



**U.S. Department of Justice**

Office of the Solicitor General

*Washington, D.C. 20530*

Executive Officer

March 15, 2011

SENT VIA EMAIL AND US MAIL

Mr. Terence P. Jeffrey  
CNSNews.com  
325 S. Patrick St.  
Alexandria, VA 22314

RE: Freedom of Information Act Request

Dear Mr. Jeffrey:

This is in response to your letters of May 25, 2010, and June 25, 2010, requesting records from the Office of the Solicitor General (Office) regarding certain communications concerning former Solicitor General Elena Kagan. Specifically, as clarified in your letter of June 25, 2010, you request:

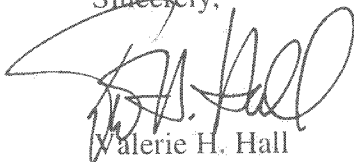
1. Any communications to or from Solicitor General Elena Kagan and any record or notation of any meeting attended personally or electronically by Solicitor General Elena Kagan in which the then-pending legislative health-care proposals were discussed;
2. Any communication to or from Solicitor General Elena Kagan and any record or notation of any meeting attended personally or electronically by Solicitor General Elena Kagan in which any legal challenge to the health-care reform bill signed by President Barack Obama was a topic; and
3. Any communication to or from Solicitor General Elena Kagan and any record or notation of any meeting attended personally or electronically by Solicitor General Elena Kagan in which the question of whether Solicitor General Elena Kagan ought to recuse herself from involvement in any particular case in her role as Solicitor General due to the prospect that it might later come before her were she to be confirmed to a seat on a federal court was discussed.

A search of records in the Office yielded approximately 1400 pages of potentially responsive records. Most of those potentially responsive records were ultimately determined not to be responsive to your request; many others reflect duplicative material within email chains in which the more recent email responses include prior emails that the search separately identified; and some others were not agency records.

The agency records that include at least some material responsive to your request constitute a total of 86 pages of records. Many, if not all, of those records are not subject to mandatory disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. 552, because they are fully exempt from compelled disclosure under FOIA Exemption 5, 5 U.S.C. 552(b)(5). The Office, however, has determined that it would be appropriate to release significant portions of such records as a matter of agency discretion. The Office accordingly has enclosed 45 pages of agency records responsive to your FOIA request, some of which have been partially redacted under FOIA Exemptions 2, 5, and 6, 5 U.S.C. 552(b)(2), (5), and (6). The remaining 41 pages are being withheld in full under FOIA Exemption 5. Eight of those 41 pages are drafts of letters or views concerning subjects unrelated to your FOIA request but that were attached to a responsive email that has itself been released. The remaining 33 pages are a one-page email with two attachments, nearly all of which is not responsive to your FOIA request (the two paragraphs that are responsive are located in the second attachment and indicate that issues related to an internal agency proposal might be affected if the then-pending health-care-reform legislation was enacted).

In addition to the responsive agency records, the Office identified other agency records during its review of potentially responsive records that appear to concern matters related to the general subject-matter of your FOIA request. Although such additional records are not themselves subject to mandatory disclosure under FOIA because they are not responsive under the terms of your request, and although many if not all of the additional records would be fully exempt from mandatory disclosure under FOIA Exemption 5 if they were responsive to a FOIA request, the Office has determined that it would be appropriate to release such records as a matter of agency discretion. The Office accordingly has enclosed an additional 18 pages of non-responsive agency records, some of which have been partially redacted. If the non-responsive records were to be the proper subject of a FOIA request, the redactions would be warranted under FOIA Exemption 5 and 6.

Sincerely,



Valerie H. Hall

Enclosure(s)

**Kagan, Elena**

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**From:** Kagan, Elena  
**Sent:** Friday, January 08, 2010 11:01 AM  
**To:** Katyal, Neal  
**Subject:** Re: Health Care Defense

You should do it.

---

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Fri Jan 08 10:57:38 2010  
**Subject:** FW: Health Care Defense

I am happy to do this if you are ok with it. Otherwise Ed would be the natural person. Or both of us

---

**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 10:54 AM  
**To:** Katyal, Neal  
**Subject:** Health Care Defense

Hi Neal – Tom wants to put together a group to get thinking about how to defend against inevitable challenges to the health care proposals that are pending, and hoped that OSG could participate. Could you figure out the right person or people for that? More the merrier. He is hoping to meet next week if we can.

Thanks,  
Brian

7/15/2010

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 10:58 AM  
**To:** Kagan, Elena  
**Subject:** FW: Health Care Defense

I am happy to do this if you are ok with it. Otherwise Ed would be the natural person. Or both of us

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**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 10:54 AM  
**To:** Katyal, Neal  
**Subject:** Health Care Defense

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Thanks,  
Brian

**Kagan, Elena**

---

**From:** Katyal, Neal  
**Sent:** Thursday, March 18, 2010 1:37 PM  
**To:** Perrelli, Thomas J.  
**Cc:** Kagan, Elena  
**Subject:** RE: Health Care

Tom, I was just looking at the draft complaint by Landmark Legal Foundation. It is clearly written to be filed when the House approves the reconciliation bill and before the President signs it. See paras 15-17.  
[http://www.landmarklegal.org/uploads/Landmark%20Complaint%20\(00013086-2\).pdf](http://www.landmarklegal.org/uploads/Landmark%20Complaint%20(00013086-2).pdf)

Also para 27 says the action is being brought before it is signed by President so that no expectations of regularity can be asserted, etc. As such, we could be in court very very soon.

In light of this, for what it is worth, my advice (I haven't discussed this with Elena, but am cc'ing her here) would be that we start assembling a response, (b) (5) so that we have it ready to go. They obviously have their piece ready to go, and I think it'd be great if we are ahead of the ball game here.

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**From:** Perrelli, Thomas J.  
**Sent:** Wednesday, March 17, 2010 9:25 AM  
**To:** Katyal, Neal  
**Subject:** Re: Health Care

Neal - I tabled it when things looked bleak, but we should do it. I'll get something together in the next week.

---

**From:** Katyal, Neal  
**To:** Perrelli, Thomas J.  
**Sent:** Wed Mar 17 09:17:13 2010  
**Subject:** Health Care

Tom, I recall you were going to set up a group to deal with the inevitable challenges to this legislation. Now that this may be coming back, I wanted to circle back and see if you still are developing such a litigation group.  
Thanks, N

**Kagan, Elena**

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**From:** Katyal, Neal  
**Sent:** Sunday, March 21, 2010 6:19 PM  
**To:** Kagan, Elena  
**Subject:** Fw: Health care litigation meeting

This is the first I've heard of this. I think you should go, no? I will, regardless, but feel like this is litigation of singular importance.

---

**From:** Perrelli, Thomas J.  
**To:** Gershengorn, Ian (CIV); Brinkmann, Beth (CIV); West, Tony (CIV); Martinez, Brian (CIV); Adiga, Mala; Guerra, Joseph R.; Delery, Stuart F. (ODAG); Cedarbaum, Jonathan; Golder, Chad (ODAG); Monaco, Lisa (ODAG); Katyal, Neal  
**Cc:** Gunn, Currie (SMD); Guerra, Joseph R.  
**Sent:** Sun Mar 21 18:11:12 2010  
**Subject:** Health care litigation meeting

All -

It sounds like we can meet with some of the health care policy team tomorrow at 4 to help us prepare for litigation. It has to be over there. Can folks send me the waves info (full name, SSN, DOB) of everyone that should attend as soon as possible? WH wants it tonight, if possible. I know we won't get everyone's in tonight.

Also, we need to think about the key issues/questions for the agenda. (b) (5) tops on my list, but I know there are others. Tony/Ian/Beth -- can CIV flesh out what we feel like we need to discuss? Jonathan and OLC may have some ideas as well.

Thanks!

Tom

**Kagan, Elena**

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**From:** Kagan, Elena  
**Sent:** Sunday, March 21, 2010 6:20 PM  
**To:** Katyal, Neal  
**Subject:** Re: Health care litigation meeting

What's your phone number?

---

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Sun Mar 21 18:18:45 2010  
**Subject:** Fw: Health care litigation meeting

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**From:** Perrelli, Thomas J.  
**To:** Gershengorn, Ian (CIV); Brinkmann, Beth (CIV); West, Tony (CIV); Martinez, Brian (CIV); Adiga, Mala; Guerra, Joseph R.; Delery, Stuart F. (ODAG); Cedarbaum, Jonathan; Golder, Chad (ODAG); Monaco, Lisa (ODAG); Katyal, Neal  
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Thanks!

Tom

6/24/2010

**Kagan, Elena**

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**From:** Katyal, Neal  
**Sent:** Sunday, March 21, 2010 6:22 PM  
**To:** Kagan, Elena  
**Subject:** Re: Health care litigation meeting

(b) (6)

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**From:** Kagan, Elena  
**To:** Katyal, Neal  
**Sent:** Sun Mar 21 18:19:46 2010  
**Subject:** Re: Health care litigation meeting

What's your phone number?

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**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Sun Mar 21 18:18:45 2010  
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Thanks!

Tom

6/24/2010



**Kagan, Elena**

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**From:** Dreeben, Michael R  
**Sent:** Wednesday, March 24, 2010 2:31 PM  
**To:** Kagan, Elena; Kneeder, Edwin S  
**Subject:** Fw; Health care challenges

Elena and Ed,

Re the message below, several USAs volunteered that they hoped that our office would be involved in structuring the government's defense of health care. For all I know, we are involved. Just wanted to pass this on.

Thanks,

Michael

----- Original Message -----  
**From:** Dreeben, Michael R  
**To:** Brinkmann, Beth (CIV)  
**Sent:** Wed Mar 24 14:25:55 2010  
**Subject:** Health care challenges

Hi Beth,

I spoke at the US Attorney's conference today in Tempe AZ and several of them came up to me afterwards to ask how the Department is coordinating responses to the state AG lawsuits. They'd like to know what if anything they should say publicly in response and equally important who should they communicate with about defending these suits. I assume that Civil is going to take the lead in the defense of these cases, no? Is there a task force or lead person to whom I should refer the USAs? If we haven't already done so, it seems to me that we (the Department) should take the initiative to contact the USAs in the districts where states have sued to let them know what the process and lines of responsibility will be. My apologies if this has already been done. If it has, some USAs haven't gotten the word.

Michael

**Kagan, Elena**

---

**From:** Dreeben, Michael R  
**Sent:** Wednesday, March 24, 2010 2:32 PM  
**To:** Kagan, Elena; Knesdler, Edwin S  
**Subject:** Fw: Health care challenges

Beth's response.

----- Original Message -----  
**From:** Brinkmann, Beth (CIV)  
**To:** Dreeben, Michael R  
**Sent:** Wed Mar 24 14:29:59 2010  
**Subject:** RE: Health care challenges

Michael,

Yes, Ton, Ian and I had a nationwide conference call yesterday with the Civil Chiefs. A memo also went out the day before. I am forwarding right after this. Let's discuss if you have ideas about what more to do.

Beth

-----Original Message-----  
**From:** Dreeben, Michael R  
**Sent:** Wednesday, March 24, 2010 2:26 PM  
**To:** Brinkmann, Beth (CIV)  
**Subject:** Health care challenges

Hi Beth,

I spoke at the US Attorney's conference today in Tempe AZ and several of them came up to me afterwards to ask how the Department is coordinating responses to the state AG lawsuits. They'd like to know what if anything they should say publicly in response and equally important who should they communicate with about defending these suits. I assume that Civil is going to take the lead in the defense of these cases, no? Is there a task force or lead person to whom I should refer the USAs? If we haven't already done so, it seems to me that we (the Department) should take the initiative to contact the USAs in the districts where states have sued to let them know what the process and lines of responsibility will be. My apologies if this has already been done. If it has, some USAs haven't gotten the word.

Michael

**Kagan, Elena**

---

**From:** Dreeben, Michael R  
**Sent:** Wednesday, March 24, 2010 2:32 PM  
**To:** Kagan, Elena; Kneedler, Edwin S  
**Subject:** Fw: Health care challenges

More.

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Michael

**Kagan, Elena**

---

**From:** Kneedler, Edwin S  
**Sent:** Wednesday, March 24, 2010 3:38 PM  
**To:** Dreeben, Michael R; Kagan, Elena  
**Subject:** RE: Health care challenges

Thanks.

-----Original Message-----

**From:** Dreeben, Michael R  
**Sent:** Wednesday, March 24, 2010 2:32 PM  
**To:** Kagan, Elena; Kneedler, Edwin S  
**Subject:** Fw: Health care challenges

More.

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Michael

**Kagan, Elena**

---

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:19 PM  
**To:** Kagan, Elena  
**Subject:** FW: HCR litigation

This is what I told Tracy about health care

-----Original Message-----

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:04 PM  
**To:** Schmalzer, Tracy  
**Subject:** RE: HCR litigation

No, she never has been involved in any of it. I've run it for the Office, and have never discussed the issues with her one bit.

-----Original Message-----

**From:** Schmalzer, Tracy  
**Sent:** Monday, May 17, 2010 1:03 PM  
**To:** Katyal, Neal  
**Subject:** HCR litigation

Has Elena been involved in any of that to the extent SG office was consulted? Know you've been point but expect I'll get this q.

**Kagan, Elena**

---

**From:** Kagan, Elena  
**Sent:** Monday, May 17, 2010 1:20 PM  
**To:** Katyal, Neal  
**Cc:** Schmalzer, Tracy  
**Subject:** Re: HCR litigation

This needs to be coordinated. Tracy, you should not say anything about this before talking to me.

----- Original Message -----

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Mon May 17 13:18:45 2010  
**Subject:** FW: HCR litigation

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**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:04 PM  
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Kagan, Elena

**From:** Kneeder, Edwin S  
**Sent:** Monday, March 22, 2010 7:40 PM  
**To:** Katyal, Neal; Kagan, Elena; Dreeben, Michael R; Stewart, Malcolm L  
**Subject:** RE: 2 week report

I have no merits filings in the next two weeks.

Invitations:

1. Williamson: now that (b) (6) is finished with Asian Carp, he is turning back to this case and plans to get me the draft in the next few days.
2. Golden Gate: (b) (6) plans to turn to this after his argument. He has requested from DOL by early next week an insert for the brief identifying the provisions of the health care bill (as it will be reconciled) that are relevant to the preemption issue in this case.

---

**From:** Katyal, Neal  
**Sent:** Monday, March 22, 2010 12:39 PM  
**To:** Kagan, Elena; Dreeben, Michael R; Kneeder, Edwin S; Stewart, Malcolm L  
**Subject:** RE: 2 week report

1. CVSGs

Candeleria -- I will receive from (b) (6) on March 29, and I will provide to you later that week after your argument.

Pfizer -- not looking good. (b) (5)  
(b) (5) So I fear this one is still a ways off.

Camichael (CVSG, political question, Iraqi contractor case) -- (b) (6) and I are holding meetings with the parties on March 29 at 2pm, that Ed may join. I think the issues aren't sufficiently crystallized for you to come to this one.

2. Merits

None

3. Other

Witt/DADT may present some issues. I will continue to monitor.

I will be away from tomorrow late in the afternoon through the weekend. Michael has graciously agreed to monitor my inbox, but I don't anticipate anything.

**Kagan, Elena**

---

**From:** Kagan, Elena  
**Sent:** Monday, March 22, 2010 8:14 PM  
**To:** Kneeder, Edwin S  
**Subject:** Re: 2 week report

Thanks, Ed. And is (b) (5) on Golden Gate?

---

**From:** Kneeder, Edwin S  
**To:** Katyal, Neal; Kagan, Elena; Dreeben, Michael R; Stewart, Malcolm L  
**Sent:** Mon Mar 22 19:39:50 2010  
**Subject:** RE: 2 week report

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6/24/2010



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**Kagan, Elena**

---

**From:** Kneedler, Edwin S  
**Sent:** Monday, March 22, 2010 8:16 PM  
**To:** Kagan, Elena  
**Subject:** Re: 2 week report

I don't think so. Let me check.

---

**From:** Kagan, Elena  
**To:** Kneedler, Edwin S  
**Sent:** Mon Mar 22 20:13:37 2010  
**Subject:** Re: 2 week report

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**From:** Stewart, Malcolm L  
**Sent:** Friday, June 19, 2009 10:26 AM  
**To:** Kagan, Elena  
**Subject:** FW: Cipro brief - DOJ comments on Request for comments on S. 369, the Preserve Access to Affordable Generics Act (Reverse Payments)

**Importance:** High

**Attachments:** Kohl S. 369 reply 061509.wpd; s. 369. Reverse Payments. Kohl. 6.10.2009.DOC; S. 369 Preserve Access to Generics.pdf; Kohl letter 04.21.09 Gen Drug DOJ.pdf; h.r. 1706. DOJ comments. 6.9.2009.DOC

Elena,

Here's the e-mail chain I received yesterday, which contains two versions of the letter. The first one you get to (the WordPerfect document is a more generic version, which (b) (5) (b) (5) The second one (the Word document right below the e-mail from (b) (6) ) is the one that (b) (5) (b) (5) I'll ask Marisa how satisfied/unsatisfied they would be with a letter that expressed opposition to a per se rule but didn't identify a specific alternative, and I'll ask Cathy O'Sullivan to tell the agencies to focus on this immediately.

Malcolm

**From:** Chun, A Marisa  
**Sent:** Thursday, June 18, 2009 6:47 PM  
**To:** Stewart, Malcolm L  
**Subject:** Cipro brief - DOJ comments on Request for comments on S. 369, the Preserve Access to Affordable Generics Act (Reverse Payments)  
**Importance:** High

Malcolm, Thanks very much for your time on this and for offering to speak to the Solicitor General about this. Attached at the bottom are the Senate and House versions of bills which would make these 'reverse payments' settlements per se illegal, the letter from Sen. Kohl to the AG, and the original response prepared by OLA, before we spoke to you. After our initial conversation with you, (b) (5) (b) (5) I've also pasted below the latest communication this afternoon from Sen Leahy's folks inquiring when DOJ would be sending over our letter articulating our 'different view.' Thanks and look forward to hearing from you. Marisa



Kohl S. 369 reply  
061509.wpd (...)

-----Original Message-----

**From:** Garland, James  
**Sent:** Thursday, June 18, 2009 3:42 PM  
**To:** Chun, A Marisa; Verrilli, Donald; Appelbaum, Judy; Kimmelman, Gene; Farhadian, Tali  
**CC:** Potter, Robert; Temple Claggett, Karyn; Hauck, Brian  
**Subject:** RE: Kohl Response - Input from ATR appellate

Good plan, Marisa, thanks.

I spoke again this morning to Leahy's antitrust counsel. He called to ask whether the Committee should expect to hear from DOJ on the proposed bill.

(b) (5)

He also said that there is a desire not to let this bill get swept up into the broader healthcare legislation effort, which is why they're pushing to mark it up this Thursday.

I said that we were still considering our position over here, (b) (5)

(b) (5) and asked when they needed to hear from us. He said as soon as possible, but that early next week (Monday/Tuesday) would be okay. I asked

(b) (5)

I noted that we had not been formally asked by Senator Kohl to provide our views; he suggested that we could still send a letter to the Committee leadership (although the Chairman would not formally request such a letter, insofar as that would be perceived by Senator Kohl as an effort to sabotage the bill).

Please let me know if there's anything we can do to help move this along. Thanks.

**From:** (b)(6)  
**Sent:** Thursday, June 11, 2009 10:57 AM  
**To:** Chun, A Marisa; Hauck, Brian; Hirsch, Sam; Verrilli, Donald; Burrows, Charlotte  
**Subject:** FOR FINAL APPROVAL -- DOJ comments on Request for comments on S. 369, the Preserve Access to Affordable Generics Act (Reverse Payments)  
**Importance:** High

Attached is a draft letter comprised of comments received from ATR on S. 369. Senator Kohl has requested DOJ's views on S. 369. (see attached). These comments are similar to ones submitted to OMB on H.R. 1706 (also attached). Please let me know if the letter can be sent to OMB for approval to send to the Hill.



s. 369. Reverse Payments. Kohl...



S. 369 Preserve Access to Gene...



Kohl letter 04.21.09 Gen Drug ...



h.r. 1706. DOJ comments. 6.9.2...

pages 20 through 25  
have been withheld in full  
pursuant to (b)(5)

PATRICK J. LEAHY, VERMONT, CHAIRMAN

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## United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

BRUCE A. COHEN, *Chief Counsel and Staff Director*  
STEPHANIE A. MIDDLETON, *Republican Staff Director*  
NICHOLAS A. ROSSI, *Republican Chief Counsel*

April 21, 2009

The Honorable Eric Holder  
Attorney General  
United States Department of Justice  
950 Pennsylvania Avenue, N.W.  
Washington, D.C. 20530

Dear Attorney General Holder:

On April 6, 2009, the Court of Appeals for the Second Circuit invited the Justice Department, through the Solicitor General, to address whether certain patent settlements involving generic drugs violate the antitrust law. I am writing to request that the Justice Department respond by advising the Court that these settlements are contrary to antitrust law.

As you may know, I have introduced legislation to ban payments from brand name drug companies to generic drug companies to settle patent cases which are designed to delay the entry of generic drug competition (what are commonly known as "reverse payments"), the Preserve Access of Affordable Generics Act, S. 369. The President has made clear that these types of patent settlements are anti-competitive, declaring in his proposed budget that "[t]he administration will prevent drug companies from blocking generic drugs from consumers by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market." Office of Management and Budget, *A New Era of Responsibility: Renewing America's Promise*, at 28.

Reverse payments in patent settlements significantly delay the entry of generic competition to brand name drugs and cost consumers and taxpayers billions of dollars. Generic drugs save consumers between \$ 8 and \$ 10 billion each year. In 2007, the average retail price of a generic prescription drug was \$ 34.34, while the average retail price of a brand name drug was \$ 119.51.<sup>1</sup> Under the Hatch-Waxman Act, Congress encouraged the entry of generic pharmaceuticals by providing an incentive – a 180 day exclusivity period – for generic drug makers to successfully challenge a patent and enter the market prior to expiration of the patent.

Until recently this system worked well to promote entry by generic drug competition. In 2002, the FTC reported that generic drug companies prevailed in more

<sup>1</sup> Generic Pharmaceutical Association, *Facts at a Glance*, available at <http://www.gphaonline.org/about-gpha/about-generics.facts>.

than 73% of pharmaceutical patent cases litigated to conclusion.<sup>2</sup> However, in recent years pharmaceutical manufacturers began to offer settle patent cases brought by generic firms by making large cash payments -- sometimes valued at hundreds of millions of dollars -- in exchange for a promise to keep the competing generic drugs off the market for many years. The Federal Trade Commission has sought to pursue legal actions against such settlements, contending they are contrary to antitrust law.

However, two court of appeals decisions in 2005 and 2006 (the Eleventh Circuit in Schering-Plough v. FTC, 403 F.3d 1056 (11<sup>th</sup> Cir. 2005) and the Second Circuit in In Re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006)) rejected the FTC's claims that these reverse payment patent settlement violated antitrust law. The effect of these court decisions has been stark. In the two years after these two decisions, the FTC has found, half of all patent settlements involved payments from the brand name from the generic manufacturer in return for an agreement by the generic to keep its drug off the market. In the year before these decisions, not a single patent settlement reported to the FTC contained such an agreement.

These reverse payment patent settlements are anti-competitive and should be banned, and that is why I have introduced legislation to expressly state these settlements violate antitrust law. The Second Circuit Court of Appeals is now considering a case involving the settlement of patent litigation involving generic drugs, In re Ciprofloxacin Hydrochloride Antitrust Litigation. As recited in the April 6, 2009 letter from Catherine O'Hagan Wolfe, Clerk, U.S. Court of Appeals for the Second Circuit, the case involves a patent settlement in which the "generic manufacturers conceded the validity of Bayer's Cipro patent in exchange for \$ 49.1 million, and either (1) a license to manufacture Cipro or (2) quarterly payments of between \$ 12.5 and 17.125 million for the duration of the patent except for the last 6 months, and finally, a guaranteed license for six months prior to the Cipro patent's expiration."

The Second Circuit specifically requests "the Executive Branch to address . . . whether settlement of patent infringement lawsuits violate the federal antitrust laws when a potential generic drug manufacturer withdraws its challenge to the patent's validity, which if successful would allow it to market a generic version of a drug, and the brand-name patent holder, in return, offers the generic manufacturer substantial payments." I urge the Justice Department to answer this inquiry by stating that these settlements -- settlements that directly eliminate competition and which cost consumers billions of dollars -- do violate the federal antitrust laws. They are simply agreements between competitors in which one competitor agrees to delay entry into a market in exchange for a payment. As such, they should be viewed as per se violations of antitrust law. Such an answer is essential to advance the President's agenda, to protect consumers, and to vindicate the Justice Department's mission in preventing harm to competition.<sup>3</sup>

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<sup>2</sup> See Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," at 16 (July 2002).

<sup>3</sup> In making this recommendation, I express no opinion regarding the facts underlying this litigation nor the outcome of the litigation. I write only regarding the legal issue about which the Second Circuit requested the Justice Department's views.



Thank you for your attention to this matter.

Sincerely,

Handwritten signature of Herb Kohl in black ink, written in a cursive style. The signature is positioned above a horizontal line.

HERB KOHL

Chairman, Subcommittee on Antitrust,  
Competition Policy, and Consumer  
Rights

cc: Hon. Elena Kagan, Solicitor General  
Hon. Christine Varney, Assistant Attorney General, Antitrust Division

111TH CONGRESS  
1ST SESSION

# S. 369

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

---

## IN THE SENATE OF THE UNITED STATES

FEBRUARY 3, 2009

Mr. KOHL (for himself, Mr. GRASSLEY, Mr. FEINGOLD, Mr. DURBIN, and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preserve Access to Af-  
5 fordable Generics Act”.

6 **SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF**  
7 **PURPOSES.**

8 (a) **FINDINGS.**—The Congress finds that—

1 (1) prescription drugs make up 10 percent of  
2 the national health care spending but for the past  
3 decade have been one of the fastest growing seg-  
4 ments of health care expenditures;

5 (2) 67 percent of all prescriptions dispensed in  
6 the United States are generic drugs, yet they ac-  
7 count for only 20 percent of all expenditures;

8 (3) generic drugs, on average, cost 30 to 80  
9 percent less than their brand-name counterparts;

10 (4) consumers and the health care system  
11 would benefit from free and open competition in the  
12 pharmaceutical market and the removal of obstacles  
13 to the introduction of generic drugs;

14 (5) full and free competition in the pharma-  
15 ceutical industry, and the full enforcement of anti-  
16 trust law to prevent anticompetitive practices in this  
17 industry, will lead to lower prices, greater innova-  
18 tion, and inure to the general benefit of consumers;

19 (6) the Federal Trade Commission has deter-  
20 mined that some brand name pharmaceutical manu-  
21 facturers collude with generic drug manufacturers to  
22 delay the marketing of competing, low-cost, generic  
23 drugs;

24 (7) collusion by pharmaceutical manufacturers  
25 is contrary to free competition, to the interests of

1 consumers, and to the principles underlying anti-  
2 trust law;

3 (8) in 2005, two appellate court decisions re-  
4 versed the Federal Trade Commission's long-stand-  
5 ing position, and upheld settlements that include  
6 pay-offs by brand name pharmaceutical manufactur-  
7 ers to generic manufacturers designed to keep ge-  
8 neric competition off the market;

9 (9) in the 6 months following the March 2005  
10 court decisions, the Federal Trade Commission  
11 found there were three settlement agreements in  
12 which the generic received compensation and agreed  
13 to a restriction on its ability to market the product;

14 (10) the FTC found that  $\frac{1}{2}$  of the settlements  
15 made in 2006 and 2007 between brand name and  
16 generic companies, and over  $\frac{2}{3}$  of the settlements  
17 with generic companies with exclusivity rights that  
18 blocked other generic drug applicants, included a  
19 pay-off from the brand name manufacturer in ex-  
20 change for a promise from the generic company to  
21 delay entry into the market; and

22 (11) settlements which include a payment from  
23 a brand name manufacturer to a generic manufac-  
24 turer to delay entry by generic drugs are anti-com-  
25 petitive and contrary to the interests of consumers.

1 (b) PURPOSES.—The purposes of this Act are—

2 (1) to enhance competition in the pharma-  
3 ceutical market by prohibiting anticompetitive agree-  
4 ments and collusion between brand name and ge-  
5 neric drug manufacturers intended to keep generic  
6 drugs off the market;

7 (2) to support the purpose and intent of anti-  
8 trust law by prohibiting anticompetitive agreements  
9 and collusion in the pharmaceutical industry; and

10 (3) to clarify the law to prohibit payments from  
11 brand name to generic drug manufacturers with the  
12 purpose to prevent or delay the entry of competition  
13 from generic drugs.

14 **SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.**

15 (a) IN GENERAL.—The Clayton Act (15 U.S.C. 12  
16 et seq.) is amended by inserting after section 28 the fol-  
17 lowing:

18 **“SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MAR-  
19 KETING.**

20 “(a) It shall be unlawful under this Act for any per-  
21 son, in connection with the sale of a drug product, to di-  
22 rectly or indirectly be a party to any agreement resolving  
23 or settling a patent infringement claim in which—

24 “(1) an ANDA filer receives anything of value;  
25 and

1           “(2) the ANDA filer agrees not to research, de-  
2           velop, manufacture, market, or sell the ANDA prod-  
3           uct for any period of time.

4           “(b) Nothing in this section shall prohibit a resolu-  
5           tion or settlement of patent infringement claim in which  
6           the value paid by the NDA holder to the ANDA filer as  
7           a part of the resolution or settlement of the patent in-  
8           fringement claim includes no more than the right to mar-  
9           ket the ANDA product prior to the expiration of the pat-  
10          ent that is the basis for the patent infringement claim.

11          “(c) In this section:

12           “(1) The term ‘agreement’ means anything that  
13           would constitute an agreement under section 1 of  
14           the Sherman Act (15 U.S.C. 1) or section 5 of the  
15           Federal Trade Commission Act (15 U.S.C. 45).

16           “(2) The term ‘agreement resolving or settling  
17           a patent infringement claim’ includes, any agree-  
18           ment that is contingent upon, provides a contingent  
19           condition for, or is otherwise related to the resolu-  
20           tion or settlement of the claim.

21           “(3) The term ‘ANDA’ means an abbreviated  
22           new drug application, as defined under section  
23           505(j) of the Federal Food, Drug, and Cosmetic Act  
24           (21 U.S.C. 355(j)).

1           “(4) The term ‘ANDA filer’ means a party who  
2           has filed an ANDA with the Food and Drug Admin-  
3           istration.

4           “(5) The term ‘ANDA product’ means the  
5           product to be manufactured under the ANDA that  
6           is the subject of the patent infringement claim.

7           “(6) The term ‘drug product’ means a finished  
8           dosage form (e.g., tablet, capsule, or solution) that  
9           contains a drug substance, generally, but not nec-  
10          essarily, in association with one or more other ingre-  
11          dients, as defined in section 314.3(b) of title 21,  
12          Code of Federal Regulations.

13          “(7) The term ‘NDA’ means a new drug appli-  
14          cation, as defined under section 505(b) of the Fed-  
15          eral Food, Drug, and Cosmetic Act (21 U.S.C.  
16          355(b)).

17          “(8) The term ‘NDA holder’ means—

18                 “(A) the party that received FDA approval  
19                 to market a drug product pursuant to an NDA;

20                 “(B) a party owning or controlling enforce-  
21                 ment of the patent listed in the Approved Drug  
22                 Products With Therapeutic Equivalence Eval-  
23                 uations (commonly known as the ‘FDA Orange  
24                 Book’) in connection with the NDA; or

1           “(C) the predecessors, subsidiaries, divi-  
2           sions, groups, and affiliates controlled by, con-  
3           trolling, or under common control with any of  
4           the entities described in subclauses (i) and (ii)  
5           (such control to be presumed by direct or indi-  
6           rect share ownership of 50 percent or greater),  
7           as well as the licensees, licensors, successors,  
8           and assigns of each of the entities.

9           “(9) The term ‘patent infringement’ means in-  
10          fringement of any patent or of any filed patent ap-  
11          plication, extension, reissue, renewal, division, con-  
12          tinuation, continuation in part, reexamination, pat-  
13          ent term restoration, patents of addition and exten-  
14          sions thereof.

15          “(10) The term ‘patent infringement claim’  
16          means any allegation made to an ANDA filer,  
17          whether or not included in a complaint filed with a  
18          court of law, that its ANDA or ANDA product may  
19          infringe any patent held by, or exclusively licensed  
20          to, the NDA holder of the drug product.”.

21          (b) REGULATIONS.—The Federal Trade Commission  
22          may, by rule promulgated under section 553 of title 5,  
23          United States Code, exempt certain agreements described  
24          in section 29 of the Clayton Act, as added by subsection  
25          (a), if the Commission finds such agreements to be in fur-



1 therance of market competition and for the benefit of con-  
 2 sumers. Consistent with the authority of the Commission,  
 3 such rules may include interpretive rules and general  
 4 statements of policy with respect to the practices prohib-  
 5 ited under section 29 of the Clayton Act.

6 **SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.**

7 (a) NOTICE OF ALL AGREEMENTS.—Section  
 8 1112(c)(2) of the Medicare Prescription Drug, Improve-  
 9 ment, and Modernization Act of 2003 (21 U.S.C. 3155  
 10 note) is amended by—

11 (1) striking “the Commission the” and insert-  
 12 ing “the Commission (1) the”; and

13 (2) inserting before the period at the end the  
 14 following: “; and (2) a description of the subject  
 15 matter of any other agreement the parties enter into  
 16 within 30 days of an entering into an agreement  
 17 covered by subsection (a) or (b)”.

18 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
 19 of such Act is amended by adding at the end the following:

20 “(d) CERTIFICATION.—The Chief Executive Officer  
 21 or the company official responsible for negotiating any  
 22 agreement required to be filed under subsection (a), (b),  
 23 or (c) shall execute and file with the Assistant Attorney  
 24 General and the Commission a certification as follows: ‘I  
 25 declare under penalty of perjury that the following is true

1 and correct: The materials filed with the Federal Trade  
2 Commission and the Department of Justice under section  
3 1112 of subtitle B of title XI of the Medicare Prescription  
4 Drug, Improvement, and Modernization Act of 2003, with  
5 respect to the agreement referenced in this certification:  
6 (1) represent the complete, final, and exclusive agreement  
7 between the parties; (2) include any ancillary agreements  
8 that are contingent upon, provide a contingent condition  
9 for, or are otherwise related to, the referenced agreement;  
10 and (3) include written descriptions of any oral agree-  
11 ments, representations, commitments, or promises be-  
12 tween the parties that are responsive to subsection (a) or  
13 (b) of such section 1112 and have not been reduced to  
14 writing.’”.

15 **SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

16 Section 505 of the Federal Food, Drug and Cosmetic  
17 Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by insert-  
18 ing “section 29 of the Clayton Act or” after “that the  
19 agreement has violated”.

○

pages 38 through 39  
have been withheld in full  
pursuant to (b)(5)

May 13, 2010

**MEMORANDUM FOR THE SOLICITOR GENERAL**

**FROM NEAL KATYAL**

**RE: CURRENT CASES THAT YOU HAVE WORKED ON**

The below contains a list of cases in which we feel that you have substantially participated. It is organized by Deputy. We have not done an exhaustive search, so this should not be used as the basis for deciding recusals, should you be confirmed. It is simply a document that you may use to guide your decisions about which cases to participate in pending your nomination.

**I. ED**

**A. CVSGs:**

Holy See Elena chaired meetings with counsel for both sides.

Golden Gate Ed discussed with Elena several times (b) (5)

**B. Merits briefs:**

NASA v. Nelson our merits brief is now due May 20. Elena's name is on the petition, and has been heavily involved in that case.

Montana v. Wyoming the recommendation OSG has received from ENRD (b) (5)

hat recommendation has not been submitted to Elena. Such a brief would not be due until late June or early July. She has been substantively involved in the case.

Bruesewitz an amicus brief supporting respondents would be due July 30. We filed a CVSG last fall in a related case taking the position that supports the respondent's position in Bruesewitz, and we told the Court to grant in Bruesewitz. Elena's name was on that brief.

U.S. v. Tohono O'Odham Nation. Our brief is due in late June. Elena's name is on the petition in that case.

### C. Recommendations:

OPEC (CA5 invited the U.S. to file on act of state and political question in this antitrust case against corporations owned or controlled by OPEC members) Civil is seeking a 30-day extension. Ed discussed the case with Elena last summer when the defendants were urging the U.S. to file uninvited.

## II. Michael

A. CVSGs. None.

B. Merits Briefs.

Michael has no merits matters due until July and only one merits case in July.

Abbott and Gould (due July 15). Elena has not worked on this case, but she did work on the petition in U.S. v. Williams on the same issue.

C. Oppositions

Lance and Dotson (child pornography case). Separately discussed. Neal will handle.

D. Recommendations

Broadcom (U.S. v. Nicholas and Samuelli). Michael discussed it in some depth with Elena, but she neither attended meetings or read paper on it. (b) (6) did call her about the case, on behalf of Samuelli.

E. Tobacco

1. Our cert reply is due approximately June 4. You worked heavily on it.

2. We have to file opps from the industry petitions around May 25. Due to the relationship with our cert petition, it might fall into the category of cases in which you have worked. The issue on which we filed a petition has to do with remedy for a RICO violation by the tobacco industry. The industry cert petitions all deal with liability in the first instance with only a sliver of attention to remedy, and they range over a wide array of complex first amendment, RICO, extraterritoriality, and procedural questions on which she's not had reason or occasion to focus. (Some of them were discussed at our meeting with the tobacco lawyers and summarized in the cert memos, so they are not entirely new.) To the extent that remedy is at issue in the industry petitions, it has to do with the form of the injunction and the interaction with the new tobacco legislation. The first of those is not addressed in any way in our cert. petition and the second only in a brief footnote.

### III. Malcolm

A. CVSGs. None. All are ones in which Elena hasn't had substantial involvement.

B. Merits Briefs. None.

C. Oppositions

Henderson v. United States, No. 09-1036, which is due on May 28. Elena previously chaired a meeting in which petitioner's counsel (b) (6) urged us to acquiesce.

D. Appeals

In Re Ciprofloxacin Hydrochloride Antitrust Litigation, Nos. 05-2852, 05-2852 (2d Cir.). Elena will handle this.

Republican National Committee v. FEC, No. 09-1287. Our response to the RNC's jurisdictional statement is due May 24. Malcolm briefly explained to Elena what the case is about, but has had no meaningful substantive discussions of the merits. However, the RNC filed a motion that pertained solely to the timing of the Court's consideration of the case, and Elena decided that we would not oppose the motion (basically we agreed that we would not seek an extension of the time to file our response to the J.S.). So in that case, Elena has actually made a decision, even though the decision went solely to the position we would take on the opposing party's timing-related motion.

### IV. Neal

A. CVSGs.

Candeleria v. Chamber of Commerce. Very heavy participation by Elena.

Pfizer v. Abdullah (Alien tort statute, Nigeria). Elena chaired meetings with both sides and has been involved in some issues with the State Department.

Carmichael (injury to servicemember in Iraq, political question doctrine, contractor liability). Elena has been informed about aspects of the case.

Thompson v. North American Stainless (Title 7 retaliation against fiancé). Elena has been involved and chaired a decisional meeting.

B. No merits briefs, opps, or appeals in which Elena has been substantially involved.

**Katyal, Neal (SMO)**

---

**From:** (b) (6)  
**Sent:** Thursday, May 13, 2010 7:41 PM  
**To:** Katyal, Neal  
**Subject:** RE: document  
**Attachments:** CURRENT CASES OF SG.wpd

Neal:

Attached is your memo to the SG.

---

**From:** Katyal, Neal  
**Sent:** Thursday, May 13, 2010 7:13 PM  
**To:** (b) (6)  
**Subject:** document



U.S. Department of Justice  
Office of the Solicitor General

Principal Deputy Solicitor General

Washington, D.C. 20530

May 13, 2010

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(b) (6)

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:24 PM  
**To:** Kagan, Elena  
**Subject:** RE: HCR litigation

Got it. I have been receiving a plethora of inquiries, from Tracy, Ali, Kravis, etc. about a whole variety of things like the below for several days now. Most of them aren't that sensitive so I don't pass them on to you. I am very happy to just stay out of this and have you field these inquiries if you'd like. Just let me know.

Also, I'd like to discuss Witt with you when you have a moment. I'm at (b) (2); (b) (6)

Neal

-----Original Message-----

**From:** Kagan, Elena  
**Sent:** Monday, May 17, 2010 1:20 PM  
**To:** Katyal, Neal  
**Cc:** Schmalzer, Tracy  
**Subject:** Re: HCR litigation

This needs to be coordinated. Tracy, you should not say anything about this before talking to me.

----- Original Message -----

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Mon May 17 13:18:45 2010  
**Subject:** FW: HCR litigation

This is what I told Tracy about health care

-----Original Message-----

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:04 PM  
**To:** Schmalzer, Tracy  
**Subject:** RE: HCR litigation

No, she never has been involved in any of it. I've run it for the Office, and have never discussed the issues with her one bit.

-----Original Message-----

**From:** Schmalzer, Tracy  
**Sent:** Monday, May 17, 2010 1:03 PM  
**To:** Katyal, Neal  
**Subject:** HCR litigation

Has Elena been involved in any of that to the extent SG office was consulted? Know you've been point but expect I'll get this q.

(b) (6)

---

**From:** Schmalzer, Tracy  
**Sent:** Monday, May 17, 2010 2:27 PM  
**To:** Kagan, Elena; Katyal, Neal  
**Subject:** RE: HCR litigation

Sure - no one has asked yet ... Just expecting it.

-----Original Message-----

**From:** Kagan, Elena  
**Sent:** Monday, May 17, 2010 1:20 PM  
**To:** Katyal, Neal  
**Cc:** Schmalzer, Tracy  
**Subject:** Re: HCR litigation

This needs to be coordinated. Tracy, you should not say anything about this before talking to me.

----- Original Message -----

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Mon May 17 13:18:45 2010  
**Subject:** FW: HCR litigation

This is what I told Tracy about health care

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**To:** Schmalzer, Tracy  
**Subject:** RE: HCR litigation

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-----Original Message-----

**From:** Schmalzer, Tracy  
**Sent:** Monday, May 17, 2010 1:03 PM  
**To:** Katyal, Neal  
**Subject:** HCR litigation

Has Elena been involved in any of that to the extent SG office was consulted? Know you've been point but expect I'll get this q.

(b) (6)

**From:** Katyal, Neal  
**Sent:** Tuesday, June 15, 2010 12:54 PM  
**To:** Kagan, Elena  
**Subject:** Fw: connecting you two

Fyi.

Also AG just told me that he expects a big story coming out shortly about whether you are recused in health care litigation. I went over the timing and that you have been walled off from Day One.

(b) (5)

Not responsive

(b) (5)

Not responsive

(b) (6)

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**From:** Kagan, Elena  
**Sent:** Tuesday, June 15, 2010 1:33 PM  
**To:** (b) (2); (b) (6)  
**Subject:** Fw: connecting you two

Fyi

---

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Tue Jun 15 12:54:17 2010  
**Subject:** Fw: connecting you two

Fyi.

Also AG just told me that he expects a big story coming out shortly about whether you are recused in health care litigation. I went over the timing and that you have been walled off from Day One.

---

(b) (5)

Not responsive



(b) (5)

Not responsive

**Kagan, Elena**

---

**From:** Katyal, Neal  
**Sent:** Tuesday, May 11, 2010 7:38 PM  
**To:** Kagan, Elena  
**Subject:** Recusals (not urgent)

Dan M called me to talk further about this [REDACTED] (b)(5); not responsive

I raised 2 issues:

- 1) There are a bunch of items in the Office where you have had minimal involvement, such as a Deputy telling you something about a case, such as an agency position on the case, or perhaps even just a brief description of the Question Presented or a description of the lower court opinion. There are several such CVSGs. Does that constitute new or old work? I think this is a matter just for you to decide. My recommendation (gulp) is that it constitutes new work and that I should do it as Acting.
- 2) More important: I raised with Dan the issue of whether time constraints would be the basis for recusal and how it would work. For example, the opp certs do not currently take much (if any) of your time, with Arar-like opps being the exception. If the basis for recusal is time commitments, there might be someone who says those opps don't take much time. On the other hand, any of the opps could trigger your recusal should the Court grant a case, and you might be asked about any of the opps that our office is signing over the next few months. So I think it worth thinking through this issue some more. My recommendation -- but I am no expert -- would be that you treat all opps as new work and recuse, but that there be two different reasons for the recusal, not simply time constraints but also the need, should you be confirmed, to participate in as many cases at the Court as possible/presumption against recusal, etc.

Neal

**Kagan, Elena**

---

**From:** Kagan, Elena  
**Sent:** Tuesday, May 11, 2010 10:03 PM  
**To:** Katyal, Neal  
**Subject:** Re: Recusals (not urgent)

Thanks, Neal. I agree on the first question. As to the second, I think the basic time rationale is right -- I don't think we should do case by case analysis of what will and won't require real time.

---

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Tue May 11 19:37:40 2010  
**Subject:** Recusals (not urgent)

Dan M called me to talk further about this.

(b)(5); not responsive

I raised 2 issues:

- 1) There are a bunch of items in the Office where you have had minimal involvement, such as a Deputy telling you something about a case, such as an agency position on the case, or perhaps even just a brief description of the Question Presented or a description of the lower court opinion. There are several such CVSGs. Does that constitute new or old work? I think this is a matter just for you to decide. My recommendation (gulp) is that it constitutes new work and that I should do it as Acting.
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Neal

6/24/2010

**Kagan, Elena**

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**From:** Katyal, Neal  
**Sent:** Tuesday, May 11, 2010 10:15 PM  
**To:** Kagan, Elena  
**Subject:** Re: Recusals (not urgent)

Agreed with you on 2. But do you want all opps now converted over to me as acting? Sorry to belabor this, just want to be clear.

N

---

**From:** Kagan, Elena  
**To:** Katyal, Neal  
**Sent:** Tue May 11 22:02:56 2010  
**Subject:** Re: Recusals (not urgent)

Thanks, Neal. I agree on the first question. As to the second, I think the basic time rationale is right -- I don't think we should do case by case analysis of what will and won't require real time.

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**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Tue May 11 19:37:40 2010  
**Subject:** Recusals (not urgent)

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(b)(5); not responsive

I raised 2 issues:

- 1) There are a bunch of items in the Office where you have had minimal involvement, such as a Deputy telling you something about a case, such as an agency position on the case, or perhaps even just a brief description of the Question Presented or a description of the lower court opinion. There are several such CVSGs. Does that constitute new or old work? I think this is a matter just for you to decide. My recommendation (gulp) is that it constitutes new work and that I should do it as Acting.
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Neal

6/24/2010

**Kagan, Elena**

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**From:** Kagan, Elena  
**Sent:** Tuesday, May 11, 2010 10:16 PM  
**To:** Katyal, Neal  
**Subject:** Re: Recusals (not urgent)

Yes (sorry!)

---

**From:** Katyal, Neal  
**To:** Kagan, Elena  
**Sent:** Tue May 11 22:14:52 2010  
**Subject:** Re: Recusals (not urgent)

Agreed with you on 2. But do you want all opps now converted over to me as acting? Sorry to belabor this, just want to be clear.

N

---

**From:** Kagan, Elena  
**To:** Katyal, Neal  
**Sent:** Tue May 11 22:02:56 2010  
**Subject:** Re: Recusals (not urgent)

Thanks, Neal. I agree on the first question. As to the second, I think the basic time rationale is right -- I don't think we should do case by case analysis of what will and won't require real time.

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**Sent:** Tue May 11 19:37:40 2010  
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I raised 2 issues:

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Neal

6/24/2010

**Kagan, Elena**

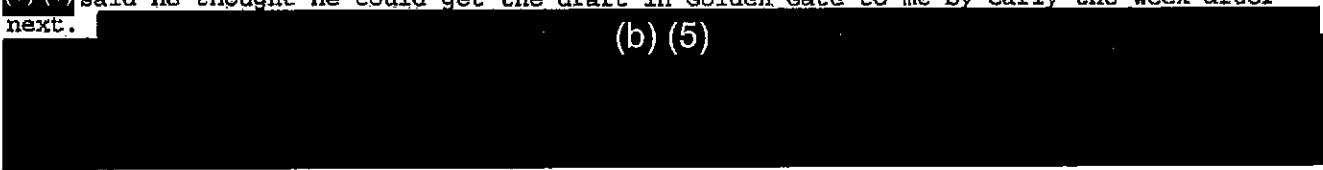
---

**From:** Knedler, Edwin S  
**Sent:** Friday, April 02, 2010 1:33 PM  
**To:** Kagan, Elena  
**Subject:** RE: Cvsgs

I received the draft from (b) (6) in Williamson this morning. I haven't started looking at it yet, but I will plan on getting it to you next week.

(b) (6) said he thought he could get the draft in Golden Gate to me by early the week after next.

(b) (5)



-----Original Message-----

**From:** Kagan, Elena  
**Sent:** Friday, April 02, 2010 8:03 AM  
**To:** Knedler, Edwin S  
**Subject:** Cvsgs

Ed -- could you give me time of arrival on (b) (6) and (b) (6)? Thanks. Elena

**Kagan, Elena**

---

**From:** Kagan, Elena  
**Sent:** Friday, April 02, 2010 1:45 PM  
**To:** Kneeder, Edwin S  
**Subject:** Re: Cvsgs

Ok, let me know

----- Original Message -----

**From:** Kneeder, Edwin S  
**To:** Kagan, Elena  
**Sent:** Fri Apr 02 13:32:40 2010  
**Subject:** RE: Cvsgs

I received the draft from (b) (6) in Williamson this morning. I haven't started looking at it yet, but I will plan on getting it to you next week.

(b) (6) said he thought he could get the draft in Golden Gate to me by early the week after next.

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-----Original Message-----

**From:** Kagan, Elena  
**Sent:** Friday, April 02, 2010 8:03 AM  
**To:** Kneeder, Edwin S  
**Subject:** Cvsgs

Ed -- could you give me time of arrival on (b) (6) and (b) (6)? Thanks. Elena

**Katyal, Neal (SMO)**

---

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 10:57 AM  
**To:** Hauck, Brian  
**Subject:** RE: Health Care Defense

Absolutely right on. Let's crush them. I'll speak with Elena and designate someone.

---

**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 10:54 AM  
**To:** Katyal, Neal  
**Subject:** Health Care Defense

Hi Neal -- Tom wants to put together a group to get thinking about how to defend against inevitable challenges to the health care proposals that are pending, and hoped that OSG could participate. Could you figure out the right person or people for that? More the merrier. He is hoping to meet next week if we can.

Thanks,  
Brian



## Katyal, Neal (SMO)

---

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 1:05 PM  
**To:** Hauck, Brian; (b) (6) SMO  
**Subject:** RE: Health Care Defense

Brian, Elena would definitely like OSG to be involved in this set of issues. I will handle this myself, along with an Assistant from my office, (b) (6) and we will bring Elena in as needed.

I am out of town from Jan 12-15 though, so if we could do it the following week it'd be ideal. If so, I can do almost anytime from Jan 19-21, except 10-1115 on the 19th, and 1030-1230 on the 20th, which is when our office is in arguments at the Court.

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**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 10:54 AM  
**To:** Katyal, Neal  
**Subject:** Health Care Defense

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Thanks,  
Brian

**Katyal, Neal (SMO)**

---

**From:** Kneedler, Edwin S  
**Sent:** Tuesday, May 11, 2010 1:28 PM  
**To:** Katyal, Neal  
**Subject:** RE: CVSGs

I don't think she has had any involvement at all in the Commonwealth of Virginia case, in which she now has a draft. She also has had no involvement that I know of in the Providence Hospital case in which I have a draft from (b) (6) or in the Amara ERISA invitation, in which we have just received a draft from Labor.

The Golden Gate case presents special considerations because of the possible nexus to the Health Care bill. I think I did have some minimal discussions with her about that case.

---

**From:** Katyal, Neal  
**Sent:** Tuesday, May 11, 2010 1:23 PM  
**To:** Kneedler, Edwin S; Stewart, Malcolm L  
**Subject:** CVSGs

As I understand it, Elena is going to recuse from all new cases. Are there any CVSGs you have due by cutoff in which she has not participated at all (either in meetings, phone calls, discussions with you, etc.)? She has participated in all of mine, what about yours?

Neal

## Katyal, Neal (SMO)

---

**From:** Katyal, Neal  
**Sent:** Tuesday, May 11, 2010 1:29 PM  
**To:** Kneedler, Edwin S  
**Subject:** RE: CVSGs

Thanks so much. That is the full range of your cvsgs due by cutoff? 4?

---

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**Sent:** Tuesday, May 11, 2010 1:28 PM  
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Neal

**Katyal, Neal (SMO)**

---

**From:** Kneedler, Edwin S  
**Sent:** Tuesday, May 11, 2010 1:30 PM  
**To:** Katyal, Neal  
**Subject:** RE: CVSGs

I have one more – Holy See – in which Elena chaired a meeting with counsel for each side. I have (b) (6)s draft in that case.

---

**From:** Katyal, Neal  
**Sent:** Tuesday, May 11, 2010 1:29 PM  
**To:** Kneedler, Edwin S  
**Subject:** RE: CVSGs

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Neal

**Katyal, Neal (SMO)**

---

**From:** Kneedler, Edwin S  
**Sent:** Wednesday, May 12, 2010 6:31 PM  
**To:** Katyal, Neal  
**Subject:** RE: Elena's name on briefs, opps, appeal recs

**CVSGs:**

Holy See -- Elena chaired meetings with counsel for both sides.

Commonwealth of Virginia, Providence Hospital, and the consolidated Amara and Cigna cases -- Elena has had no substantive involvement in, as far as I know.

Golden Gate -- I discussed with Elena several times [REDACTED] (b) (5) [REDACTED] Especially now that health care has passed, she may not want to be involved in that brief.

**Merits briefs:**

NASA v. Nelson -- our merits brief is now due May 20. Elena's name is on the petition, so she obviously has been heavily involved in that case.

Montana v. Wyoming -- the recommendation OSG has received from ENRD [REDACTED] (b) (5) [REDACTED] That recommendation has not been submitted to Elena. Such a brief would not be due until late June or early July. She has been substantively involved in the case.

Bruesewitz -- an amicus brief supporting respondents would be due July 30. We filed a CVSG last fall in a related case taking the position that supports the respondent's position in Bruesewitz, and we told the Court to grant in Bruesewitz. Elena's name was on that brief.

U.S. v. Tohono O'Odham Nation. Our brief is due in late June. Elena's name is on the petition in that case.

Kasten -- an amicus brief supporting petitioner would be due June 24. Elena has not been involved in that case.

Flores-Villar -- the government's brief as respondent is due in Late August. Elena has not been involved in that.

**Recommendations:**

OPEC -- (CA5 invited the U.S. to file on act of state and political question in this antitrust case against corporations owned or controlled by OPEC members) Civil is seeking a 30-day extension. I think I discussed the case with Elena last summer when the defendants were urging the U.S. to file uninvited.

---

**From:** Katyal, Neal  
**Sent:** Wednesday, May 12, 2010 5:33 PM  
**To:** Dreeben, Michael R; Kneedler, Edwin S  
**Subject:** FW: Elena's name on briefs, opps, appeal recs

I really need your list shortly. This is important.

---

**From:** Katyal, Neal

**Sent:** Wednesday, May 12, 2010 9:53 AM

**To:** Kneeder, Edwin S; Stewart, Malcolm L; Dreeben, Michael R; [REDACTED] (b) (6)

**Subject:** Elena's name on briefs, opps, appeal recs

From now on, until the outcome of her pending confirmation hearing, Elena will not be participating in new cases. All opps, appeal recs, etc., will not have her name on them, and [REDACTED] (b) (5) we should use my name as Acting SG.

There is a small universe of cases in which Elena has substantially participated already (this includes CVSGs where she chaired meetings, etc.). As to those cases, she very well may sign the briefs. With this email, I'd ask each Deputy sometime today to send me a full list of cases that you think fall into that category. Exclude matters in which you have had short conversations with her. This isn't a list regarding her recusals at the Supreme Court should she be confirmed; rather it is a list for her so that she knows what cases she might be signing briefs in.

Thanks,

Neal

**Katyal, Neal (SMO)**

---

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:05 PM  
**To:** Katyal, Neal; Schmalzer, Tracy  
**Subject:** RE: HCR litigation

Hcr is health care reform, right? If so, then my previous answer stands

-----Original Message-----

**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:04 PM  
**To:** Schmalzer, Tracy  
**Subject:** RE: HCR litigation

No, she never has been involved in any of it. I've run it for the Office, and have never discussed the issues with her one bit.

-----Original Message-----

**From:** Schmalzer, Tracy  
**Sent:** Monday, May 17, 2010 1:03 PM  
**To:** Katyal, Neal  
**Subject:** HCR litigation

Has Elena been involved in any of that to the extent SG office was consulted? Know you've been point but expect I'll get this q.

**Katyal, Neal (SMO)**

---

**From:** Schmalter, Tracy  
**Sent:** Monday, May 17, 2010 1:11 PM  
**To:** Katyal, Neal  
**Subject:** RE: HCR litigation

Yes - thanks.

-----Original Message-----  
**From:** Katyal, Neal  
**Sent:** Monday, May 17, 2010 1:05 PM  
**To:** Katyal, Neal; Schmalter, Tracy  
**Subject:** RE: HCR litigation

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**To:** Katyal, Neal  
**Subject:** HCR litigation

Has Elena been involved in any of that to the extent SG office was consulted? Know you've been point but expect I'll get this q.



**Katyal, Neal (SMO)**

---

**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 1:25 PM  
**To:** Katyal, Neal (b) (6) (SMO)  
**Subject:** RE: Health Care Defense

Great. We may end up having to go ahead with the meeting next week without you, but it will be more of a table-setting meeting -- so worst case is that (b)(6) or we catch you up as work gets moving.

---

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 1:05 PM  
**To:** Hauck, Brian (b) (6) (SMO)  
**Subject:** RE: Health Care Defense

Brian, Elena would definitely like OSG to be involved in this set of issues. I will handle this myself, along with an Assistant from my office, (b) (6) and we will bring Elena in as needed.

I am out of town from Jan 12-15 though, so if we could do it the following week it'd be ideal. If so, I can do almost anytime from Jan 19-21, except 10-1115 on the 19th, and 1030-1230 on the 20th, which is when our office is in arguments at the Court.

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Thanks,  
Brian

**Katyal, Neal (SMO)**

---

**From:** (b) (6) (SMO)  
**Sent:** Wednesday, January 13, 2010 7:11 PM  
**To:** Katyal, Neal  
**Subject:** RE: Health Care Defense

I attended the meeting today - Tom P. led it, and there were folks from Civil, OLC, and Antitrust. The basic plan is to do some anticipatory thinking about claims that will be asserted and how we will defend against them. It turns out that Civil has already started this, and hopes to produce some model briefs or memos. The big areas of possible litigation are (b) (6)

(b) (5)

the expectation is that a bill could pass and be signed by mid-February, so we could be in litigation soon after. There is the possibility of both well-financed, sophisticated challenges, as well as numerous pro se and frivolous claims.

Ian G. and Tony West will make a recommendation to Tom on how to structure the process going forward, i.e., should there be weekly meetings, etc. I spoke to Ian afterwards and told him we would like to be involved and to please keep us in the loop.

Please let me know if you have any questions or want to discuss.

---

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 1:05 PM  
**To:** Hauck, Brian (b) (6) (SMO)  
**Subject:** RE: Health Care Defense

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Brian

**Katyal, Neal (SMO)**

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**Sent:** Wednesday, January 13, 2010 7:16 PM  
**To:** (b) (6) (SMO)  
**Subject:** Re: Health Care Defense

Great. I appreciate it. I want to make sure our office is heavily involved even in the dct. Also one random q- (b) (5)  
(b) (5)

**From:** (b) (6) (SMO)  
**To:** Katyal, Neal  
**Sent:** Wed Jan 13 19:11:22 2010  
**Subject:** RE: Health Care Defense

I attended the meeting today - Tom P. led it, and there were folks from Civil, OLC, and Antitrust. The basic plan is to do some anticipatory thinking about claims that will be asserted and how we will defend against them. It turns out that Civil has already started this, and hopes to produce some model briefs or memos. The big areas of possible litigation are (b) (5)

The expectation is that a bill could pass and be signed by mid-February, so we could be in litigation soon after. There is the possibility of both well-financed, sophisticated challenges, as well as numerous pro se and frivolous claims.

Ian G. and Tony West will make a recommendation to Tom on how to structure the process going forward, i.e., should there be weekly meetings, etc. I spoke to Ian afterwards and told him we would like to be involved and to please keep us in the loop.

Please let me know if you have any questions or want to discuss.

**From:** Katyal, Neal  
**Sent:** Friday, January 08, 2010 1:05 PM  
**To:** Hauck, Brian; (b) (6) (SMO)  
**Subject:** RE: Health Care Defense

Brian, Elena would definitely like OSG to be involved in this set of issues. I will handle this myself, along with an Assistant from my office, (b) (6) and we will bring Elena in as needed.

I am out of town from Jan 12-15 though, so if we could do it the following week it'd be ideal. If so, I can do almost anytime from Jan 19-21, except 10-1115 on the 19th, and 1030-1230 on the 20th, which is when our office is in arguments at the Court.

N

**From:** Hauck, Brian  
**Sent:** Friday, January 08, 2010 10:54 AM  
**To:** Katyal, Neal  
**Subject:** Health Care Defense

Hi Neal -- Tom wants to put together a group to get thinking about how to defend against inevitable challenges to the health care proposals that are pending, and hoped that OSG could participate. Could you figure out the right person or people for that? More the merrier. He is hoping to meet next week if we can.

Thanks,  
Brian

pages 72 through 104  
have been withheld in full  
pursuant to (b)(5)  
and as not responsive