

# The New York Times

## Health Reform's Missing Ingredient

By RON WYDEN

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“MY guiding principle is, and always has been, that consumers do better when there is choice and competition,” President Obama said last week in [an address to Congress](#) on health care reform. It’s a good principle, one that may determine the ultimate success or failure of reform, but unfortunately it’s not really guiding the [Senate bill](#) unveiled on Wednesday or any of the other health reform legislation now under consideration in Congress.

Under the nation’s current employer-based system, most people have little if any choice about where they get their insurance. They just have to accept the plan that comes with their job. That insurance company, in turn, is provided a captive group of customers, so it has no incentive to earn their loyalty.

Empowering Americans to choose from a broad selection of health plans would turn the tables. Those insurers that charged affordable rates and provided good coverage would attract more customers, while those that treated customers badly would be forced to change their ways or go out of business. To stay competitive, insurers would need to follow the example of places like the Mayo Clinic and offer good, low-cost coverage.

The various bills making their way through Congress would, as the president explained, provide some consumer choice by establishing large marketplaces where people could easily compare insurance plans and pick the one that best suits their needs. Companies participating in these insurance exchanges would be required to offer coverage to anyone who wants to buy it, regardless of their age, gender or health status, and they would be barred from charging someone more for having a pre-existing condition.

The problem with these bills, however, is that they would not make the

exchanges available to all Americans. Only very small companies and those individuals who can't get insurance outside of the exchange — 25 million people — would be allowed to shop there. This would leave more than 200 million Americans with no more options, private or public, than they have today.

I understand the president's fear of overreaching. Past reform efforts have failed in part because of the public's distaste for government-imposed change. But walling off most of the health care system from choice and competition could create greater problems — enough to doom health care reform.

I believe there is a way to work with the present employer-based system to guarantee that all Americans have choices, and I am proposing it in an amendment to the latest Senate health care bill. My amendment, called Free Choice, would let everyone choose his health insurance plan.

It would impose only one requirement on employers — that they offer their employees a choice of at least two insurance plans, one of them a low-cost, high-value plan. Employers could meet this requirement by offering their own choices. Or they could let their employees choose either the company plan or a voucher that could be used to buy a plan on the exchange. They could also simply insure all of their employees through the exchange, at a discounted rate.

All payments that employers would make, whether in the form of premiums or vouchers, would remain tax-deductible as a business expense. Reinsurance and risk adjustment mechanisms already in the bill would balance the costs of employers who end up with disproportionately sick pools of workers, and this would avoid any disruption to existing employer coverage. Any employers that did not offer either their own choices or insurance through the exchange would be required to pay a “fair share” fee to help support the system.

My plan would actually strengthen the employer-based system by making it possible for even more employers to afford coverage than can today. Employers who offer high-quality health insurance to attract first-rate employees could continue to do so. And employees who like the coverage

they have could keep it. Those who don't, however, would be able to shop elsewhere.

According to one estimate, injecting this kind of competition into the employer-based system would save people and businesses more than \$360 billion over 10 years. At the same time, it would improve the quality of health care.

Americans could take advantage of this change, or ignore it if they like; it would not be forced on them by government mandate. Ultimately, by empowering people to select the health insurance that makes the most sense for them and their family, we could end up with a system that works better for everyone.

*Ron Wyden is a Democratic senator from Oregon.*

# The Washington Post

## Bipartisanship Shouldn't Be a Political Death Sentence

BY RON WYDEN

Friday, May 21, 2010

The message that many partisan activists want me and my congressional colleagues to take away from [this week's primaries](#) and [Utah's recent GOP convention](#) is that engaging in bipartisanship is tantamount to surrendering your political party's most-prized principles. In fact, some in my party will undoubtedly criticize me for writing kind words about my friend Sen. Bob Bennett, just as some in Bob's party thought that his working with a Democrat was sufficient grounds for losing his seat in the U.S. Senate. In other words, many of the most committed activists believe that the only way for Republicans to win legislatively is for Democrats to lose, and vice versa.

Meanwhile on Capitol Hill, legislating is treated as if there is a giant

congressional scoreboard that will ultimately determine which party gets to be in charge. What one side is for legislatively, the other is unalterably against. Many believe that is the only way to achieve clear victory.

While it is certainly true that legislating can be (and is) turned into a zero-sum game, despite what you hear on cable news, not every issue has diametrically opposed Democratic and Republican ideologies. In fact, not only are there policy areas on which Democrats and Republicans agree but when it comes to legislating, many issues present opportunities to build on the best ideas of both parties. No single party has a lock on all the good ideas.

I still think I had a pretty good idea for health reform -- despite its rejection by significant Democratic and Republican leaders -- but so did Bob Bennett. I was on the Senate floor three years ago when Bob walked across the center aisle to tell me he was willing to work with me on health reform. I had been meeting with him and other Senate colleagues for many weeks to talk about the [Healthy Americans Act](#) and what I believed was a historic opportunity for Democrats and Republicans to work together on an important issue.

Ideologically, Bob and I couldn't be more different. He's pro-life. I'm pro-choice. He voted for the Iraq war; I didn't. If Bob has ever seen a tax break he didn't like, I am unaware of it. But one thing Bob and I have in common is our fundamental belief that we were elected to do more than just get reelected, that once elections are over we have a duty to try to govern even if it means working with people with whom we don't always agree.

While I'll let others debate what became of the Wyden-Bennett health-reform bill, our effort married the best, most principled ideas that both parties had been promoting for decades. Like most Democrats, my fundamental principle was guaranteeing quality, affordable health coverage for all Americans. Like most Republicans, Bob felt strongly that market forces be used to promote expanded consumer choice and competition. Our legislation did both. As long as I would help Bob achieve his marketplace principles and avoid bigger government, Bob said he could back me on getting everyone insured.

Working in a bipartisan fashion can lead to watered-down legislation, yes, but principled bipartisanship can also lead to a value-added, better result. Personally, I believe that both sides can get much more of what they want by working together than by simply trying to prevent the other side from gaining ground. By working with those with whom we don't necessarily see eye to eye, we are forced to work harder, to test our ideas and to consider solutions that we may never have thought of on our own. Moreover, if Democrats and Republicans ever stop fighting each other, they might finally find the strength to defeat the interest groups that all too easily exploit the partisan divide.

Bob Bennett is one of the most conservative men I have ever known, but he is also one of the best. Even in defeat, he told me that he doesn't for one minute regret working with me to try to do something important for the country, which is why I consider his loss so tragic. The country needs more senators who think like Bob Bennett, not fewer.

While it may be tempting to read the recent elections as a rejection of principled bipartisanship, polling shows that the majority of the American people are sick of the status quo, and the status quo is a Washington obsessed with legislating as though Congress's sole function is to play a wholly partisan, zero-sum game. The American people want us to put our nation ahead of party allegiances. They want us to do more than devise ways to gain and maintain power. They want us to be constructive with that power.

The regrettable irony of what transpired in Utah's Republican convention is that a small number of hyperpartisan activists have just ensured that Utah's contribution to the Senate will be less bipartisanship and more of the status quo in Washington. If that is the change that partisans are offering the nation, let's make certain the American public understands.

*The writer is a Democratic senator from Oregon.*



## Sen. Ron Wyden: PIPA/SOPA Is a Congressional Wake-Up Call

BY U.S. SENATOR RON WYDEN

WASHINGTON — Most folks who run businesses know that if they ignore the internet, they do so at their own peril.

If you run a business — whether it's a restaurant or a cable company — what people on the internet say about your product and customer service has an impact on your bottom line. And if you're running a technology company, you won't succeed unless you understand that the online world doesn't always function like the tangible one.

Some businesses lament this fact when bad reviews start costing them business. But smart businesses recognize that even the bad reviews are an opportunity to understand their audience and improve their products and those that have gone the extra mile to understand the internet have, in many cases, found success.

But up until last week, Washington hadn't learned these lessons.

Sure, politicians have long seen the internet as a useful tool for raising money and receiving e-mail from constituents. There have been many online campaigns and more than a few lobbyists and special interest groups have invested a good sum of money into efforts to mobilize folks online. Success has frequently been measured by the number of e-mail addresses collected, while the efforts to rally people fizzle when recognized as little more than online astroturfing — fake grass without the roots.

But last week, when more than 10 million Americans spoke up together to express concern about the Protect IP Act (PIPA) and the Stop Online Piracy Act (SOPA) — and brought a halt to what had been a legislative juggernaut — Capitol Hill and K Street got a taste of what the internet

can really do and why it's more than just another interest group. While lobbyists have long been the middle-men between interests and Congress, last Wednesday showed that political connections and insider know-how mean little when up against an informed public willing to take action. Information is power in Washington, but last week demonstrated that the internet's ability to use information far surpasses that of any interest group, lobbyist or cable news network. And while decisions have long been made behind closed doors in Washington, last week made it very clear that the concerns of the American people can not simply be ignored.

While some have derided the events of last week as a departure from the way we do things in Washington, I believe last week is an example of the way Washington can change for the better. If more Americans took the time to be informed and call Congress when something matters to them lobbyist and special interest power would be greatly diminished.

So the question is, did Congress learn anything? Will Washington lament last week like it was a bad review that cost it business or will it recognize what happened as an opportunity to learn and do better?

If members of Congress better understood the central role that the Internet plays in their constituents' lives – the hub through which Americans work, communicate, share, learn, create and enjoy entertainment – they would understand why their constituents fought so hard to protect it.

If members of Congress better understood the digital world, they would know that downloading a digital good from a foreign site is no different than importing goods from a foreign country and if we accept that principle, we can do more than combat online infringement, we can work to promote our digital industries and tear down barriers to digital trade just as we do for any other American-made product.

When members of Congress better understand the Internet they will see it as a world of opportunity to create jobs and foster innovation, to improve education and economic mobility, and most importantly to cultivate the sort of government our founders intended in which we hear

and learn from our constituents. Congress ignores this opportunity at their peril.

## THE HUFFINGTON POST

### How Can Congress Debate a Secret Law?

BY SENATORS RON WYDEN AND MARK UDALL

05/25/2011

Members of Congress are about to vote to extend the most controversial provisions of the USA PATRIOT Act for four more years, even though few of them understand how those provisions are being interpreted and applied.

As members of the Senate Intelligence Committee we have been provided with the executive branch's classified interpretation of those provisions and can tell you that we believe there is a significant discrepancy between what most people - including many Members of Congress - think the Patriot Act allows the government to do and what government officials secretly believe the Patriot Act allows them to do.

Legal scholars, law professors, advocacy groups, and the Congressional Research Service have all written interpretations of the Patriot Act and Americans can read any of these interpretations and decide whether they support or agree with them. But by far the most important interpretation of what the law means is the official interpretation used by the U.S. government and this interpretation is - stunningly -classified.

What does this mean? It means that Congress and the public are prevented from having an informed, open debate on the Patriot Act because the official meaning of the law itself is secret. Most members of Congress have not even seen the secret legal interpretations that the executive branch is currently relying on and do not have any staff who are cleared to read them. Even if these members come down to the Intelligence Committee and read these interpretations themselves, they

cannot openly debate them on the floor without violating classification rules.

This is not acceptable. Americans recognize that their government can better protect national security if it is sometimes allowed to operate in secret and they do not expect to know all of the details about how government agencies collect intelligence. But Americans also expect their government to operate within the boundaries of publicly-understood law. As voters they have a need and a right to understand what those boundaries are so that they can ratify or reject decisions that elected officials make on their behalf.

In a democratic society, government agencies derive their power from the public's trust - what James Madison called a "Fountain of Authority." Secret laws undermine that trust and authority, which then erodes and ultimately damages our ability to fight terrorism and protect the American people.

As we saw with the Bush Administration's warrantless wiretapping program, secret laws and programs don't stay secret forever. And when the public learns that government officials have been rewriting the law in secret, the public confidence is undermined making it harder for government agencies to function effectively. When Americans learned that the Bush Administration had been relying on secret interpretations of the law to justify warrantless wiretapping many were shocked and the result was a public backlash whose impact is still being felt today.

Yesterday, we filed an [amendment](#), along with Senator Merkley of Oregon and Senator Udall of New Mexico (the text of which is below) stating the Sense of Congress that: "*United States Government officials should not secretly reinterpret public laws and statutes in a manner that is inconsistent with the public's understanding of these laws and should not describe the execution of these laws in ways that misinforms or misleads the public.*"

Our amendment would require the Attorney General to make public the U.S. government's official interpretation of the Patriot Act. This would not disclose specific intelligence collection programs or activities, but it would make the boundaries of the law clear to the public, so that

Americans can thoughtfully consider for themselves whether these boundaries are appropriately drawn and hold their elected officials accountable for them.

Members of Congress may have a variety of different views about the authorities granted by the USA Patriot Act, but we hope that all of our colleagues will agree that allowing government officials to write secret laws is a problem, and that being honest with the public is the only solution.



## Senator Ron Wyden Writes A Love Letter To The Internet For Anti-SOPA Activism

Oregon's Democratic Senator Ron Wyden is about to become an internet folk-legend.

Here is his [letter to the internet](#):

*January 18, 2012 Innovators, Speakers, Thinkers, and Agents for Change The World Wide Web Dear Friends: Today thousands of websites have chosen to voluntarily go offline or modify their home pages with public service information. Some have called this a stunt. I say it's a brave and poignant reminder that we can't take the Internet for granted.*

*The Internet has become an integral part of everyday life precisely because it has been an open-to-all land of opportunity where entrepreneurs, thinkers and innovators are free to try, fail and then try again. The Internet has changed the way we communicate with each other, the way we learn about the world and the way we conduct business. It has done this by eliminating the tollgates, middle men, and other barriers to entry that have so often predetermined winners and losers in the marketplace. It has created a world where ideas, products and creative expression have an opportunity regardless of who*

*offers them or where they originate.*

*Protect IP (PIPA) and the Stop Online Piracy Act (SOPA) are a step towards a different kind of Internet. They are a step towards an Internet in which those with money and lawyers and access to power have a greater voice than those who don't. They are a step towards an Internet in which online innovators need lawyers as much or more than they need good ideas. And they are a step towards a world in which Americans have less of a voice to argue for a free and open Internet around the world.*

*Proponents of these bills say these arguments are overblown, but I say any step towards an Internet in which one person's voice counts more than another is a step in the wrong direction. These are bills that should give us pause. These are bills that should be studied and debated. Congress should consult experts and consider alternatives and make 100% sure that any step it takes to police the Internet doesn't change the Internet as we know it. This is why I put a hold on the Protect IP Act and its predecessor over a year ago and introduced a bipartisan alternative last month.*

*The Senate, however, has scheduled a vote for Tuesday, January 24 at 2:15 PM to override my hold and move the Protect IP Act towards passage. This will be the deciding vote that determines whether PIPA and SOPA move through the Congress or are turned back for more sober discussion.*

*We are up against a group of the biggest, most powerful, well-funded and well-organized interest groups in Washington. No one thought millions of Internet users would speak up or that those voices could overcome the power of these interests. Today you showed that the Internet is not just a platform for ideas, commerce, and expression, but also for political action that will defend those principles. Your voices must continue to be heard.*

*Thank you for standing up for what's important, for continuing to speak out and for demonstrating that we should always stand up for what we think is right regardless of the odds. This is an opportunity to reshape the way Washington operates, not just responding to narrow interests but hearing the voices of millions of Americans whose rights and livelihoods are affected by our actions.*

*Sincerely,  
Ron Wyden  
United States Senator*



## A lesson for R&D: slowing down can help you speed up

*Tim Garnett of Eli Lilly and Company explores how sometimes slowing down can help us to get ahead and puts this into the context of drug research and development at Lilly.*

In recent years, prominent professional cyclists have argued that it's impossible to be competitive in their sport without cheating. U.S. velodrome cyclist Sky Christopherson disagreed. Doping may be the most expedient way for a cyclist to improve performance, but Sky opted for a smarter, slower approach.

First, he gathered data on the various factors that impacted his race: exercise, sleep, diet, mood, and even his chromosomal make up. Then, Sky made it his mission to optimize his performance in each area. The gains he made with each minor adjustment may have been small on their own, but they added up to make a significant difference. In fact, after a little over a year of quantified training, he broke a world sprint-cycling record.

In other words, Sky proved that sometimes the best way to speed up is to slow down.

I tell this story because at Lilly, we're taking a very similar approach to streamlining drug development. Right now, our molecular development cycle exceeds the industry's 12-year average by nearly six months, which means to stay competitive we have to find a way to get drugs to market faster.

To accomplish this, we're working to squeeze every drop of efficiency out of our development process, meaning we must approach clinical trials in much the same way that Sky approached his training. For us, the smarter,

slower approach is taking the time to understand the various factors that impact molecular development. We know there isn't a silver bullet to cut down our development time, but we believe that identifying a dozen or so smaller opportunities could ultimately add up to something significant.

For instance, we've learned that one of the best ways to avoid getting bogged down in Phase 3 clinical trials is to slow down and invest more time and resources in Phase 2 studies. While that may sound counter-intuitive on its face, applying more data-driven and iterative dosing studies in Phase 2 can help make the transition into Phase 3 more seamless – and, at the same time, help us anticipate challenges to overcome in late-stage regulatory review.

As for the studies themselves, patient participation can make or break Phase 3 work. So we've made it a point to step back and examine the process from our patients' perspectives. The fact is patients who participate in clinical trials aren't eager to repeat the experience -- only about two percent of these patients complete a second study.

This is a big problem for chronic illnesses like diabetes, osteoporosis or cardiovascular disease. To give you an idea of the scope, Lilly could be running as many as five studies for diabetes treatments over the next several years, requiring as many as 60,000 participants. And of course, we're not the only company performing research in this area.

Lilly has therefore refocused on making it easier for patients to find and participate in clinical trials, and making the experience one they'll consider signing up for again. We are putting ourselves in the mind of patients – and investigators – as we design clinical research studies. And we're also developing mobile and web-based tools for patients to increase awareness of – and access to – clinical trials in their geographic locations.

These efforts are showing progress, and our goal is to refine and build upon our progress to shave five years off our clinical development timeline by 2020. While we're optimistic, we also recognize that our industry needs to move forward together to maximize efficiencies in an evolving clinical environment. There are some great examples of what this kind of collaboration looks like. TransCelerate BioPharma is [a joint](#)

[venture founded by 10 biopharmaceutical companies](#) to support each other's mutual interest in the course of research and development for innovative medicines.

Prior to such initiatives, for example, investigators conducting clinical trials for more than one company would often have to sit through hours of redundant training sessions with each sponsor. Now, we're cross-referencing these certifications and allowing investigators to spend more time focusing on their research. It's a simple adjustment, but one that saves hours of valuable study time and has a significant impact on investigator perceptions of clinical research.

This point illustrates how slowing down to work together as an industry can help us make the sort of progress in drug development that no company could muster on its own – and that's critical for the patients at the center of our work. The process may seem counterintuitive or even tedious, but as companies and as an industry, taking the time to go slow now could ensure we're able to speed up when it counts.

## THE HUFFINGTON POST

### Learning About Life from the Woman Who Taught Us About Death

BY DIANNE GRAY

08/24/2014

I'm not sure why I walked into Barnes and Noble that afternoon, except that the "self-help" aisle seemed like a logical place to be as I pushed the wheelchair of my four-year-old son who had just been diagnosed with a rare, degenerative brain disorder.

Like many, I was first introduced to Dr. Elisabeth Kubler-Ross in college, when I was assigned to read her seminal book, *On Death and Dying*. While most associated with its outline of the "Five Stages of Grief," [the central message](#) of *On Death and Dying* is really "the importance of listening to what the dying have to tell us about their needs." The voice Dr. Kubler-

Ross gave the terminally ill with that book -- which she appropriately subtitled "What the Dying have to teach Doctors, Nurses, Clergy and their own Families" -- is just as important and poignant today as it was 40 years ago. (If you haven't read it, you should.)

What I most remembered about Dr. Kubler-Ross's work, however, wasn't what she wrote about death, but what she had to say about living:

*"It's only when we truly know and understand that we have a limited time on earth -- and that we have no way of knowing when our time is up -- that we will begin to live each day to the fullest, as if it was the only one we had."*

Yes, my college-aged brain interpreted that as a reason to stay out a little later and white-water raft a little longer, but a little over a decade later, when Dr. Kubler-Ross again found me -- this time pushing my terminally ill son through the aisles of Barnes and Noble -- the notion of having "limited time on earth" was no longer an abstract concept. It was looking up at me through the beautiful green eyes of my blond-haired, little boy.

I wish I could tell you I boldly marched into that bookstore determined to find the help I needed, but I didn't. I was broken. I didn't know where to turn and the last thing I wanted was to need a book about death. When I reached for Dr. Kubler-Ross's *On Children and Death*, that afternoon, I actually paused for a second to wonder what the top speed was on a wheelchair and how quickly I could put distance between myself and that book. When I removed it from the shelf, I felt like everyone in the store knew what I was looking at... like there was a giant, neon arrow pointing straight at me screaming: "*Look at HER! Can you believe she needs THAT book?*" (Obviously, I had not yet read Elisabeth's *On Life After Death* yet, in which she writes, "The opinion which other people have of you is their problem, not yours.") But the reality is THAT book, saved my life.

Dying can be hard work. I wish I didn't know that, but it's something you learn when you spend nine years watching a terrible illness ravage your son. If there is a pain worse than having to sit by while your child slowly petrifies to death, I do not want to know it. The fact that I am still standing -- though not always sturdily -- amazes and sometimes amuses me.

But thanks to Dr. Kubler Ross, those nine years weren't entirely horrific. In fact, I have many memories of that time with my son that make me smile, because -- as Elisabeth Kubler Ross taught me -- accepting that the end is near, frees us to make the most of the time that we have left and those are the times that sustain me.

During those nine years, I never passed up an opportunity to cook, play and pray with my son or push back the living room furniture, crank the music and hold our version of a dance party. I'll also never forget the time I convinced a nurse to help me connect 25-foot sections of oxygen tubing together so my son could experience what it felt like to "swim like a dolphin."

Did all of the nurses like that idea? Heck, no. It didn't follow the *rules* for how we were supposed to care for a terminal child. But Elisabeth's words empowered me to challenge medical convention to make the most of my son Austin's life. That's not to say we didn't follow the rules most of the time, but accepting that my son was going to die emboldened me to ask why my bedridden boy couldn't go in the pool. (What's the worst that could happen? He'll die?) And while most days -- thanks to the wretched disease he inherited -- Austin could barely move, that day - thanks to the courage Elisabeth gave me -- he swam.

Elisabeth Kubler-Ross told her children that she wanted them to release balloons when she died, to celebrate what she saw as a "graduation." Well, on this, the tenth anniversary of her "graduation," I'm thankful, not just for what she learned and taught us about death, but for what she showed me about life. "Live," she said, "So you do not have to look back and say: "God, how I have wasted my life."

Thank you, Elisabeth. Your life made mine better.

# THE HUFFINGTON POST

## What You Should Know About the Foreign Intelligence Surveillance Court

BY JENNIFER I. HOELZER

06/06/2013

*"The program Senators Feinstein and Chambliss publicly referred to today is one that I have been concerned about for years."*

That was the first sentence in [the statement](#) my former boss, Senator Ron Wyden, put out today in response to recent revelations that the NSA has a penchant for collecting citizen phone records and I highly doubt anyone was happier to read it than me.

Seriously, do you have any idea how frustrating it is to have your boss ask you to get reporters to write about something he can't tell you about? I did it for years and let's just say, it stretches you as a communicator.

(If you are interested in learning more about Senator Wyden's efforts to expose the Intelligence Community's reliance on secret legal interpretations -- and the many ways we tried to bring them to light -- you can find a timeline [here](#).)

But, apart from confirming that this is the program he had me railing about, the Senator is barred from saying anything else, at least until the Administration declassifies details about the program and its legal justification. Because, while he may be a senior member of the Senate Select Committee on Intelligence, the executive branch retains the sole authority to classify and declassify information. It's why, for example, [President Bush](#) was able to point to a handful of details supporting his case that torture works, without worrying that someone might be able to declassify (or even acknowledge the existence of) reams of evidence that didn't support his case.

While I have no idea what the Administration will choose to declassify about this NSA program, I am fairly certain that they will -- [as they have](#)

in the past -- argue that the program is perfectly legal by pointing to the Foreign Intelligence Surveillance Court's approval of their surveillance requests.

Their hope, I'm guessing, will be to summon warm fuzzy thoughts of *Law and Order* and the U.S. Criminal Justice system that we all know and, for the most part, trust.

But, since that's not the case, I thought I'd help you out with some quick FISC FAQ's:

### **What is the Foreign Intelligence Surveillance Court (FISC)?**

The Foreign Intelligence Surveillance Court was established by the Foreign Intelligence Surveillance Act (FISA) of 1978 in response to revelations that the executive branch had been using federal resources to spy on political and activist groups. (Google "[Church Committee](#)") The court was designed to provide judicial oversight over the government's surveillance activities while ensuring that national security secrets remained secret.

### **How does FISC differ from a criminal or civil court?**

While Justice Department officials like to argue that getting a subpoena from FISC is akin to getting one from a grand jury, the only similarity between the two is the fact that neither is adversarial. Meaning, in both cases, the determination of whether or not a subpoena can be issued is based solely on arguments made by the government. Neither a grand jury nor FISC hears arguments against the government's point of view. But that's where the similarities end.

By empowering a panel of citizens to review the government's case and ultimately determine whether or not they are comfortable with action being taken against one of their fellow citizens, the grand jury system acts as check on the government's authority. If the government is overreaching, these citizens are given an opportunity to speak up. States that don't employ grand juries allow judges to rule on probable cause but in the context of an adversarial preliminary hearing in which the judge hears arguments from both the government and the defense.

While FISC was originally intended to be a similar check on the

government's surveillance authority, it doesn't really work that way. At no point are citizens given an opportunity to determine whether or not they are comfortable with the way government agents are carrying out the law. Instead, the government presents their surveillance request to a single judge who -- because the system is non-adversarial -- hears only from the government before ruling on the government's request. The rulings are then kept classified.

**So, I'm guessing you have to be a real pro at interpreting surveillance law to be a judge on the FISA Court, right?**

Not exactly. FISC is currently composed of eleven federal judges already serving on the bench. While these judges are, no doubt, experts on civil and criminal law, because the federal court system doesn't handle foreign intelligence surveillance cases, it is doubtful that these judges would have a great deal of experience in these matters.

Moreover, while the original FISA law was pretty straight forward, the Patriot Act, which passed in 2001 and the subsequent FISA Amendments Act of 2008 made a lot of changes to the laws, which these judges are now in charge of interpreting.

**But wait, if these FISA court judges are interpreting the new surveillance laws with relatively little experience or precedent to draw from and they are only hearing the government's argument for how these laws should be interpreted, wouldn't they be more likely to side with the government?**

One could obviously make that argument.

**So, how does a federal judge get selected for the FISA Court?**

FISC judges are appointed by the Chief Justice of the United States. All 10 of the judges currently serving on the FISA Court were selected by the current chief justice, John Roberts. Absent a change in the law, foreign intelligence surveillance law will be interpreted exclusively by Justice Roberts's picks as long as he remains chief justice.

**But, President Bush nominated John Roberts as chief justice because he's a pretty conservative judge, wouldn't he be more likely to pick conservative judges for the FISA Court?**

That seems to be what he is doing. Of the 10 judges he has selected for the current court four were appointed to the bench by President Reagan, one was appointed by President George H. W. Bush, one by President Clinton and four by President George W. Bush.

**But FISC isn't the Supreme Court, even if one of these judges issued a controversial ruling the decision can be appealed right?**

Technically, yes. But who's going to appeal it?

Let me give you an example. Let's say a police officer wants to strip search you. You've done nothing wrong, but the police officer disagrees and says he needs to strip you to prove it. Under the criminal justice system, you get to bring that argument to a judge, who will issue a ruling only after listening to the government's reasons for wanting to strip search you and your reasons for why they shouldn't be allowed to do that. In the event that the judge rules against you and finds that the police officer has probable cause to search you, not only do you have a right to appeal that judge's decision all the way to the Supreme Court, you are welcome to talk to as many reporters, friends, relatives and elected officials as you want to along the way. And, if the public doesn't agree with the police force's policy on strip-searching, they can pressure lawmakers to change the law or -- if in California -- push for a ballot measure.

However, let's say the government wants Verizon to hand over all of your phone records (not just who you call, but who calls you, how long your conversations were and where you were when you had the conversation). You're never going to know about it, much less get a chance to argue against it. The FISC judge who signs off on the government's data collection will only hear the government's argument for why it should be lawfully allowed to collect data on you. If the judge rules against the government, the government can appeal the decision, but if/when the judge agrees with the government there is no other side to appeal the decision. Moreover, the judge's ruling is classified, so even if the ruling is outlandish, it can't be reported or even debated on the Senate floor.

**So, the Administration could be relying on some crazy/twisted interpretations of the Patriot Act and we'd never know about it?**

That is what Senator Wyden has been warning, starting as far back as [July](#)

2008 when he first argued for the declassification of FISA court opinions. I think he put it best when he said "reading the text of the Patriot Act without the secret court opinions is like being able to read McCain-Feingold without being allowed to know about Citizens United." Congress passed the Patriot Act, but Congress can't debate whether or not the Administration is interpreting the Patriot Act the way it intended the Patriot Act to be interpreted. Moreover, the American People aren't being given an opportunity to weigh in.

**But the Justice Department says this authority is essential to national security. Wouldn't telling the American people undermine that?**

By that logic it could be argued that all surveillance laws should be kept secret in order to make it harder for adversaries to guess how we collect intelligence, but that's not how a democracy works. American citizens are supposed to have a say in the laws that govern them and no matter how noble the Justice Department's intentions are, its officials don't have the right to substitute their judgment for the judgment of the American people. In the event that they have doubts that the American people will support a program they believe is necessary to national security, they are obligated to bring that program up for debate, not classify it and hope no one finds out.

**Out of curiosity, how often does FISC reject the government's request for a warrant?**

It is rare. While classification makes it difficult to gather statistics, it has been reported that through the end of 2004, FISC had granted 18,761 warrants and rejected five.

*Jennifer Hoelzer previously served as Senator Wyden's Deputy Chief of Staff and Communications Director.*

# THE HUFFINGTON POST

## The Pharmaceutical Industry Still Doesn't Want You to Pay Less for Their Products

BY JENNIFER I. HOELZER

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Thirty years ago, when the Hatch-Waxman Act made it easier for generic drugs to win Food and Drug Administration (FDA) approval, the president of what we now know as PhRMA (Pharmaceutical Research and Manufacturers of America) [told the New York Times](#):

*"Our members are concerned that the F.D.A. standards do not insure that two versions of a drug deemed equivalent will be equally safe and effective when used interchangeably."*

The industry's "concern trolling" didn't stop there.

Pharmaceutical companies hired doctors to talk to the press about the dangers of switching to generics. They argued for restrictions on automatic substitutions, publicized anecdotal observations as evidence of adverse effects and helpfully sent pharmacists forms to record the many patient complaints substituting generics would surely earn them. One brand manufacturer even issued a "Dear Pharmacist" letter cautioning that pharmacists who substituted generics for their product could be exposed to patient lawsuits.

If you know anything about the Hatch-Waxman Act, you know the only safeguards it eliminated were the ones that had been protecting name-brand profits. Since generic drugs are clinically identical versions of drugs already approved by the FDA, the FDA's clinical trial requirements before Hatch-Waxman did little more than deter generic manufacturers from selling their products in the United States, thus allowing name brands to maintain market monopolies years after their patent protections expired.

Dropping those requirements promised to flood the market with generics and cost the pharmaceutical industry billions...unless, of course, they could keep folks from switching to generics.

To its great credit, the FDA, when writing the Hatch-Waxman regulations, not only didn't fall for the industry's spin, it refused to bow to its pressure. The agency moved ahead with regulations that ensured generics would be widely available.

As a result - 30 years later - [even PhRMA acknowledges](#) generics have been a benefit to the system, citing the fact that four out of every five pharmaceuticals dispensed in the United States is a generic. According to the [Generic Pharmaceutical Association](#), generics have saved the American health care system trillions (\$239 billion in 2013 alone), while giving millions of Americans access to lifesaving medication they might not otherwise be able to afford.

Buoyed by this success, Congress passed legislation in 2010 to ease the FDA's approval process for medically equivalent versions of biologic medications - known as biosimilars - and the

FDA is currently writing the necessary regulations.

Biologics are the fastest growing class of prescription therapeutics on the market, in large part because advancements in biotechnology are leading to groundbreaking treatments for some of the hardest to treat conditions, such as: cancer, rheumatoid arthritis, diabetes, and multiple sclerosis.

Biologics are, however, the most expensive therapeutics on the market, in large part because they weren't prevalent enough in the mid-80's to be covered by Hatch-Waxman. (The first biologic didn't come to market until 1982.) Without an abbreviated pathway for FDA approval, biosimilars now face the same obstacles that once deterred generics from being brought to market. As a result, biologics currently cost as much as 20 times more per patient than traditional pharmaceuticals, while accounting for more than [28% of the industry's profits](#).

Lack of competition is, of course, not the only reason biologics cost more, but as a [recent RAND Corporation study found](#), it is a factor. The study's authors predict that added competition from biosimilars could lead to a "\$44.2 billion reduction in direct spending on biologic drugs" over the next ten years, while cautioning that "actual savings will hinge on the

specifics of the final FDA regulations."

As you may have guessed, the pharmaceutical industry has concerns about the specifics of those regulations. Namely, as a PhRMA representative told the FDA, that allowing biologics to be used interchangeably will be "unsafe for patients."

Again, the industry's concern trolling, doesn't stop there.

For example, the industry is arguing that - to protect patient safety - biosimilars should be assigned unique International Non-proprietary Names (INNs), the official generic name given to a pharmaceutical's active ingredient. They, of course, fail to mention that since INNs enable generic substitution, assigning unique names to biosimilars would also make it a lot harder for pharmacists to substitute them, which, in turn, would protect the industry's profits.

In other words, it's pretty much the mid-80's all over again.

With billions on the line, it's not surprising that the pharmaceutical industry would, once again, warn people away from their competitors, but -- given the industry's history -- it's also not surprising that Americans routinely rank the pharmaceutical industry as "untrustworthy" and in need of new regulations.

If PhRMA was smart, it would realize this lack of trust could ultimately cost the industry more than just competition from biosimilars. For example, being perceived as untrustworthy was one of the main reasons people believed Jenny McCarthy when she warned them not to vaccinate their children. (Coincidentally, vaccines are a type of biologic.)

Earlier this year, PhRMA [began a blog](#) lamenting the anti-vaxx movement, with the following quote:

*"Despite rigorous and extensive testing for safety and efficacy, a single piece of widely circulated false information can have lasting impact on the public's perception of...safety."*

I doubt the pharmaceutical industry will ever recognize the irony in its use of those words, but for the sake of patients everywhere, I hope the FDA will - once again - see through its spin.