discussed the fact that it is true t hat, if there is a virus, there are no antibiotics for fighting the flu or for fighting a virus, but that we could check to see if she in fact*

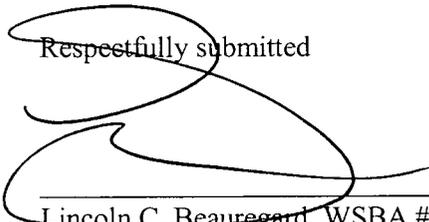
*did have a flu virus.*"<sup>13</sup> Because the jury was mis-instructed on the standard for proving an informed consent claim, this case should be reversed and remanded for a new trial.

### III. CONCLUSION

In accord with CR 59(a)(1),(8), and (9) and *In re Morris*, 288 P.3d 1140 (2012) (cumulative errors warrant new trial even when single error alone would not), the compounded legal errors noted herein warrant granting a new trial. It must not be forgotten that many of the trial court's rulings were premised upon now overturned case law in *Diaz*. CR 59(a)(9) dictates that a new trial is warranted when "substantial justice has not been done." Premised upon the arguments set forth herein, this Court should grant a new trial. *Id.*

DATED this 22<sup>nd</sup> day of July, 2013.

Respectfully submitted



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<sup>13</sup> Appendix Exhibit P-18

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KATHRYN FLYTE, on behalf of their son JACOB FLYTE, and as  
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APPENDIX FOR APPELLANTS' REPLY BRIEF

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APPENDIX OF EXHIBITS (PROMOTING PREVENTION THROUGH THE AFFORDABLE CARE ACT) ..... 1

**APPENDIX OF EXHIBIT**  
**(Promoting Prevention Through the Affordable Care Act)**

sence of obvious amyloid plaques. Laboratory modeling of traumatic brain injury should facilitate the elucidation of the underlying cellular and molecular changes. Better modeling is required, since the configurations of the brain, skull, and spine in species that are used to study traumatic brain injury in the laboratory (rodents and swine) are imperfect models for human disease. Nevertheless, genetically modified rodent models hold promise for delineating pathogenesis in post-traumatic neurodegeneration, as they have done in idiopathic diseases.

Data from helmet concussion monitors that are used on soldiers and football players can aid in predicting the character and location of lesions from an impact of a given force at given coordinates while improving the accuracy of diaries of people at risk for traumatic brain injury. Accurate diaries, in turn, should help in determining more accurately

the number and severity of head injuries, allowing estimation of athletes' cumulative risk. Individual differences in trauma tolerance and genetic influences must also be elucidated. These data can inform prospective studies of the cognitive, neuropsychiatric, and motor performance of soldiers, athletes, and other exposed populations, as well as informing the design of behavioral and pharmacologic interventions for prophylaxis or therapy. A challenge will be translating our improved understanding of the pathogenesis of traumatic brain injury into rational, evidence-based changes in public and sports policy that will minimize exposure to such injuries and their chronic neurodegenerative sequelae.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Office of the Dean and the Department of Neurology, University of Virginia School of Medicine, Charlottesville (S.T.D.); the Departments of Neurology and

Psychiatry, University of Pittsburgh School of Medicine, and the Geriatric Research Educational and Clinical Center, VA Pittsburgh Healthcare System — both in Pittsburgh (M.D.I.); and the Departments of Neurology and Psychiatry and the Alzheimer's Disease Research Center, Mount Sinai School of Medicine and the James J. Peters VA Medical Center — both in New York (S.G.).

This article (10.1056/NEJMp1007051) was published on September 22, 2010, at NEJM.org.

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## Promoting Prevention through the Affordable Care Act

Howard K. Koh, M.D., M.P.H., and Kathleen G. Sebelius, M.P.A.

Too many people in our country are not reaching their full potential for health because of preventable conditions. Moreover, Americans receive only about half of the preventive services that are recommended<sup>1</sup> — a finding that highlights the national need for improved health promotion. The 2010 Affordable Care Act<sup>2</sup> responds to this need with a vibrant emphasis on disease prevention. Many of the 10 major titles in the law, especially Title IV, Prevention of Chronic Diseases and Improving Public Health, advance a prevention theme through a wide array of new initiatives and funding. As

a result, we believe that the Act will reinvigorate public health on behalf of individuals, worksites, communities, and the nation at large (see table) — and will usher in a revitalized era for prevention at every level of society.

First, the Act provides individuals with improved access to clinical preventive services. A major strategy is to remove cost as a barrier to these services, potentially opening new avenues toward health. For example, new private health plans and insurance policies (for plans or policy years beginning on or after September 23, 2010) are required to cover a range of recommended

preventive services with no cost sharing by the beneficiary. These services include those rated as "A" (strongly recommended) or "B" (recommended) by the U.S. Preventive Services Task Force (USPSTF), vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP), and preventive care and screening included both in existing health guidelines for children and adolescents and in future guidelines to be developed for women through the U.S. Health Resources and Services Administration (HRSA). Examples of covered services include screening for breast cancer, cer-

vical cancer, and colorectal cancer; screening for human immunodeficiency virus (HIV) for persons at high risk; alcohol-misuse counseling; depression screening (when systems are in place to ensure accurate diagnosis, effective treatment, and follow-up); and immunizations.

The prevention theme also affects individuals covered by public insurance programs. A number of policy changes will be phased in over time. For example, starting January 1, 2011, Medicare will cover, without cost sharing, an annual wellness visit that includes a health risk assessment and a customized prevention plan. Full coverage of many USPSTF-recommended services will also be available under Medicare with no cost sharing. Similarly, in 2013 and beyond, state Medicaid programs that eliminate cost sharing for preventive services recommended by the USPSTF or ACIP may be eligible for enhanced federal matching funds for providing those services.

Second, the law promotes wellness in the workplace, providing new health promotion opportunities for employers and employees. For example, the Act authorizes funds for grants for small businesses to provide comprehensive workplace wellness programs. The law also requires the secretary of health and human services to assess existing federal health and wellness initiatives and directs the Centers for Disease Control and Prevention (CDC) to survey worksite health policies and programs nationally.

Third, the Act strengthens the vital role of communities in promoting prevention. New initiative opportunities are designed to strengthen partnerships between local or state governments and

community groups. For example, new Community Transformation Grants promise to improve nutrition, increase physical activity, promote smoking cessation and social and emotional wellness, and prioritize strategies to reduce health care disparities. Also, in further recognition that immunization is a foundation for public health, the Act authorizes states to use their funds to purchase vaccines for adults at federally negotiated prices. Grants for states will also support demonstration projects to improve vaccination rates.

Fourth, the Act elevates prevention as a national priority, providing unprecedented opportunities for promoting health through all policies. For example, a newly established National Prevention, Health Promotion, and Public Health Council, involving more than a dozen federal agencies, will develop a prevention and health promotion strategy for the country. The council will build on the foundation of preceding prevention initiatives, such as Healthy People (which has set the country's health promotion and disease prevention agenda for the past 30 years),<sup>3</sup> as well as efforts of expert groups such as the USPSTF, the Community Preventive Services Task Force, and the ACIP. A new Prevention and Public Health Fund, with an annual appropriation that begins at \$500 million in fiscal year 2010 and increases to \$2 billion in fiscal year 2015 and beyond, will invest in a range of prevention and wellness programs administered by the Department of Health and Human Services. Initial funds have already been invested in strengthening public health infrastructure, prevention research, surveillance, integration of primary care into community-based

behavioral health programs, HIV prevention, obesity prevention, and tobacco control. Reinvigorated planning will also involve a national strategy to improve the quality of health care, improved data collection on health disparities,<sup>4</sup> and authorization of a host of other new programs. Most newly authorized programs await appropriations and future funding as available through the annual budget process (exceptions are noted in the table).

The Act authorizes heavy investment in bolstering a primary care workforce that can promote prevention. For example, the law appropriates up to \$1.5 billion for the National Health Service Corps between fiscal years 2011 and 2015 to place health care professionals in underserved areas, complementing other new investments for community health centers administered through HRSA. To guide future placements of health care professionals, a new National Health Care Workforce Commission will analyze needs.

Since tobacco dependence and obesity represent substantial health threats, the Act addresses these specific challenges in a number of ways. For example, the directives for the new health plans established after September 23, 2010, also include coverage, with no cost sharing, of tobacco-use counseling and evidence-based tobacco-cessation interventions, as well as obesity screening and counseling for adults and children. Starting this year, pregnant women on Medicaid will receive coverage, without cost sharing, for evidence-based tobacco-dependence treatments; in 2014, states will be forbidden from excluding from Medicaid drug coverage any pharmaceutical agents for smoking cessation, including over-the-counter medications, that have been

Major Sections Related to Prevention in the 2010 Affordable Care Act		Section Name	Summary
<b>For individuals</b>			
§ 2502	Medicaid and Tobacco Pharmaceutical Coverage	Prevents states from excluding coverage for tobacco-cessation drugs from their Medicaid programs.	
§ 2713	Coverage of Preventive Health Services	Requires new employer-sponsored group health plans and private health insurance policies to provide coverage, without cost sharing, for preventive services rated A or B by the USPSTF; immunizations recommended by ACIP; preventive care and screening for infants, children, and adolescents and additional preventive services for women that are recommended by HRSA.	
§ 4103	Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Program	Eliminates copayments for Medicare enrollees who receive an annual wellness exam that includes a health risk assessment and personalized prevention plan.	
§ 4104	Removal of Barriers to Preventive Services in Medicare	Eliminates copayments for Medicare preventive services that are rated A or B by the USPSTF.	
§ 4106	Improving Access to Preventive Services for Eligible Adults in Medicaid	Federal medical assistance percentage increased by 1% for preventive services in states that eliminate cost sharing for services rated A or B by the USPSTF and immunizations recommended by ACIP.	
§ 4107	Coverage of Comprehensive Tobacco Cessation Services for Pregnant Women in Medicaid	Provides coverage without cost sharing for evidence-based tobacco-dependence treatments for all pregnant women covered by Medicaid.	
§ 4206	Demonstration Project Concerning Individualized Wellness Plans	Creates a pilot program to determine the effectiveness of individualized wellness plans at federally qualified community health centers.	
<b>For businesses and workplaces</b>			
§ 4207	Reasonable Break Time for Nursing Mothers	Requires employers to provide sufficient break time and appropriate facilities for nursing mothers.	
§ 4303	CDC and Employer-Based Wellness Plans	Requires the CDC to provide technical assistance in evaluating employer-based wellness programs, as well as to conduct a survey of existing programs.	
§ 4402	Effectiveness of Federal Health and Wellness Initiatives	Requires the secretary of health and human services to evaluate the effectiveness of existing federal health and wellness initiatives and requires a report to Congress.	
§ 10408	Grants for Small Businesses to Provide Comprehensive Workplace Wellness Grants	Authorizes a grant program for small businesses to establish workplace wellness programs.	
<b>For communities and states</b>			
§ 4108	Incentives for Prevention of Chronic Diseases in Medicaid	Provides grants to states to provide incentives to Medicaid enrollees who adopt and maintain healthy behaviors. Appropriates up to \$100 million that becomes available in FY 2011.	
§ 4201	Community Transformation Grants	Authorizes competitive grants for state and local government agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based programs to reduce the rates of chronic conditions, improve prevention, reduce disparities, and decrease rates of disease.	
§ 5313	Grants to Promote the Community Health Workforce	Authorizes grants to improve health care in medically underserved areas through the use of community health workers.	
<b>National</b>			
§ 3011	National Strategy to Improve Healthcare Quality	Requires the secretary of health and human services to establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.	
§ 4001	National Prevention, Health Promotion, and Public Health Council	Creates a council to provide coordination and leadership of prevention and wellness and health promotion practices at the federal level, and directs the council to develop a national strategy on prevention.	

§ 4002	<i>Prevention and Public Health Fund</i>	Expands and sustains national investment in prevention and public health programs. Appropriates up to \$500 million for FY 2010, \$750 million for FY 2011, \$1 billion for FY 2012, \$1.25 billion for FY 2013, \$1.5 billion for FY 2014, and \$2 billion for FY 2015 and beyond.
§ 4003	<i>Clinical and Community Preventive Services</i>	Promotes expanded coordination among the USPSTF, Community Preventive Services Task Force, and ACIP.
§ 4004	<i>Education and Outreach Campaign Regarding Preventive Benefits</i>	Requires the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.
§ 4102	<i>Oral Healthcare Prevention Activities</i>	Creates education, surveillance, and research demonstration grants.
§ 4205	<i>Nutrition Labeling of Standard Menu Items at Chain Restaurants</i>	Requires the disclosure of specified nutritional information for food sold in certain chain restaurants and vending machines.
§ 4301	<i>Research on Optimizing the Delivery of Public Health Services</i>	Supports research in the area of public health services and systems.
§ 4302	<i>Understanding Health Disparities: Data Collection and Analysis</i>	Requires any federally conducted and supported public health programs to report appropriate data for analysis.
§ 5101	<i>National Health Care Workforce Commission</i>	Establishes a national commission to provide comprehensive information on workforce needs.
§ 5207	<i>Funding for National Health Service Corps</i>	Expands and reauthorizes the National Health Service Corps.
§ 10413	<i>Young Women's Breast Health Awareness and Support of Young Women Diagnosed with Breast Cancer</i>	Authorizes a program to support awareness, knowledge, research, and support for breast cancer in young women.
§ 10501	<i>National Diabetes Prevention Program</i>	Authorizes a national program focused on reducing preventable diabetes in at-risk adult populations.
§ 10503	<i>Community Health Centers and the National Health Service Corps</i>	Provides for expanded and sustained investment in community health centers. Appropriates up to \$9.5 billion for Community Health Center Initiative between FY 2011 and FY 2015. Appropriates up to \$1.5 billion for National Health Service Corps between FY 2011 and FY 2015. Appropriates up to \$1.5 billion for the construction and renovation of community health centers between FY 2011 and FY 2015.

\* Unless specifically noted, newly authorized programs await appropriations and future funding as available through the annual budget process. ACIP denotes Advisory Committee on Immunization Practices, CDC Centers for Disease Control and Prevention, FY fiscal year, GAO Government Accountability Office, HRSA Health Resources and Services Administration, and USPSTF U.S. Preventive Services Task Force.

approved by the Food and Drug Administration. To promote healthy weight for populations, the Act appropriates funds for fiscal years 2010 through 2014 for demonstration projects to develop model programs for reducing childhood obesity. And on the policy front, menu-labeling provisions require the disclosure of specified nutrient information for food sold in certain chain restaurants and vending machines. Collectively, these complementary actions in the clinic and the community will benefit individuals as well as populations.

In short, to prevent disease and promote health and wellness, the Act breaks new ground. We believe the law reaffirms the principle that “the health of the individual is almost inseparable from the health of the larger community. And the health of each community and territory determines the overall health status of the Nation.”<sup>3</sup> Moving prevention toward the mainstream of health may well be one of the most lasting legacies of this landmark legislation.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Dr. Koh is Assistant Secretary for Health, and Ms. Sebelius is the Secretary for Health and Human Services, Department of Health and Human Services, Washington, DC.

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COURT OF APPEALS, DIVISION II  
STATE OF WASHINGTON

KENNETH FLYTE, P.R., *et al.*

Appellants,

v.

SUMMIT VIEW CLINIC, a Washington  
Corporation,

Respondent.

No. 43964-6-II

CERTIFICATE OF SERVICE

The undersigned certifies under penalty of perjury under the laws of the state of Washington, that she is now, and at all times materials hereto, a citizen of the United States, a resident of the state of Washington, over the age of 18 years, not a party to, nor interested in the above entitled action, and competent to be a witness herein.

I caused to be served this date the following:

- Appellants' Reply Brief; and
- Appendix for Appellants' Reply Brief

in the manner indicated to the parties listed below:

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DATED this 22<sup>nd</sup> day of July, 2013.

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