October 18, 2010

VIA FEDEX®

Division of Dockets Management
Food and Drug Administration
Department of Human and Health Services (HFA-305)
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

On behalf of Lupin Limited, the undersigned submits this Citizen Petition, in quadruplicate, pursuant to 21 C.F.R. §§ 10.25, 10.30, and 10.20, requesting that the Commissioner of the U.S. Food and Drug Administration (“FDA”) confirm that Teva Pharmaceuticals USA, Inc.’s abbreviated new drug application (“ANDA”) is not entitled to 180-day exclusivity for lamivudine and zidovudine tablets, 150 mg/300 mg. In addition, Lupin requests that FDA confirm that Lupin, and not Teva, is eligible for 180-day exclusivity for lamivudine and zidovudine tablets, 150 mg/300 mg. The undersigned respectfully requests expedited consideration of this petition, as any delay would severely and irreparably harm Lupin.¹

A. ACTION REQUESTED

Petitioner respectfully requests that FDA promptly confirm that:

1. Teva Pharmaceuticals USA, Inc. is not entitled to 180-day generic exclusivity for lamivudine and zidovudine tablets, 150 mg/300 mg; and,

2. Lupin, and not Teva, is eligible for 180-day generic exclusivity, pursuant to 21 U.S.C. § 355(j)(5)(B)(iv), for lamivudine and zidovudine tablets, 150 mg/300 mg.

B. STATEMENT OF GROUNDS

I. Factual Background.

Based on public filings and other publicly available information, Petitioner sets forth the following relevant background facts.

A. The Brand RLD And Listed Patents.

This submission concerns generic exclusivity for ANDAs seeking FDA approval for lamivudine and zidovudine tablets, 150 mg/300 mg, and referencing the listed drug Combivir®, used in the treatment of HIV-1 infection. At all times relevant here, FDA’s Orange Book has listed four patents in connection with Combivir®:

- U.S. Patent No. 7,119,202 (“the ‘202 patent”), which expired on February 8, 2009, with pediatric exclusivity that expired on August 8, 2009;

- U.S. Patent No. 5,047,407 (“the ‘407 patent”), which expired on November 17, 2009, with pediatric exclusivity that expired on May 17, 2010;

- U.S. Patent No. 5,859,021 (“the ‘021 patent”), which purportedly expires on May 15, 2012; and

- U.S. Patent No. 5,905,082 (“the ‘082 patent”), which purportedly expires on May 18, 2016, with pediatric exclusivity that purportedly expires on November 18, 2016.

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2 GlaxoSmithKline was the original NDA-holder for Combivir®. FDA currently lists the NDA-holder for Combivir® as Viiv Healthcare. For purposes of convenience and clarity, Lupin refers herein to the NDA-holder as “GSK.”

3 FDA’s electronic Orange Book does not list a period of pediatric exclusivity in connection with the ‘021 patent. Assuming, for present purposes only, that pediatric exclusivity applies to the ‘021 patent, as it does to other patents listed in connection with Combivir®, such pediatric exclusivity would not expire until November 15, 2012.
B. Teva’s Paragraph IV ANDA.

Teva purportedly filed its ANDA (No. 79-081) on or about June 26, 2007, with a paragraph IV certification to the ‘021 patent only.\footnote{This date corresponds to the date posted on FDA’s paragraph IV website as the first date on which an ANDA for a generic Combivir® product containing a paragraph IV certification purportedly was filed.} Teva’s original ANDA filing contained a paragraph III certification to all other listed patents—the ‘407 and ‘202 patents, and most critically, the ‘082 patent, which expires after the ‘021 patent. In other words, contrary to the statute, FDA’s regulations, and Teva’s own paragraph IV certification, Teva did not seek approval of its ANDA prior to expiration of the ‘021 patent in May 2012. Indeed, Teva did not seek approval until expiration of the ‘082 patent in 2016 – over four years after expiration of the ‘021 patent.


According to public records, on or about October 1, 2008—nearly one and a half years after Teva’s original ANDA filing date—Teva amended its ANDA to include a paragraph IV certification to the latest-expiring Orange Book patent, the ‘082 patent. GSK did not sue Teva for infringement of this patent. Instead, on December 8, 2008, GSK offered Teva a covenant-not-to-sue for the ‘082 patent.

On December 24, 2009, FDA awarded Teva tentative approval for its lamivudine/zidovudine tablet ANDA. At that time, Teva was not eligible for final approval because of its paragraph III certification to the ‘407 patent. On February 19, 2010, Teva informed GSK of Teva’s intent to launch its generic lamivudine/zidovudine product on May 17, 2010, the expiration date of the pediatric exclusivity for the ‘407 patent. The district court set a preliminary injunction hearing for May 3, 2010. Before the hearing, however, the parties entered into a settlement agreement, and the court entered a Stipulation to Stay the litigation on April 19, 2010, terminating all deadlines in the case. On May 26, 2010, the court entered a Stipulation of Dismissal, dismissing all claims and defenses in the litigation. The terms of the GSK/Teva Settlement are not publicly available, and Teva still has tentative approval only. To date, Teva has not launched, and without FDA approval cannot launch, its generic lamivudine/zidovudine drug product.

C. Lupin’s Paragraph IV ANDA.

Lupin filed an ANDA for lamivudine and zidovudine tablets, 150 mg/300 mg, on January 11, 2008. Unlike Teva’s original ANDA submission, Lupin’s original ANDA
submission contained paragraph IV certifications to both the ‘021 and ‘082 patents, as well as paragraph III certifications to the ‘407 and ‘202 patents. In other words, Lupin filed the first ANDA containing a paragraph IV certification to, inter alia, the latest-expiring Orange Book patent, and did so nearly 10 months before Teva amended its ANDA to include a paragraph IV certification to that patent. In other words, Lupin was the first ANDA applicant to seek FDA approval prior to expiration of the ‘021 patent.

As required by statute and FDA regulations, Lupin sent notice of its paragraph IV certifications to the NDA-holder and patent owners. After receipt of that notice, Lupin was sued for infringement of the ‘021 patent on August 29, 2008, in the United States District Court for the District of Delaware. On October 15, 2008, Lupin counterclaimed for non-infringement and invalidity of the ‘082 patent.

On December 8, 2008, as it did with Teva, GSK offered Lupin a covenant-not-to-sue on the ‘082 patent and simultaneously moved to dismiss Lupin’s counterclaims. Lupin thereafter dismissed its counterclaims as to the ‘082 patent and GSK withdrew its motion. On March 18, 2009, the district court entered a consent order staying the Lupin litigation pending final judgment in the Teva litigation. Because no final judgment was entered in the Teva litigation, the Lupin litigation remains pending. The 30-month ANDA approval stay will expire on or around January 17, 2011.

II. Legal Background.

A. The 180-Day Generic Exclusivity Incentive.

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"encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers’ patents"); Apotex, 53 F. Supp. 2d at 461 (noting that the "purpose of the exclusivity incentive and the entire ANDA regime is to make available more low cost generic drugs").

When enacting Hatch-Waxman, Congress knew that brand drug companies obtain numerous patents to protect their high-priced products from competition. As a result, and as Congress recognized, the public will never have access to affordable generic drugs before patent expiration unless generic companies challenge the suspect and overbroad patents that commonly prevent immediate generic competition. Congress also recognized that challenging patents would require generic drug companies to assume considerable risks and costs. To encourage the patent challenges needed to bring lower-priced medicines to patients before patent expiration, Congress created an incentive: "the right to sell [the generic] drug without competition for 180 days." Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 879 (D.C. Cir. 2004) (citing 21 U.S.C. § 355(j)(5)(B)(iv)). Congress created the 180-day generic exclusivity period by preventing FDA from approving subsequently-filed ANDAs during that period. 21 U.S.C. § 355(j)(5)(B)(iv).

FDA has recognized the importance of the generic exclusivity period to the entire Hatch-Waxman statutory system. See 64 Fed. Reg. 42873, 42877 (Aug. 6, 1999) (acknowledging that the 180-day period is "the incentive created by Congress for ANDA applicants to challenge patents"); (see also 7/29/88 Ltr. from C. Peck to All NDA or ANDA Holders and Applicants (stating that "section 505(j)(4)(B)(iv) may be interpreted as providing a reward to the applicant who benefits the public by challenging a patent and allowing competition"), attached hereto as Ex. A). The courts, too, have recognized the critical role that generic exclusivity plays in carrying out Congress’ purpose for Hatch-Waxman. See, e.g., Teva, 595 F.3d at 1305, 1318; Teva Pharms., 395 F.3d at 1328; Ranbaxy, 459 F. Supp. 2d at 3; Mylan, 81 F. Supp. 2d at 33; Apotex, 53 F. Supp. 2d at 461. Indeed, the courts routinely direct the Agency to act in a manner that upholds "the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire." Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 126 (D.C Cir. 2006). The D.C. Circuit has, in fact, explained in no uncertain terms, that FDA “may not . . . change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'” Id. (quoting MCI Telecomms. Corp. v. AT&T Co., 512 U.S. 218, 231 n.4 (1994)) (emphasis added); see also Teva, 595 F.3d at 1318 (exclusivity is the "device Congress has chosen to induce challenges to patents"). This, again, is because the 180-day exclusivity period "is a pro-consumer device," as it expedites the public’s access to safe and affordable medicines. Teva, 595 F.3d at 1318.

Because of the importance of the generic exclusivity period to bringing affordable drugs to market before patent expiration, Congress, FDA and the courts alike stressed that the ANDA process should not be manipulated in an effort to improperly secure exclusivity. See,
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e.g., H.R. REP. No. 98-857, pt. I, at 24 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2657 (warning against the filing of “sham ANDAs or ANDAs which are substantially incomplete”), excerpt attached hereto as Ex. B; 59 Fed. Reg. 50338, 50350 (Oct. 3, 1994) (“To permit an ANDA applicant to provide notice before FDA has determined whether the ANDA is sufficiently complete would be contrary to the legislative history because it would only encourage ANDA applicants to file incomplete or ‘sham’ ANDAs and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.”).

In fact, for its part, Congress not only reaffirmed the importance of a strong 180-day exclusivity period to carrying out the goal of early access to affordable medicines, but modified those provisions to, inter alia, prevent abuse of that incentive. More specifically, when it revisited the 1984 Hatch-Waxman Act in 2003, rather than eliminate generic exclusivity as some advocated, Congress took steps to ensure that this exclusivity period would continue to act as the incentive needed to bring generic medicines to market before patent expiration, while at the same time revising the exclusivity provisions to eliminate abuses that could unduly delay full generic competition.\textsuperscript{5} See, e.g., 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) (observing that the MMA amendments would “ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition”), attached hereto as Ex. C; 149 Cong. Rec. S15884 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (noting that the 180-day exclusivity incentive “mean[s] that consumers will be able to enjoy the lower prices provided by generic companies sooner rather than later”), attached hereto as Ex. D. For example, prior to the 2003 MMA, FDA had interpreted Hatch-Waxman such that submitting a “substantially complete” ANDA was a requirement for generic exclusivity eligibility. 64 Fed. Reg. 42873, 42875 (Aug. 6, 1999). FDA adopted this policy “out of concern that, in the rush to be the first ANDA” to challenge a brand patent, applicants would submit ANDAs that did not meet statutory requirements. \textit{Id.} Congress, also wanting to avoid abuse of the generic exclusivity provisions, codified a “substantially complete” ANDA requirement as part of the MMA. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc). Thus, while Congress has confirmed the importance of the generic exclusivity period because it encourages pre-patent expiration marketing, it also has made clear that those provisions should not be abused in a way contrary to its stated purpose.

B. Patent Certifications.

Hatch-Waxman requires ANDAs to contain a patent “certification” and offers applicants four certification options: (I) there is no patent information listed in the Orange Book for the drug; (II) the listed patent has expired; (III) the ANDA applicant will not market its generic drug until after the listed patent has expired, a so-called “paragraph III certification”; or (IV) the listed patent is invalid and/or not infringed by the proposed ANDA product, a so-called “paragraph IV certification.” See 21 U.S.C. § 355(j)(2)(A)(vii). Thus, under the plain language

of the statute, an applicant unwilling to challenge the listed patent and risk potentially costly patent litigation in an effort to bring its product to market before patent expiration must file a paragraph III certification.

Congress has, in fact, made clear that a paragraph IV certification is only appropriate if the generic applicant seeks approval before the listed patent(s) expire. See Ex. B, H.R. REP. NO. 98-857, pt. I, at 15 (“Generic copies of [approved] drugs may be approved when the patents expire unless the generic company certifies that the patent is invalid or will not be infringed”). FDA, too, has recognized this fact, stating that an applicant should file a paragraph IV certification only “when it seeks to market its generic product prior to the expiration of a listed patent.” (1/29/08 FDA Ltr. at 6, Docket No. 2007N-0382) (emphasis added). In other words, a paragraph IV certification is proper only if the applicant seeks FDA approval before patent expiration. FDA has stated time and time again, “[i]f . . . an applicant wishes to seek approval of its ANDA before a listed patent has expired by challenging the validity of a patent or claiming that a patent would not be infringed by the product proposed in the ANDA, the applicant must submit a paragraph IV certification to FDA.” (6/17/10 FDA Ltr. at 4, Docket No. FDA-2009-P-0601; 3/15/10 FDA Ltr. at 5, Docket No. FDA-2009-P-0411; 12/4/08 FDA Ltr. at 5, Docket Nos. FDA-2008-P-0343, FDA-2008-P-0411.) The Courts agree. Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 272 (4th Cir. 2006) (“an ANDA applicant making a paragraph IV certification intends to market its product before the relevant patents have expired”).

III. Analysis.

A. Teva Is Not Entitled To 180-Day Exclusivity For Lamivudine/Zidovudine Tablets.

1. Teva’s Original ANDA Submission Did Not “Contain” A Paragraph IV Certification.

Viewing the statute in accordance with both its plain language and Congressional intent, FDA must find that Teva did not have a valid paragraph IV certification when Teva originally filed its ANDA. Teva’s original ANDA submission contained a paragraph III certification to the ‘082 patent, which expires four years after the patent to which Teva purportedly submitted a paragraph IV certification. Teva’s original “paragraph IV certification” to the ‘021 patent was a complete sham designed solely as an improper attempt to secure exclusivity. For this reason alone, Teva is not eligible for 180-day exclusivity.

a. Teva’s Original ANDA Submission Did Not Contain A Valid Paragraph IV Certification Under The Plain Language Of The Statute.

Under the plain language of the statute, Teva is not a lawful “first applicant” because Teva’s initial ANDA submission can neither be considered to have “contain[ed]” a valid
paragraph IV certification, nor can it be deemed a “substantially complete application.” 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)-(cc). Because Teva elected to submit a paragraph III certification to the ‘082 patent, FDA could not finally approve Teva’s ANDA during the entire life of the supposedly “challenged” ‘021 patent. In fact, FDA could not have awarded Teva final approval until four years after the ‘021 patent expires. Based on these facts, Teva could not have intended to—and as a matter of law and fact could not—“market its generic product prior to the expiration of a listed patent” at the time of its original filing. (1/29/08 FDA Ltr. at 6, Docket No. 2007N-0382.) Significantly, Teva also could not have in any way “benefit[ed] the public” or “allow[ed] competition” prior to expiration of the ‘021 patent through its original ANDA submission. (Ex. A, 7/29/88 Ltr. from C. Peck to all NDA or ANDA Holders and Applicants, at 5.) Because Teva made itself ineligible for final approval until years after the ‘021 patent expired, Teva’s purported paragraph IV certification to the ‘021 patent was, in fact, a paragraph III certification for all legal and practical purposes. As such, FDA cannot lawfully conclude that Teva’s original ANDA submission “contain[ed]” a valid paragraph IV certification.

As required by the plain language of the statute, both FDA and the courts have recognized that an ANDA applicant making a paragraph IV certification must seek to market its product before patent expiration. See Mylan Pharm., 454 F.3d at 272; see also (6/17/10 FDA Ltr. at 4, Docket No. FDA-2009-P-0601; 3/15/10 FDA Ltr. at 5, Docket No. FDA-2009-P-0411; 12/4/08 FDA Ltr. at 5, Docket Nos. FDA-2008-P-0343, FDA-2008-P-0411). Here, however, Teva could not market before expiration of the ‘021 patent when Teva submitted its original ANDA, even if it prevailed in its litigation. Indeed, it was a legal and factual impossibility of Teva’s own making based upon its paragraph III certification to the later-expiring ‘082 patent.

In point of fact, Teva’s purported paragraph IV certification was nothing more than a sham filing designed solely to attempt to secure generic exclusivity. At the time of ANDA submission, Teva knew that, even if it succeeded in obtaining a final court decision finding the ‘021 patent invalid or not infringed, it still could not receive final approval—and thus could not have benefitted the public with a pre-patent expiration launch—until well after the ‘021 patent expired. Consequently, Teva did not file a paragraph IV certification under the statute. The statute specifically directs FDA to approve, “effective immediately,” a paragraph IV ANDA, unless suit is filed within the statutory 45-day period, and then “approval shall be made effective upon the expiration of the [30-month stay]”. 21 U.S.C. § 355(j)(5)(B)(iii). But again, Teva’s original patent certifications prevented FDA from following this clear statutory mandate because Teva’s paragraph III certification to the ‘082 patent prohibited FDA from approving Teva’s application until the ‘082 patent expired four years after the ‘021 patent expired. FDA therefore cannot find that Teva’s original paragraph IV certification to the ‘021 patent was lawful without violating the long-standing rule that the Agency must “give effect, if possible, to every clause and word of a statute’ and should avoid rendering any of the statutory text meaningless or as mere surplusage.” Sharp v. United States, 580 F.3d 1234, 1238 (Fed. Cir. 2009) (citation omitted).
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The fact is, at the time of Teva’s filing, the only benefit Teva could possibly have enjoyed by racing to file an incomplete ANDA was not helping patients by early generic market entry, but the unlawful blocking of subsequent ANDA-filers. Such a certification cannot qualify an ANDA-filer for “first applicant” status, and similarly cannot give rise to 180-day exclusivity. Indeed, the Agency repeatedly has emphasized that 180-day exclusivity is not a reward for applicants who simply race to be first-to-file. Rather, 180-day exclusivity is reserved for applicants that file “legitimate” paragraph IV certifications,” and applicants that “manipulate their patent certification filings . . . jeopardize their chances of obtaining the valuable 180-day exclusivity.” 68 Fed. Reg. 36676, 36689 (June 18, 2003) (emphasis added). In other words, 180-day exclusivity must be limited to applicants who can further Congress’ “goal of permitting earlier entry into the market of generic competitor products;” an ANDA applicant must not be permitted to file a “frivolous”, much less unlawful, certification solely to qualify for exclusivity. 64 Fed. Reg. 42873, 42875-76 (Aug. 6, 1999).

Here, Teva did not file a legitimate paragraph IV certification—Teva did not actually file a paragraph IV certification at all. Teva filed an ANDA hoping to secure generic exclusivity even though that submission made it impossible for the public to obtain access to generic versions of Combiqiv before expiration of the ‘082 patent in 2016. Teva’s original ANDA submission thus did not “contain” a valid paragraph IV certification, and Teva is not a “first applicant” under the plain language of the statute.

b. Teva Is Not Eligible For 180-Day Exclusivity In View Of Clear Legislative Intent.

In addition to being unlawful under the plain language of the statute, Teva’s original paragraph IV filing violates clear Congressional intent, and amounts to exactly the kind of manipulation and abuse of the Hatch-Waxman process that both FDA and Congress have tried for years to prevent through statutory amendments and regulatory rulemaking. In light of such clear statutory intent, FDA must find that Teva is not entitled to 180-day exclusivity for lamivudine/zidovudine tablets, as any other conclusion would be contrary to Congress’ express intent and thus arbitrary, capricious and contrary to law. See e.g., Dole v. United Steelworkers of Am., 494 U.S. 26, 35 (1990) (instructing that, “in expounding a statute, [courts] are not guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy” (internal quotation marks and citation omitted)); accord FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (“It is a fundamental cannon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”) (internal quotations and citation omitted)).

As discussed above, Congress created the paragraph IV process to “make available more low cost generic drugs.” See Ex. B, H.R. REP. No. 98-857, pt. I, at 14; see also Ex. D, 149 Cong. Rec. S15884 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (noting that the purpose of Hatch-Waxman is “to enable competitors to bring cheaper, generic copies of . . . drugs to market as quickly as possible”); Barr Labs., 930 F.2d at 76 (observing that Hatch-
Waxman was designed to “get generic drugs into the hands of patients at reasonable prices—fast”).

Teva’s original ANDA submission could never have done that. Teva’s paragraph III certification to the ‘082 patent prevented FDA from approving Teva’s generic lamivudine/zidovudine tablet ANDA until well after the ‘021 patent had expired. This would have been true regardless of whether Teva, or any other filer for that matter, had ultimately been successful at designing around or invalidating the ‘021 patent. Such a patent certification strategy is inconsistent with the plain language and purpose of Hatch-Waxman, and cannot serve as the basis for the highly valuable 180-day exclusivity period. The purpose behind the 180-day exclusivity provision is furthered only when the first applicant actually has the potential to open up the market to generic competition before the brand’s blocking patents expire.

Moreover, both Congress and FDA sought to prevent “ANDA applicants [from] filing] incomplete or ‘sham’ ANDAs and to supplement them later to secure a place in the review queue in an attempt to secure the first ANDA approval.” 59 Fed. Reg. at 50350; Ex. B, H.R. REP. NO. 98-857, pt. I, at 24. Teva hopes that its original ANDA filing has done precisely that. Teva, by filing an incomplete application with an invalid paragraph IV certification, hopes to bottleneck all generic competition. Indeed, even now, instead of marketing upon expiration of the pediatric exclusivity associated with the ‘407 patent, as Teva promised to do, Teva is sitting on its hands and is using generic exclusivity to block lawful generic entry for this product indefinitely. Teva cannot manipulate and abuse the statute in such a manner—one that is so clearly contrary to both the express language and purpose of the Act.

In sum, Teva’s original ANDA did not contain a lawful paragraph IV certification and thus was not substantially complete. Consequently, Teva cannot be deemed a “first applicant,” and Teva’s original ANDA filing cannot give rise to any period of generic marketing exclusivity. For FDA to conclude otherwise would “change the incentive structure adopted by the Congress,” which the Agency cannot lawfully do. Ranbaxy, 469 F. 3d at 126; see also Teva, 595 F.3d at 1318 (exclusivity is “precisely the device Congress has chosen to induce challenges to patents”).


Teva further does not qualify as a “first applicant” for exclusivity purposes because Teva did not “lawfully maintain” a paragraph IV certification to the ‘021 patent. As explained above, Teva’s purported paragraph IV certification to the ‘021 patent was not an actual, valid paragraph IV certification at least because Teva never intended to receive, nor could it have received, final approval before expiration of the ‘021 patent, even if it won its patent litigation. Teva’s application therefore did not contain a lawful paragraph IV certification to the ‘021 patent until Teva amended its ANDA in October 2008 to include a paragraph IV certification to the later-expiring ‘082 patent.
As a matter of fact and a matter of law, Teva cannot “lawfully maintain” that which it never had. At all times prior to Teva’s October 2008 amendment, Teva’s purported paragraph IV certification to the ‘021 patent was not accurate and therefore must be treated as a paragraph III certification at least because Teva’s paragraph III certification to the ‘082 patent prevented FDA from approving Teva’s ANDA until well after the ‘021 patent expired. See *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1281 (D.C. Cir. 2004) (upholding FDA’s determination that a patent certification must be amended, or deemed amended, if it is not accurate); see also 21 C.F.R. § 314.94(a)(12)(viii)(C). The statute, FDA’s regulations, and Congressional intent thus compel FDA to conclude that Teva maintained a paragraph III certification to the ‘021 patent until October 1, 2008, at the earliest. In other words, from the date Teva filed its ANDA in June 2007, through the date Teva amended its ANDA in October 2008, its ANDA contained a paragraph III certification to the ‘021 patent and did not contain any valid paragraph IV certifications. Any other conclusion would be “at variance with the legal reality.” See *Mylan Labs.*, 389 F.3d at 1281.

In sum, because Teva’s original ANDA submission must be deemed, under the plain language of the statute and Congressional intent, to have contained solely paragraph III certifications, Teva cannot be said to have ever “contained” or “lawfully maintained” a paragraph IV certification to the ‘021 patent for purposes of satisfying the statutory definition of “first applicant.” Teva therefore is not now, and never was, eligible for 180-day exclusivity. This, again, is the only outcome consistent with the plain language of the statute, legislative intent, and FDA’s long-standing position that applicants that “manipulate their patent certification filings . . . jeopardize their chances of obtaining the valuable 180-day exclusivity.” 68 Fed. Reg. 36676, 36689 (June 18, 2003). Indeed, any other conclusion would be arbitrary, capricious, and contrary to law.

B. **Lupin Is The First Applicant Eligible For 180-Day Exclusivity.**

Once FDA lawfully concludes that Teva’s original ANDA submission did not contain, nor did it lawfully maintain, a paragraph IV certification, FDA must then conclude that Lupin is entitled to 180-day exclusivity for lamivudine/zidovudine tablets. Lupin filed a substantially complete ANDA for lamivudine/zidovudine tablets on **January 11, 2008**, containing a lawful paragraph IV certification to both the ‘021 and ‘082 patents. Lupin has lawfully maintained those certifications since that date. Teva did not submit an ANDA containing a valid paragraph IV certification to any patent, including the ‘082 patent, until **October 1, 2008—10 months after Lupin filed its paragraph IV ANDA**. Lupin thus is the “first applicant” for lamivudine/zidovudine tablets, and therefore alone is eligible for 180-day exclusivity for this drug product.

C. **Conclusion.**

Teva’s original ANDA submission did not contain a valid paragraph IV certification to any listed patent under either the plain language of the statute or express
Congressional intent. Teva’s original ANDA submission neither contained nor lawfully maintained a valid paragraph IV certification, nor was Teva’s original submission substantially complete until, at the earliest, October 2008. FDA therefore must find that Lupin is the “first applicant” for lamivudine/zidovudine tablets, and is entitled to 180-day exclusivity as a result. Were FDA to conclude otherwise would be arbitrary, capricious, and contrary to law in violation of the plain language of the statute and express Congressional intent.

Lupin thus respectfully requests that FDA determine that Lupin, not Teva, is the “first applicant” for lamivudine/zidovudine tablets, and alone is eligible for 180-day exclusivity for this product.

C. ENVIRONMENTAL IMPACT

Under 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. CERTIFICATION

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition. Pursuant to 21 U.S.C. § 355(q)(1)(H), the undersigned certify that, to their best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) the undersigned have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to them. The undersigned further certify that the information upon which they have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: December 8, 2008. If we received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, we received or expect to receive those payments from the following persons or organizations: Lupin Limited. We verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.
Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

William A. Rakoczy

Lara E. FitzSimmons

Counsel for Lupin Limited

cc (via email):
Robert West, Deputy Director, Office of Generic Drugs
Elizabeth Dickinson, Counsel, Office of Chief Counsel
EXHIBIT A
GUIDANCE FOR INDUSTRY

The FDA published Good Guidance Practices in February 1997. This guidance was developed and issued prior to that date.

Additional copies are available from:
Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857

(Tel) 301-827-4373
(Internet) http://www.fda.gov/cder/guidance/index.htm

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
To all NDA or ANDA Holders and Applicants

Dear Sir or Madam:

This is the seventh in a series of letters issued by the Food and Drug Administration to keep you informed of developments in the agency's implementation of the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Amendments). On April 28, 1988, the agency issued a letter compiling agency policies and procedures on the so-called three and five-year exclusivity provisions of the 1984 Amendments (the sixth letter). In this seventh letter, the agency is providing related guidance on the so-called "180-day exclusivity" provision in section 505(j)(4)(B)(iv) of the Federal Food Drug and Cosmetic Act (the Act), which requires the agency to delay the approval of subsequent ANDAs for a drug product when a previous ANDA applicant has challenged a patent on the listed drug product.

The policies and procedures described in this letter do not resolve every question of interpretation presented by the 180-day exclusivity provision; they are simply those policies and procedures that have been developed in response to particular cases before the agency. The agency expects that as future cases arise, additional policies and procedures will be developed to handle issues not addressed in this letter. If any policy or procedure described in this letter is inconsistent with or modifies previous advice, the new policy or procedure contained in this letter supersedes the previous advice:

I. How an ANDA Applicant Qualifies for 180-Day Exclusivity.

Section 505(j)(4)(B)(iv) grants to certain ANDA applicants who challenge a patent on a listed drug a 180-day period of marketing free from competition from subsequent ANDA applicants who also allege non-infringement or the invalidity of the patent. FDA believes that Congress intended this provision to reward the first generic applicant to successfully litigate the scope or validity of a patent on a listed drug.

A. The ANDA Must Be the First Complete Application Containing a Paragraph IV Certification.

The statute requires FDA to delay the effective date of an ANDA for 180 days from one of two specified dates when the application contains a certification under 505(j)(2)(A)(vii)(IV) (a paragraph IV certification) and "is for a drug for which a previous application has been submitted under [section 505(j)] containing...a certification [described in subclause iv of section 505(j)(2)(A)(vii)]." To be eligible for the 180-day exclusivity, an ANDA must therefore qualify as a "previous application...containing a [paragraph IV] certification."
As FDA interprets this provision, a "previous application" means a previous substantially complete application. Among other things, a substantially complete application must contain the results of any appropriate bioequivalence studies. An appropriate bioequivalence study is one that meets a specific FDA guidance for the drug product at issue or is otherwise reasonable in design and that purports to show that the proposed drug product is bioequivalent to the listed drug product. Even if the study is ultimately determined to be deficient for reasons that should not have been apparent at the time of filing, the study will be considered adequate to form the basis of a substantially complete application. Neither a protocol nor a pilot study, however, will satisfy these requirements.

To facilitate the implementation of the 180-day exclusivity provision, applications containing paragraph IV certifications are not accepted for filing unless they contain the results of any required bioequivalence studies. If the proposed drug product is one for which the submission of a bioequivalence study is not required for approval, e.g., a parenteral product, the application will be accepted for filing and will be considered a complete application if it contains a request for a waiver of a bioequivalence study and otherwise meets the agency's filing requirements.

The date of submission of a previous application for purposes of determining priority for the 180-day exclusivity will be the date that an application contains both a paragraph IV certification and the appropriate bioequivalence studies.

B. The Applicant Must Be Sued For Patent Infringement.

To qualify for the 180-day exclusivity an applicant must, in addition to being the first to submit a complete application containing a paragraph IV certification, also be sued for patent infringement. FDA bases this interpretation on the logic of the statutory dates from which the 180-day delay runs. The date from which the 180 days runs under subclause (II) of 505(j)(4)(B)(iv) expressly requires that the applicant have won a patent infringement lawsuit.

Moreover, Congress' decision to use the date of "first commercial marketing" as the alternative date in subclause (I) serves a rational purpose only where there has been a lawsuit. It is reasonable to select the date of first commercial marketing rather than the effective date of the ANDA only if an ANDA is in effect but the applicant's decision not to market the drug should be

1 FDA's interpretation of "previous application" was upheld in Barr Laboratories v. Bowen (D.C.N.J. Nov. 20, 1987).
encouraged because a delay in marketing serves the public interest. Such a situation occurs where, under the terms of section 505(j)(4)(B)(iii) an ANDA becomes effective 30 months after a lawsuit is filed, but the lawsuit is still unresolved. Because it serves the public interest to permit a defendant in a patent infringement action to stay off the market until the patent issues are resolved, subclauses (I) and (II) were drafted so that the reward of exclusivity would not provide an incentive for immediate marketing: the 180 days does not begin until the applicant wins the lawsuit or actually begins marketing, "whichever is earlier." Outside the context of a lawsuit, however, dating the 180 days from the date of first commercial marketing would protect delays in competition without any countervailing public benefit.

C. First Applicant to Qualify for 180-Day Exclusivity Must "Actively Pursue" ANDA Approval.

Because an applicant can meet all the criteria for the 180-day exclusivity before its ANDA is approved, and because subsequent applications may be delayed for 180 days from the first applicant's approval, an applicant entitled to exclusivity could unreasonably delay the marketing of all generic competitors if the applicant failed to actively pursue approval of its ANDA. Accordingly, FDA will delay the effective date of subsequent ANDA's only so long as the first applicant actively pursues approval of its ANDA.

II How FDA Determines the Date from which 180 Days Runs.

A. "First Commercial Marketing"

The agency defines the date of "first commercial marketing" as the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer, except for investigational use under 21 CFR Part 312. Commercial marketing does not encompass transfer of a drug product within the control of the manufacturer or application holder for reasons other than sale. An applicant entitled to exclusivity under section 505(j)(4)(B)(iv) who begins commercial marketing of the drug product after the effective date of the ANDA but before completion of the action for patent infringement should notify the Division of Generic Drugs, FDA immediately of the date of first commercial marketing. This notice should be filed with the application.

B. "Court Decision" Includes a Consent Decree

Subclause II specifies as one of the two dates from which the 180 days runs "the date of a decision of a court...holding the patent...to be invalid or not infringed." A final adjudication on the merits is not required to trigger the 180-day period. A settlement order or consent decree signed by a federal judge, which enters final judgment and includes a finding that the patent is
invalid or not infringed, constitutes "a decision of a court" within the meaning of subclause II. Also, FDA believes that a lawsuit that is settled because the ANDA applicant accepts a license from the patent holder under the patent does not entitle that ANDA applicant to the 180-day exclusivity. A settlement of a lawsuit based upon a licensing agreement does not constitute a decision of the court finding the patent invalid or not infringed because, among other reasons, a license is not necessary for a non-infringing product.

C. Appeal of a District Court Decision

For purposes of determining the date from which the 180-day period runs, the decision of a district court finding a patent invalid or not infringed will be considered the date of a final judgment. The 180 days will begin to run from the date of the initial court's decision even if that decision is appealed, unless the initial court's decision is stayed. (See Request for Comments below.)

III Which Subsequent ANDAs Are Delayed?

When an applicant satisfies the criteria for the 180-day exclusivity, FDA will delay until the expiration of the first applicant's exclusivity the effective date of any application that 1) contains a paragraph IV certification, 2) is subsequently submitted, and 3) refers to the same listed drug.

A. "Subsequently Submitted"

As noted above, for purposes of section 505(j)(4)(B)(iv), the date of submission is the date that a substantially completed ANDA is submitted containing, among other things, a paragraph IV certification and any required bioequivalence studies. For example, if applicant "A" submits an ANDA meeting all the agency's filing requirements with a paragraph IV certification on January 1 and then submits a required bioequivalence study on February 1, while applicant "B" submits an ANDA meeting all the agency's filing requirements on January 15, a paragraph IV certification on January 16 and a required bioequivalence study on January 17, ANDA "A" will be considered to have been submitted on February 1, while ANDA "B" will have been submitted on January 17. Thus, ANDA "A" will have been submitted subsequent to ANDA "B" for purposes of potential 180-day exclusivity.

B. Formulation Patents

It has been suggested that section 505(j)(4)(B)(iv) should be applied differently to formulation or composition patents than to active ingredient (substance) patents. Some have argued that, for formulation patents, the exclusivity granted under section 505(j)(4)(B)(iv) should delay the effective date only of subsequent
drug products that raise claims of noninfringement identical or similar to those raised by the applicant entitled to the exclusivity. The basis for this argument is that the 180-day exclusivity is intended as a reward to the first applicant who resolves an issue of the validity or scope of a patent common to subsequent applicants. FDA, does not, however, possess the expertise in patent law to determine whether two formulations raise common patent infringement issues. Moreover, section 505(j)(4)(B)(iv) may be interpreted as providing a reward to the applicant who benefits the public by challenging a patent and allowing competition, even if subsequent generic applicants are not directly benefitted. Because the statutory language permits several interpretations, FDA has concluded that an applicant who obtains exclusivity by challenging a formulation patent delays all subsequent applications that refer to the same listed drug (and contain a paragraph IV certification), even if the products that are the subjects of the subsequent applications have different formulations from the product entitled to exclusivity.

C. Effect of Removal of a Patent from the Orange Book

If a patent is removed from the Orange Book for reasons other than a court decision finding that the patent is invalid after one or more applicants have made paragraph IV certifications, any applicant with a pending application or delayed effective date should submit a new patent certification under section 505(j)(2)(A)(vi)(I) (a "paragraph I certification"). Once a new certification has been submitted, the application will no longer be considered to be an application containing a paragraph IV certification.

IV Request for Comments

When Should the 180-Day Exclusivity Period Begin to Run?

As stated above (at page four) the agency's current policy is that the 180-day exclusivity period begins to run from the date of the initial or district court decision. It has been suggested, however, that a prudent ANDA applicant who is successful in its litigation in the lower court may desire to remain off the market until either the time for appeal of the lower court decision has passed or if an appeal has been taken until the appeal has been decided. Those suggesting this change have said that even with a lower court decision in its favor an ANDA holder may still be liable for treble damages if it loses on appeal. Therefore, they argue that fairness requires that the 180-day exclusivity period should be stayed if the ANDA holder chooses to remain off the market during this time so that the holder is not forced to choose between losing some of its exclusivity or risking potential treble damages.
The agency is interested specifically in comments about whether its current interpretation (that the 180-day exclusivity period begins to run when the initial court decision has been made) should be modified as has been suggested above. Any comment in favor of such changes should include the rationale and policy reasons to support those changes. And, as with all previous letters, I encourage your comments on any of the other policies and interpretations contained in this letter. Comments concerning this letter may be sent to the attention of Mr. Edwin V. Dutra, Jr., Office of Drug Standards, Center for Drug Evaluation and Research (HFD-203), Room 13-H-22, Parklawn Building, Rockville, Maryland 20857.

Sincerely yours,

[Signature]

Carl C. Peck, M.D.
Director
Center for Drug Evaluation and Research
EXHIBIT B
DRUG PRICE AND PATENT TERM ACT
P.L. 98-417

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT
P.L. 98-417, see page 98 Stat. 1565

Senate Report (Judiciary Committee) No. 98-547, June 26, 1984 [To accompany S. 1538]

DATES OF CONSIDERATION AND PASSAGE
Senate June 29, August 10, September 12, 1984
House September 6, 1984

S. 1538 was passed in Sen of the House bill after amending its language to contain the text of the House bill. The House Report (Part I, this page, and Part II, page 2686) and a Related Report (page 2721) are set out.

HOUSE REPORT NO. 98-857, Part I
[Page 1]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3605) to amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

[Page 14]

PURPOSE AND SUMMARY

TITLE I

The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1982. Under current law, there is a generic drug approval procedure for pioneer drugs approved before 1982, but not for pioneer drugs approved after 1982.

Title I of the bill generally extends the procedures used to approve generic copies of pre-82 drugs to post-82 drugs. Generic copies

2647
The purpose of this act is to require the maintenance of a comprehensive, coordinated statewide plan for the prevention, administration, and treatment of mental illness and mental retardation in the state.

Mental illness includes: (a) Alzheimer's disease; (b) autism spectrum disorder; (c) bi-polar disease; (d) chronic mental illness; (e) dementia; (f) depression; (g) Down's Syndrome; (h) drug addiction; (i) eating disorders; (j) Down Syndrome; (k) mental retardation; (l) mental illness; and (m) schizophrenia.

The act provides for the creation of a Mental Health Council, which shall consist of not more than three members, each of whom shall be appointed by the Governor with the advice and consent of the Senate. The Council shall be appointed for a term of three years, and may be reappointed for an additional term of three years. The Council shall have the power to make rules and regulations for the administration of this act.

In order to carry out the provisions of this act, the Council shall, among other things, (a) establish a comprehensive mental health program; (b) develop a plan for the prevention, administration, and treatment of mental illness and mental retardation; (c) provide for the coordination of mental health services; (d) provide for the training of mental health professionals; and (e) provide for the establishment of mental health facilities.

The act also provides for the creation of a Mental Health Advisory Committee, which shall consist of not more than five members, each of whom shall be appointed by the Governor with the advice and consent of the Senate. The Committee shall be appointed for a term of three years, and may be reappointed for an additional term of three years. The Committee shall have the power to make rules and regulations for the administration of this act.

In order to carry out the provisions of this act, the Committee shall, among other things, (a) review and evaluate the programs established by the Council; (b) provide for the coordination of mental health services; (c) provide for the training of mental health professionals; and (d) provide for the establishment of mental health facilities.

The act also provides for the creation of a Mental Health Task Force, which shall consist of not more than five members, each of whom shall be appointed by the Governor with the advice and consent of the Senate. The Task Force shall be appointed for a term of three years, and may be reappointed for an additional term of three years. The Task Force shall have the power to make rules and regulations for the administration of this act.

In order to carry out the provisions of this act, the Task Force shall, among other things, (a) review and evaluate the programs established by the Council; (b) provide for the coordination of mental health services; (c) provide for the training of mental health professionals; and (d) provide for the establishment of mental health facilities.
EXHIBIT C
PLEDGE OF ALLEGIANCE

The PRESIDENT pro tempore led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Repub-
lic for which it stands, one nation under God, indivisible, with liberty and justice for all.

The PRESIDENT pro tempore. Does the Senator from Iowa seek recognition?

Mr. GRASSLEY. Mr. President, I was told we should report the bill first, and then I
will make my statement.

RESERVATION OF LEADER TIME

The PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003—CONFERENCE REPORT

The PRESIDENT pro tempore. Under the previous order, the Senate will re-
sume consideration of the conference report to accompany H.R. 1, which
the clerk will report.

The assistant legislative clerk read as follows:

Conference report to accompany H.R. 1, an
act to amend Title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the Medicare Pro-
gram and to strengthen and improve the Medicare Program, and for other purposes.

The PRESIDENT pro tempore. Under the previous order, the time until 12:30
shall be equally divided between the chairman of the Finance Committee or
his designee and the Democratic leader or his designee, with the last 10
minutes prior to the vote to be allocated between the Democratic leader for
5 minutes to be followed by the majority leader for the final 5 minutes.

The Senator from Iowa.

SCHEDULE

Mr. GRASSLEY. Mr. President, I would like to state the plan for today.
Under the previous order, the cloture vote will occur today at 12:30. The
debate until that vote is limited, and Members will only be allocated
short debate times. The cloture vote on the conference report will be the first
vote of the day. It is the leader's hope and expectation that cloture will be
successful. Once cloture is invoked, the leader hopes we will be able to proceed
to a vote on the passage of the Medi-
care prescription drug bill in very
short order after that.

On our side, we are obviously going to start with the Senator from New Hampshire. But since the time is very
tight, probably most Members would be
limited to 5 minutes or less, beyond
that of Senator Gregg. I would like to
make sure people are very orderly as
they come over here and ask me for
the time. I cannot speak for the Demo-
cratic side, but for the Republican side,
it is very essential for people to be here
and be ready to speak.

Does the Democratic whip wish to be
recognized?

Mr. REID. Yes, if my distinguished
friend will yield.

The PRESIDENT pro tempore. The Senator from Nevada.

Mr. REID. Mr. President, we have, on
this side, a number of people who wish
to speak. It is my understanding, to
make this debate fair, that on this side
the time will be given to those who are
opposed to cloture being invoked. So
the people who speak on this side will
be opposed to cloture. I want all
the people who have asked for time on
this side to understand that. And we are—
this is just for Democrats—we are
going to give 9 minutes to the fol-
lowing: AKAKA, LAUTENBERG, KERRY,
LIEBERMAN, DODD, CLINTON, MIKLUSKI,
PRIOR, KENNEDY, with KENNEDY to
have the last time because the Demo-
cratic leader speaks, closing the de-
bate.

Now, again, I want to tell those lis-
tening, this side is for those who op-
pose cloture.

Mr. GRASSLEY. Mr. President, could I make an inquiry?

Mr. REID. Yes. And I think it would be better if we alternated back and forth until
Mr. GRASSLEY. That is the point I
wanted to make.

Mr. FRIST. Mr. President, today we stand on the threshold of a truly histor-
ic moment. Not for Republicans. Not for Democrats. Or for the House of Represen-
tatives. Or the United States Senate. But, for over 40 million Amer-
ican seniors and individuals with dis-
abilities, who may finally be getting
prescription drug coverage under Medi-
care.

Saturday morning, the House of Rep-
resentatives passed H.R. 1, the "Medi-
care Prescription, Improvement,
and Modernization Act of 2003."

Also Saturday, President Bush called upon the Senate, once again, to finish the job. He urged us to send him legis-
ative text that will provide badly needed
prescription drugs to seniors.

For years, Congress has debated
whether, and how, to provide prescrip-
tion drug coverage to seniors and to
strengthen and improve the Medicare
program. Now, it is time for us to Act.

Mr. President, this generation of sen-
iors survived the depression, fought
World War II, and helped make the
United States into a prosperous and
thriving Nation. Time and again, they
stepped forward to serve. Now, is the
time to fulfill our duty to that great
generation. Now is the time to answer
their call.

What President Lyndon Johnson said in
1965 still stands:

... No longer will this Nation refuse the
hand of justice to those who have given
a lifetime of service and wisdom and labor to
the progress of this ... country.

Let us not stay that hand of justice
ow. Let us not turn our back on America’s seniors and individuals with
disabilities.

There are nearly one quarter of a
million seniors in my State of Ten-
nessee who have no prescription
drug coverage. There are millions more
across the Nation for whom this legis-
lation, literally, means the difference
between life and death. They cannot af-
ford to wait any longer. I have treated
tens of thousands of patients by hand,
and I know firsthand that, without Medicare,
millions of seniors would not have re-
cieved needed medical services. Mil-
ions more would have faced financial
ruin. Medicare has helped save and heal
lives.

This cherished program has failed to
keep pace with medical and scientific
progress. Prescription drugs are an
integral part of modern medicine.
They are as important as the surgeon’s
knife. Yet, they are not part of the
Medicare program.

In the nearly four decades since the
Medicare program was created, the
American medical system has trans-
formed from one focused on treating
episodic illness in hospitals to one
characterized by an increasing empha-
sis on managing and preventing chron-
ic disease in outpatient settings with
advanced medical technologies and pres-
cription drugs. Life expectancy has in-
creased by nearly ten years. Death
rates associated with heart disease have
been cut in half, and new treatments
and diagnostic tools have improved
survival rates for prostate, colon, and breast cancer. Our medical
and scientific knowledge and, along
with it, our ability to treat illness and
disease has improved dramatically over
the past four decades. Yet, Medicare
itself has not kept pace with these dra-
matic changes. It has been too inflexi-
ble and bureaucratic. Designed for the
1960s health care system, it has been
unable to adapt to changing medical
practice. Medicare does not provide
true preventive coverage, disease man-
agement, or protection against cata-

drophic health care costs.

As a result, we have today glaring
and unacceptable gaps in the coverage
that is available to seniors and individu-
als with disabilities—the most obvi-
ous of which is the lack of prescription
drug coverage.

Over the past three decades, for ex-
ample, the death rate from athero-
sclerosis has declined by over 70 per-
cent and deaths from ischemic heart
disease have declined more than 6 per-
cent, largely due to the advent of beta
blockers and ACE inhibitors. During
the same period, death rates from em-
physema have dropped nearly 60 per-
cent due to new treatments involving
anti-inflammatory medications and
bronchodilators.
Mr. ENZI. I thank the distinguished chairman for this clarification.

Mr. INOUYE. Mr. President, I have voted today to oppose the termination of debate on the Medicare Conference Report because I have carefully analyzed, and come to the conclusion that far from being a bipartisan compromise on prescription drug benefits, the report is nothing short of an attempt to compromise the integrity of the Medicare and Medicaid system as we know it.

When it comes to health care in America, there are many parties in interest—providers, patients, care facilities, and pharmaceutical suppliers, to name a few. These groups have interests that may, at times, be in conflict, but I believe one overwhelming interest unites them all: providing the American public with the health care services and treatment that it needs. Regrettably, I find that the report we have been asked to consider has abandoned this powerful unifying principle. Abandoning our commitment to the health of our Nation, when viewed as a whole, the report strikes at the foundation of the Medicare and Medicaid system. Rather than buttressing the system of comprehensive health care for our senior citizens and disabled persons, the report actually sows the seeds of its demise by undermining its ability to provide a prescription drug benefit, subsidizing competing private health plans, and increasing Medicaid premiums without increasing the benefits provided.

The overwhelming drive to reconsider the Medicare and Medicaid systems came from listening to our constituents and their frustration with the ever-increasing cost of the medications they need. From blood thinners, to antibiotics, to state-of-the-art pharmaceuticals for cancer and HIV/AIDS, the cry for help was clear: the cost of prescription drugs was breaking the backs of the Americans who were paying for these expensive, but life-saving therapies.

Far from addressing these needs, however, the report actually makes the problem worse. On the administrative level, the report dilutes the Medicare systems’ purchasing power by mandating the purchase of necessary medications by individual Medicare regions, rather than as a whole system. With more independent buying of pharmaceuticals, companies are more able than ever to raise their prices, because the individual regions will have less bargaining power.

The report will also impact average beneficiaries by potentially depriving them of the specific drugs they need by providing coverage for only one or two of each class of drug. In a world where antibiotic-resistant strains of common ailments are on the rise, this could be a very expensive proposition, if the drug you need is not one of the covered drugs in the antibiotic class. Difficulties only escalate in medically complex cases where patients’ individual responses to pharmaceuticals may vary dramatically, as in treatments for high blood pressure, high cholesterol, cancer, and HIV/AIDS.

Even worse, what flexibility there is in the report to tailor the limited drug benefit to individual patients must now be requested and petitioned for by the patients themselves. Placing the paperwork burden on seniors and the disabled only shifts the burden to the people least able to bear it, and I would not be surprised to learn that as a result, more and more beneficiaries will lose access to the medicines they need.

Finally, the report strikes a further blow to more than 6 million of our neediest citizens, those who are eligible for both Medicare and Medicaid. At present, States have the statutory flexibility to make any copayments for persons who are “dual eligible.” Under the report, however, persons with dual coverage will face increased out-of-pocket expenses because States will lose this flexibility. As a result, Americans who are already below the poverty level would be expected to make copayments between $1 and $3—a great hardship for single persons with incomes of less than $10,000 per year, and couples with incomes of less than $12,120 per year.

More than failing to provide the promised prescription drug benefit, however, the report moves the system one step further down the path for eventually dismantling Medicare and Medicaid altogether. The report establishes a demonstration project for “premium support” in six metropolitan areas. “Premium support” does not mean, as one might think, additional Federal support for areas where costs are especially high, and premiums are not sufficient to cover the cost of a composite. It is a way of increasing the Medicare premiums Americans pay in order to compensate for rising health care costs. Moreover, with a “demonstration project” in place, it would be a simple step to broaden the “project” to include the entire United States—and with an estimate average 25 percent increase in premiums, the costs to American citizens would be substantial.

The report would also provide a $12 billion subsidy to private Health Maintenance Organizations and Preferred Provider Organizations—HMOs and PPOs. With a massive subsidy such as this, there will be no question but that HMOs and PPOs will have a competitive edge over Medicare because they will receive more money per plan participant than Medicare will—and with more money, subsidized insurers will be able to provide more benefits. “Premium support” and a $12 billion subsidy for HMOs and PPOs look suspiciously like a one-two punch aimed at Medicare. On the one hand, “premium support” will increase the cost of Medicare without raising benefit levels, while on the other, a multi-billion dollar subsidy will allow HMOs and PPOs to slash premiums and provide more services. Add to this a prescription drug benefit that actually leaves millions of Americans worse off than they are now, and it is difficult to see how this conference report responds to the goal of maintaining the bipartisan principle of our health care system: providing Americans with the health care they need.

Mr. SCHUMER. Mr. President, our seniors deserve a comprehensive, meaningful drug benefit under Medicare. It’s something that I, like so many of my colleagues, have been fighting for years. The world of health care has changed, and Medicare should be updated to give seniors the services and care they need.

I voted for this bill when it first came to the Senate because I thought it was a good start, and I hoped we could build on it in conference. Unfortunately, now that I see the result, I have to say this is not good enough for New York’s seniors—in fact, the bad parts outweigh the good. It misses the mark on so many things—

It provides a good benefit for seniors who have low incomes or very high drug costs who have no other drug coverage. But for the average middle class senior, with moderate drug costs, the benefit is much too small.

In fact, the way this benefit is structured, hundreds of thousands of New Yorkers who currently have coverage may actually end up worse off than they are today—and that doesn’t sound like a benefit to me.

When I voted for the bill the first time around, I said that if it got any weaker, got any closer to the House version, I could not, in good conscience, support it. And, unfortunately, that seems to be what has happened here.

Farther than the generic drug provisions—which represent a huge win for consumers across the board—it seems in every other case where the choice was between seniors and the big drug companies, the big drug companies have won.

Of all the bad things in this bill, the thing that angers me the most is that Congress has squandered away the single best weapon we have against rising drug costs by forbidding Medicare from using its buying power to negotiate lower drug prices with the drug companies.

This is at a time of rising budget deficits and escalating costs, it really makes you wonder why the Congress would go out of its way to forbid the Federal Government from using its buying power to get prices like we do through the VA.

If the Federal Government leveraged its full buying power under Medicare, we might not have a doughnut hole in the first place. And this is just the tip of the iceberg.

The impact of this reckless prohibition is best seen by a Boston University study that shows that the drug companies will end up with windfall profits of $139 billion over the next eight years alone from this bill.
This bill not only ensures we will be paying the highest possible price for drugs in this country, but it also guts any chance at reimportation—guaranteeing the drug companies a captive American market.

Is that the Republicans’ idea of cost containment?

What this bill does is ensure that the government is gouged by the drug companies while putting a huge bull’s-eye on the Medicare program. The prohibition on negotiating and artificial “cost containment” mechanisms in this bill will simply help the opponents of Medicare justify shifting more and more costs onto the backs of seniors.

Under the drug benefit before the Senate today, the average middle class senior could still be saddled with up to 80 percent of their drug costs. And almost 30 percent of beneficiaries would actually pay more for this Medicare drug benefit than they would be getting back in drug coverage. What kind of relief is this?

So this bill represents a paltry benefit—or no benefit at all—for most people who currently have no drug coverage. I had hoped that the bill would—at a very least—help provide a down payment for the one-third of New Yorkers who currently have no coverage, but I don’t think it ever does that.

In fact, there is a very good chance this benefit will actually jeopardize access to affordable drugs for New Yorkers who currently have good coverage. 7.7 million Medicare beneficiaries in New York State, 980,000 have prescription drug coverage from their former employers; 339,000 are enrolled in the state’s pharmaceutical program—known as EPIC, and about 337,000 are covered under New York’s Medicaid program.

First, let’s look at the EPIC program. Right now, EPIC is available to individuals with incomes less than $40,000 for families with incomes less than $50,000. People in EPIC currently have access to nearly any drug their doctors prescribe, and can go to virtually any pharmacy in the state to get their prescriptions filled.

I fought to get strong language in the Senate version of the Medicare bill that would have provided these New Yorkers with a benefit better than the one they get through EPIC.

The Senate bill would have provided New York State a subsidy equal to about $375 million per year to help it continue the EPIC and even expand it to provide a more generous benefit, to cover the disabled, which the State currently does not do, and to enroll even more people.

The watered down compromise in the conference report leaves far too many questions unanswered.

Under the bill, if the State wants to use any of the new Federal Investment in Medicare, it has to force EPIC seniors to go and enroll in a Medicare private plan and the State legislature will have to go back to the drawing board and restructure the entire EPIC program to coordinate with the Medicare plans.

The end result will be a program so laden with tape that it is a virtual certainty that seniors fall through the cracks and lose coverage. It will be an administrative nightmare for the State to implement.

I have yet to hear one compelling argument for how the bill before the Senate will enhance the EPIC program. The State can’t even tell me what will happen to EPIC and the 328,000 seniors who depend on it if this Medicare bill passes.

Even more shocking is that the bill gives the private Medicare plans a say in how generous an additional state coverage can be. The way I read it, under the new scheme, the Medicare plans will be able to limit which drugs an enrollee has access to and limit what pharmacies an enrollee can go to—no restrictions currently exist for EPIC enrollees. In short, when it comes to EPIC, many seniors may be worse off with the bill than without it.

One of my concerns I have about this bill is that it simply doesn’t do enough to protect retirees who have good employer-sponsored coverage.

The changes made some progress toward reducing the employer drop rate by giving employers a tax break worth an additional $18 billion. However, to truly protect retirees from losing coverage would cost about $65 billion.

Even with the change made in conference, an estimated 215,000 New Yorkers will likely lose their retiree coverage if this bill becomes law, and many others may see their options narrowed. That’s simply too big a risk for me.

In addition, starting in 2005, all Medicare beneficiaries would be saddled with higher deductibles for doctor visits. Under the bill, Medicare premiums would no longer be universal, but higher for all beneficiaries with incomes of $80,000 and up—a provision which disproportionately affects states like New York.

In addition, over 500,000 Medicare beneficiaries in New York—living in Rochester, Buffalo, Glens Falls and the Capital Region—may be selected for the premium support demonstration program which would provide seniors with a false choice: either entering a private plan or being forced to pay more for traditional Medicare.

As I have said, the bill does provide a good benefit for low-income seniors and enrollees who have very high drug costs who don’t have access to any other drug coverage. However, the new asset test in the conference version of the bill means that about 150,000 fewer people will qualify for these low income subsidies than under the Senate bill.

Even the seniors who do get this additional assistance will face confusing and difficult choices. It is also a measure about which Medicare plan to choose.

They will face a confounding maze trying to figure out which plan will cover the drugs they use and allow them to continue to go to the drug store down the street. If they are even lucky enough to find such a plan, it could be gone the next year, or change its premiums or its list of covered drugs, and seniors would be back to square one.

Of course, despite all of these negatives, there are some very important provisions in this bill which make my decision a very difficult one.

The bill includes significant relief for rural, small community and small city hospitals—about $444 million over 10 years for New York’s hospitals, which is crucial to ensuring access to high quality care not only in the very rural areas of the state, but also in and around upstate cities like Syracuse, Rochester, and Buffalo.

There is also modest relief for the nation’s teaching hospitals in the bill—but it is not nearly enough. New York institutions would see an additional $76 million over the next four years, but this only restores about 11 percent of the total cuts they face over that time period.

The Nation’s teaching hospitals are the backbone of our health care system—they do the research and they train the doctors—and I am worried we won’t get another opportunity to provide them the resources they need to do their job.

The bill also addresses the crisis in physician payments which has lingering over most of the Medicare program and leaving seniors in the lurch. These provider issues must be addressed—we’ve fought back the draconian cuts in the Balanced Budget Act for five years now. Our providers are struggling, and it’s time to set things straight.

I am pleased that the bill includes provisions based on a bill I introduced with Senator SANTORUM to stabilize the Medicare-Choice program in the short term.

The changes will ensure that plans in places like Long Island and Westchester get paid on par with plans in other areas of the country and will help significantly bring down premiums in these areas over the next few years.

Perhaps the biggest win in the bill— not only for seniors, but for all consumers, employers, and purchasers of prescription drugs—is the extraordinary victory we have achieved in the face of the unprecedented influence of the big pharmaceutical companies: generic drugs.

The forward-looking drug provisions which Senators Gregg, Kennedy, McCain and I have been fighting for over the past few years—and which passed the Senate by a vote of 94-1—represent a huge step forward for all seniors, consumers, and purchasers of prescription drugs.

The provisions close loopholes in the law and end the abusive practices in the fiercely protective industry which have kept lower-priced generics off the market and cost consumers billions of dollars.
The Gregg-Schumer amendments to the Hatch-Waxman Act, would put an end to the practice of brand companies listing frivolous patents for the sole purpose of automatically delaying generic. They would also ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.

First, the Gregg-Schumer provisions would limit brand drug companies to a single 30-month stay of generic approval, and only on patents listed at the FDA before a generic application is filed. This way, the 30-month stay—if there is one at all—will run concurrent with FDA approval of the generic application and minimize delay.

Second, to ensure that patent issues are resolved in a timely way, the provisions clarify that a generic applicant has a right to seek a declaratory judgment that its product does not infringe a patent or that a patent is invalid, and have courts that they must hear these declaratory judgment cases to the maximum extent permitted by the Constitution.

The removal of the automatic 30-month stay, if the generic company did not have a clear right to seek resolution of potential patent disputes on its own, the brand company could simply put a new patent and sit back and wait—leaving the generic at risk of being sued and having to pay triple the brand's lost profits if it does decide to enter the market. This clarification of the courts' jurisdiction will have an immediate effect on both pending and future declaratory judgment actions brought by generic applicants.

Third, the provisions enforce the patent listing requirements at the FDA by allowing a generic applicant when it has been sued for patent infringement, to file a counterclaim to have the brand drug company dislist the patent or share the pertinent information in FDA's Orange Book.

Fourth, the generic provisions revamped the 180-day exclusivity incentive provided in the Hatch-Waxman Act. Under the act, the first generic drug company to challenge a patent on a brand drug has the exclusive right to market its drug for 6 months before any other generic can compete. This feature encourages generic applicants to challenge the patents and bring consumers much quicker access to affordable generic drugs.

However, at times, brand and generic companies have abused this exclusivity period—both through collusive agreements and use of other tactics that allow the provision to act as a bottleneck to generic competition. The Gregg-Schumer provisions end this abuse because the generic company forfeits its exclusivity if it doesn't go to market in a timely manner.

The way the provision works, if an applicant has resolved patent disputes on the patents which earned the first to file its exclusivity—either through a court decision, settlement, or withdrawal of the patent by the brand company—then the first generic applicant to gain approval and go to market within 75 days of the patent, or it forfeits its right to the exclusivity.

If it forfeits, then the exclusivity is lost and any other generic applicant that is ready to be approved and go to market can go. Either way, the provision ensures that consumers have access to a low-cost generic as soon as possible.

I am very pleased that the conference preserved these important, pro-consumer cost containment provisions. Indeed, they are the only part of this bill where consumers, seniors, and taxpayers prevail over the big drug companies.

In closing, I had truly hoped this Congress would craft and pass a meaningful Medicare drug benefit for seniors—only a protected group of beneficiaries who have access to good coverage through other programs and which would have provided real relief to seniors with no other choice. While it contains some good provisions, the package before us does neither. I think we can do better, and we owe it to the 40 million seniors in this nation who have waited decades for drug coverage under Medicare to do better than this.

Mr. ROCKEFELLER. Mr. President, on July 30, 1985, President Lyndon B. Johnson stood with President Harry Truman and, together, they delivered the Medicare program. They proudly addressed the American people as President Johnson proclaimed, "No longer will older Americans be denied the healing miracle of modern medicine. No longer will illness crush and destroy the savings that they have so carefully put away over a lifetime so that they might enjoy dignity in their latter years. Old Americans are not entitled to be moved me and yet, if I am to be honest, they also haunt me as we consider the Medicare reform legislation before us. I know that this legislation charts a course that will begin to undo the good works of our former Presidents and of a program that is perhaps the single most effective public initiative in our nation's history. Medicare has literally saved the lives of our seniors, keeping them from overworking and Congressing the peace of mind that comes with security. For this reason, I have a heavy heart and a sense of near dread about this bill. My heart is heavy because I know that this bill to reform and "Improve" Medicare is deeply, fundamentally flawed. This is not what Presidents Johnson and Truman wanted for the millions of our parents and grandparents. This plan is too weak, too flawed, and it is not what I want, either.

For many years, we have talked about the need for a prescription drug benefit for Medicare. For a brief moment, I believed we in the Senate were serious about delivering a meaningful benefit. However, I cannot support the Republican Medicare prescription drug bill because it forces seniors to choose between paying more for their own doctor or signing up with an HMO; leaves them to pay themselves out of pocket costs; eliminates employer drug coverage for 2.7 million retirees; prevents efforts to keep drug costs down; and effectively prohibits seniors from importing cheaper drugs from Canada.

I recognize that this bill commits $400 billion to a Medicare prescription drug benefit and truly helps some low income seniors who are without coverage today, and I am glad that it gives a critical boost to rural hospitals and doctors. But the fine print matters and will have very dangerous consequences for how many seniors have to pay for their Medicare benefit, whether this drug benefit really serves seniors, and whether we are strengthening or weakening Medicare for the future. I have always said that a Medicare prescription drug benefit must be affordable and accessible to all Medicare beneficiaries; must truly help with the high cost of prescription drugs; and must strengthen the Medicare program for the future. This bill falls on all counts.

West Virginians and many of my colleagues know I have been working on Medicare for 20 years. I sat on the House Committee on Education and Labor during which we debated the best way to improve Medicare. Before that, I chaired the U.S. Bipartisan Commission on Comprehensive Health Care, which discussed ways to address the problems of the uninsured and the need for long-term care reform in this country. Today, I am the ranking member of the health subcommittee of the Senate Finance Committee. I was a member of the conference committee on this bill—but in name only, not in practice. Nevertheless, my goal has always been, and continues to be, improving Medicare so that the quality of health care is available to all Americans. This bill does not improve this program. This bill harms this program—actually harms Medicare.

This bill is a tool to force seniors to leave the traditional Medicare program they know and trust in order to obtain the drug benefit they need and deserve. Many people have said that this plan is voluntary and that seniors choose to stay in traditional Medicare and get a drug benefit, he or she can do so. This legislation does not guarantee that in any way. Under this legislation, seniors will have two different options for receiving a drug benefit. The first option is to stay in traditional Medicare for their doctor and hospital services and enroll in a "drug-only plan" to receive their drugs. The second option is to enter voluntary, or "voluntary," and enroll in a HMO or PPO for all of their health care services. You may ask: what is a drug-only plan and how does it work? The answer is simple. There is no idea because no such entity exists today. It is a completely new concept.
EXHIBIT D
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CONGRESSIONAL RECORD—SENATE  
November 25, 2003  

Barbara Burke, who operates the switchboard at the senior center, disparagingly called the new benefit "a Band-Aid.

It's not enough with the high cost of medications," said Burke, who said she's still working at 66 because she won't be able to afford her prescriptions if she retires. The center doles out health benefits for seniors, she said, and she has chronic lung disease that costs her more than $200 a month for inhalers alone.

"People who can't afford to buy medications should get it at a minimum charge," she said. . .

An Kim Hoang, 87, said she can't afford a copayment of $1 for a brand-name drug, which will be required under the new plan. Those with incomes from $8,900 to $12,123 will face copayments up to $5 per prescription. Seniors currently getting drug coverage through the MassHealth, the state-federal Medicaid program for the poor, would be shifted to the federal program.

In fact, that is going to be eliminated in terms of coverage. That is part of the 6 million low-income seniors who will pay more.

Hoang, speaking through a translator, said she borrows from friends to cover the $2 co-payment required by Medicaid for each of the eight prescriptions she takes to treat her mental illness. "$1 is OK," she said, "but $2 is too much."

This is the real world, Mr. President. This is putting a face and name on the 6 million low-income seniors who will pay more.

"$1 is OK," she said, "but $2 is too much."

That was put in here to save some $12 billion to $15 billion put into a slush fund to provide additional benefits to the HMOs. Because of the Medicaid copayment, her friend Quy Nguyen, 71, said she limits herself to four prescriptions she needs most and tries to get by without several others. She said she envisions that choice becoming more difficult under [this program].

Josephine DeSantis said the new benefit would have helped her immensely, since she struggles to scrape together the $197 she spends every three months for drugs to prevent ulcers and dizziness. But at 78, she said, she's unsure how the benefit won't start until 2006.

"In two years," she said, "I'll probably be dead."

There you have it, Mr. President, reaction in a working class community in Dorchester. We have the reaction in real life about what the low-income seniors pay.

When we talk and bring out these charts, as we have in the past few days, this is the very instance about which we were talking. It did not have to be this way. This is just an illusion of the overall challenges of this legislation and a reason that it should not pass the Senate.

How much time do I have, Mr. President?

The PRESIDENT pro tempore. The Senator has 15 minutes remaining.

Mr. KENNEDY. Mr. President, I yield 7 minutes to the Senator from Florida.

The PRESIDENT pro tempore. The Senator from Florida is recognized.

SCHEDULE

Mr. FRIST. Mr. President, this morning there will be 1 hour of debate prior to the vote on adoption of the conference report to accompany H.R. 1, the Medicare Prescription Drug Modernization Act. That vote will occur at 9:15 this morning. I will have more to say about the bill on this important occasion just prior to the vote. I thank all Members for their cooperation and participation throughout this debate. I also want to note that we are continuing our efforts to act on the remaining appropriations bill. This morning, I will continue my discussions with the Democratic leadership as to the possible consideration of that bill. I will have more to say about this and the final schedule after the vote on final passage.

Having said that, we are prepared for the final closing remarks on this landmark legislation.

RESERVATION OF LEADER TIME

The PRESIDENT pro tempore. Under the previous order, leadership time is reserved.

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MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003—CONFERENCE REPORT

The PRESIDENT pro tempore. Under the previous order, the Senate will resume consideration of the conference report to accompany H.R. 1, which the clerk will now read.

The legislative clerk read as follows:

Conference report to accompany H.R. 1, an act to amend title XVIII of the Social Security Act to provide a voluntary prescription drug benefit under the Medicare program and to strengthen and improve the Medicare program, and for other purposes.

The PRESIDENT pro tempore. The Senator from Nevada is recognized.

Mr. REID. Mr. President, the majority leader has asked me to designate the opposition manager for the half hour that we have. In a short time, I will delegate that time to the senior Senator from Massachusetts.

As we begin this half hour on our side and half hour on the other side, I extend my appreciation and that of the whole Democratic caucus to Senator KENNEDY for leading the opposition, literally, to this measure. He has had a lot of help. I have sat through days of speeches on this matter and I have been impressed with the quality of the speeches, really, on both sides. Especially on our side, I have been impressed with Senator KENNEDY, and I will mention a number of names who I thought did such a wonderful job: Senators Bayh, Boxer, Cantwell, Clinton, Dayton, Dodd, Harkin, Pryor, Nelson of Florida, and Graham of Florida. What a loss it is going to be to this institution and our country that this fine man is going to no longer be part of the Senate after 1 year.

I believe there is no one who has a better grasp of this legislation than the Senator from Florida. He has done such an outstanding job of articulating his views.

Of course, I add a congratulatory note to Senator STABENOW who has worked on this measure long and hard.

Senator DURBIN has always done such a good job of expressing his views. He was never any better than on this issue.

Mr. President, I reserve the last 5 minutes for Senator DASCHLE. I delegate the rest of our time to the senior Senator from Massachusetts.

The PRESIDENT pro tempore. Under the previous order, the last 5 minutes is reserved.

Mr. KENNEDY. Mr. President, on the question of time, we have the last 5 minutes. That will probably be leader time. The leader, obviously, ought to have what time there is.

Mr. REID. Mr. President, we have 23 minutes on our side; 23 minutes on the other side.

The PRESIDENT pro tempore. The Chair addresses the Senator from Massachusetts that the final 5 minutes of the first half of the time is for the minority leader, and the final 5 minutes of the debate time is for the majority leader.

Mr. KENNEDY. I thank the Chair. Mr. President. I bring to the attention of the Members a picturesque description of what the reaction is to this proposed legislation. It is written in a very explicit article this morning in the Boston Globe. I want to share the article with the Members.

The title is "In Dorchester, Seniors Weigh Changes Against Their Needs."

It reads:

Thomas Lombardi dropped his private health insurance a few years ago when the price rose steeply. Then he switched from Coumadin, a blood-thinning anticoagulant he took for heart disease, to half an aspirin to save about $15 a month. Living on Social Security and retirement savings, Lombardi, 75, says he frequently has to "cut corners to stay alive."

But over lunch at the Kit Clark Senior Center in Dorchester, he said he doesn't support the $400 billion Medicare drug benefit that is about to become law and provide coverage to millions of seniors like him. Echoing the comments of many others at the center yesterday, he said it's far too complex and probably won't go far enough to help him because of the coverage designed to keep down the cost of the new benefit.

Besides, many said, it will be two years before the full benefits kick in.

"I don't believe it's good for me," said Lombardi, who owned a welding business in Dorchester.

"This is part of the Bush strategy to destroy programs put in place years ago," said Richard Schultz, who qualifies for Medicare at age 95 and is disabled. "I understand that it would benefit some low-income people in the short term, but combined with huge tax cuts, this is going to drive the deficit up. Then they're going to decide they don't have the money, and, in the long run, the program will be dissolved." . . .

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are going to not only end up in a place they do not want to go, because people would rather not go to hospitals, rather not go to operating rooms. It is going to save our programs a lot of money, both private and public payment programs, for doctors and hospitals, when we can have people go into programs where they can get prescription drugs and keep their health up so they don't have to go into the hospital.

So we are bringing Medicare and the practice of medicine into the 21st century. In strengthening and improving Medicare, we are doing today exactly what we would be doing if we were writing a Medicare Program in the year 2003 as opposed to the year 1965.

I hope the opponents. In a few years, can look back and say we have the right thing for seniors, for their economic life, for the quality of their life; we have done the right thing for our hospitals and our doctors; we have done the right thing for America.

I would like to spend just a little bit of time counteracting the arguments that have been made about this bill. People who say we are not doing enough for low-income people. In fact, this bill is coming back from conference doing better for low-income people than it did when it went into conference.

One of those major changes that were made, not only at the behest of the House of Representatives but also at the behest of a lot of people in this body, particularly prominent in the Democratic Party than in the Republican Party, was to make sure the category of people we call dual eligibles—those low-income seniors who are already on Medicaid—those to be put all of those in the Medicare Program so we didn't have an inequality. Maybe it was not a very big inequality but at least there was some inequality from one state to another state because of the Federal-State partnership in Medicaid that enables the State legislatures in some States to have set up a little different, a little more rich, a little less rich—what might be done in another State.

So dual eligibles are in this bill because of the demands of mostly Democrat Senators and people in the House of Representatives. That is something I didn't believe should be done, but I supported it because that was a necessary compromise. But now I find people who were advocating that position complaining about the legislation. So I want to tell them how wrong they are or how, if they are right, a little bit better. It is in such an important way that it is immaterial because that ought to be seen as something that results from something they wanted us to do in this legislation.

This conference report then contains a generous drug benefit for these dual eligible seniors. There is, first of all, no donut hole for low-income Medicare beneficiaries. Let's get this clear. Let me make it clear. People on that side of the aisle are complaining about a donut hole. But for low-income people there is no donut hole. The bill guarantees all 8 million dual eligibles access to prescription drugs.

Under our conference report, dual eligibles will have better access through Medicare, especially since State Medicaid programs are being required to start making drugs more affordable to beneficiaries. And that is what brings about greater inequity from State to State. Since States are in a budget crunch, forced to deny dual eligibles might then be treated less generously in one state as opposed to another but when they are all under the Federal Medicare Program that will not be the case.

Further, States have the flexibility to provide coverage for classes of drugs, including over-the-counter drugs, that are not now covered by the Medicare Program. This bill ensures appeal rights for dual eligibles. Under the agreement, dual eligibles will maintain appeal rights for those in the Medicare program. Dual eligibles are a fragile population and I think, because of the conference report as opposed to either bill in its original form, is a lot better in this bill. The conference report recognizes and provides generous coverage to these 8 million people.

I hope we can take the sum of the AARP when they said this bill is "a historic breakthrough and [an] important milestone in the Nation's commitment to strengthen and expand health security for its citizens." I hope that will be conceived of or considered as a toning down of the partisan opposition to this legislation.

I reserve the remainder of my time just in case some colleagues come over. I have more to say, but I will say it later if other colleagues don't show up, so I yield the floor.

Mr. KENNEDY. Mr. President, I oppose the Medicare bill before the Senate, but I want to express my understanding of the refinements of the Hatch-Waxman Act found in Title XI of the Medicare bill now before the Senate. I was deeply involved in the negotiations of these provisions in the conference. The Hatch-Waxman Act, which was passed in 1984, reflects efforts by the Congress to promote two policy objectives: to encourage brand-name pharmaceutical firms to make the investments necessary to research and develop new therapies, and to enable competitors to bring to market, generic copies of those drugs to market as quickly as possible.

The Hatch-Waxman Act has worked very well for almost 20 years. It has provided the incentives necessary to bring the many medicines to market that have so transformed the shape of modern medical practice. And it has brought generic drugs to market faster than ever, saving consumers billions of dollars.

As the Federal Trade Commission has shown, however, in recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the Hatch-Waxman Act found in Title XI represent refinements to the present system that will stop these abuses, will restore the original balance the law intended, and will ensure Americans more timely access to affordable pharmaceuticals.

Most significantly, the Hatch-Waxman provisions in this bill limit brand-name drug companies to only one 30-month stay of enforcement of generic drugs. This change will stop the multiple, successive 30-month stays that the Federal Trade Commission identified as having delayed approval of generics between brand name and generic companies. The Hatch-Waxman exclusivity provisions work.

The 180-day exclusivity gives a generic company 180 days during which it is the only generic competitor to the brand drug. The exclusivity is a very valuable incentive to generic companies. The exclusivity encourages generic companies to challenge patents that are likely invalid or not infringed and, because it goes to the first generic applicant to challenge a brand-name drug, it encourages those companies to challenge patents as soon as possible. These incentives mean that consumers will be able to enjoy the lower prices provided by generic companies sooner rather than later.

The Federal Trade Commission reports that the exclusivity has at times been propped through collusive agreements between the brand name and generic companies. Parking the exclusivity has blocked other generic companies from getting to market and has cost consumers billions of dollars. The Hatch-Waxman exclusivity provisions are intended to prevent parking of the exclusivity. It does this by providing for several situations in which a generic company with the exclusivity forfeits the exclusivity, clearing the way for other generic companies to bring their products to market.

The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than the patent-by-patient exclusivity, and the exclusivity is available to more than one generic applicant, if they all challenge patents on the same day.

Mr. SCHUMER. Mr. President, will the Senator yield for a question?

Mr. KENNEDY. Yes, I will yield to my friend from New York.

Mr. SCHUMER. Thank you, Mr. President. Let my just say, before I ask my question, that I want to thank the Senator from Massachusetts, and the senior Senator from New Hampshire, for their leadership on this issue. The