Hispanic Caucus. Under his chairmanship, educational opportunities for Hispanic Americans have grown considerably: Hispanic Serving Institutions have received record-level funding, bilingual education programs once threatened have been strengthened, nearly $500 million has been allocated for the President's Latino Education Plan, and equal access to technology for students in rural and urban centers has been enhanced through the e-rate program.

Chairman BECERRA has demonstrated great leadership and distinguished himself as powerful legislative voice in pushing for a positive agenda that includes expanding health care, reducing the naturalization backlog at the INS, promoting fairness in our judicial system, ensuring a fair and accurate census, and protecting voting rights.

It has been a privilege for the Democratic Caucus to work with Chairman Becerra and his fellow members of the Congressional Hispanic Caucus. I am going to miss the leadership of Chairman XAVIER BECERRA, but I look forward to his continuing friendship and to developing a strong working relationship with the next Chair of the Congressional Hispanic Caucus.

COMMUNITY BROADCASTERS PROTECTION ACT OF 1998

Mr. FORD. Mr. President, the 105th Congress is likely to adjourn without enacting S. 1427, the Community Broadcasters Protection Act of 1998. Even so, I want to provide my colleagues a status report on the bill and advise them of the prospects for passage next year.

The principal purpose of S. 1427 is to provide permanent ''Class A licenses'' for low-power broadcasters. Currently these broadcasters have secondary status, which means that they can be bumped from their place on the spectrum by a full-power station. Without permanent status, these broadcasters have a hard time obtaining long-term capital.

After introducing this legislation last year, I worked with the staff of the Federal Communications Committee to refine the bill. In pursuing this matter, I have sought to provide a degree of certainty for low power broadcasters without creating any unintended consequences for other users of the spectrum. The result, which was reported from the Senate Committee on Commerce, Science, and Transportation on October 1, has achieved that goal.

The core mission of low power broadcasters is to provide programming for local communities that are not served by full power stations. These underserved communities may be in rural areas or in large metropolitan areas. In my state, we have a low-power station that provides programming that is geared to the interests of rural Kentuckians. However, in Washington, D.C., low power broadcasters provide Spanish language programming to meet the needs of the Hispanic population in this area.

The FCC has recognized the unique role that community broadcasters play in providing programming to underserved audiences. Earlier this year, when I asked Chairman Kennard for his comments on the legislation, he responded favorably. Chairman Kennard said, ''Having reviewed the legislation, I have no major concerns with the bill.''

Mr. President, I would like to thank Senator MCCAIN, the chairman of the Committee on Commerce, Science, and Transportation, Senator HOLLINGS, the ranking Democrat on the committee, and my other colleagues on the committee for their support of this legislation. As of today, 13 members of the Commerce Committee have joined as cosponsors. Also I want to express my appreciation to Senator BURNS, the chairman of the Communications Subcommittee. Senator BURNS has cosponsored S. 1427, and he has advised that he will introduce this legislation when the 106th Congress convenes next year. I thank my colleague for his continued interest in and support for community broadcasters. I am very pleased to leave this legislation in the capable hands of the Senator from Montana.

Mr. BURNS. Mr. President, I thank the Senator from Kentucky for his remarks and want to confirm that I plan to introduce this legislation next year. Also, I want to congratulate Senator FORD on his efforts on this legislation. Due to his persistence, much of the preliminary work on this bill has been done. While we will miss his presence on the Commerce Committee next year, we will continue to benefit from his work as a member of this body.

Mr. FORD. Again, I thank the Senator from Montana and wish him luck in this effort next year. The community broadcasters of the nation have earned a permanent place on the broadcast spectrum.

THE SENATE SAYS GOODBYE TO SENATOR DIRK KEMPTHORNE

Mr. BYRD. Mr. President, when one speaks of the State of Idaho, we think of her glorious and rugged landscape, her fertile valleys, her waters ideal for fishing, her world-class ski resorts, her national parks and forests, with land fit for hiking, or biking, and, of course, her reputation as the potato capital of the world. Following the end of the 105th Congress, I daresay that our associations to the State of Idaho will also include the name of DIRK KEMPTHORNE, the state's junior Senator and one of this body's most respected Members. Although our friend from the west is leaving the Senate after only one six-year term, I, for one, will remember him fondly for years to come.

Senator KEMPTHORNE and I formerly served together as Chairman and Ranking Member, respectively, of the Personnel Subcommittee of the Armed Services Committee. We worked together to introduce legislation requiring the study of gender integrated training in the military. That association has been pleasant, and, I believe, productive. To be sure, I have not always agreed with his policy proposals, or he with mine. On many issues, including the balanced budget constitutional amendment and the unfunded mandates legislation, we have held opposing views.

Throughout the lengthy debate on the unfunded mandates bill in early 1995, the Senator was conscientious, thorough, and fair. His grace and courtesy in managing that bill were impressive, particularly for someone so new to the Senate. And, as we all know, his efforts paid off after deliberate consideration and compromise. Moreover, with passage of the unfunded mandates bill, Senator KEMPTHORNE holds the honor of being the most junior member of the Senate since World War II to author, manage, and win passage of a bill numbered Senate Bill One.

When he leaves these hallowed halls, Senator KEMPTHORNE will return to his home state. Boise, of course, is familiar ground for Senator KEMPTHORNE, serving as that city's forty-third Mayor, from 1985 until 1992, when the people of Idaho elected him to his present seat in the Senate. Incidentally, he became so popular during his first term as Mayor that he faced no opposition in his bid for a second term! How many of our colleagues would like to be in that situation? How many of us would like to be so universally popular, and be held in such high respect by our constituents, that such popularity and respect would foreclose potential challengers?

I congratulate Senator KEMPTHORNE on his fine service here, and I wish him and his nice family happiness in future years.

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT

Mr. HATCH. Mr. President, 14 years ago, when I served as Chairman of the Senate Labor and Human Resources Committee, I teamed up with Representative HENRY WAXMAN, Chairman of the Subcommittee on Health and the Environment of the House Energy and Commerce Committee, to lead passage of the Drug Price Competition and Patent Term Restoration Act of 1984.

The bottom line of this law was to improve the health of the American people. The statute accomplishes this in two primary ways: First, it essentially created the market for more moderately priced generic drugs by allowing generic manufacturers to demonstrate their equivalence to pioneer products without duplicating all of the original safety and efficacy data. Relieved of this costly burden, generic drug firms can provide their products at competitive prices which are attractive to many consumers.

Second, pioneer drug firms became eligible for restoration of some of the patent term lost due to the extensive

FDA review of safety and efficacy that all new drugs must undergo. This partial restoration of patent term—up to five years in certain circumstances when such restoration would not result in a greater than 14 year effective patent life—allowed pioneer drug firms additional time to recoup the enormous investments required to bring a new drug to market. This helped attract the investment capital that pioneer firms need to develop the next generation of life-saving drugs.

Consumers benefit from this win-win dynamic because the American public gets both new drugs and competitively priced off-patent medications.

As we start the 15th year since the enactment of this important health and consumer law, we have a generic pharmaceutical sector that has developed into an integral part of the health care system, which together with innovator pharmaceutical and biotechnology companies lead the world in the development and marketing of new health care products.

While I think that the track record of the Hatch–Waxman Act is enviable, I hope that we can even do better for the American public in the future.

Accordingly, I intend to devote time during the next Congress to begin the necessary examination into how we can make changes in the law that will increase our ability to produce both the innovative products that we have come to expect and the lower priced generic products that are so attractive to the family budget.

I intend for this examination to include a serious study of how well the Drug Price Competition and Patent Term Extension Act has functioned over the past 14 years, whether the Act has fulfilled its initial promise, how the courts have interpreted the Act, and indeed, how it has been implemented. I hope to work closely in this endeavor with my good friend and colleague Senator JIM JEFFORDS, Chairman of the Labor and Human Resources Committee, which shares jurisdiction over the Act with the Judiciary Committee.

A major test of such a review will be to assemble a package of initiatives that will retain the delicate but essential balance between the innovator and generic sectors of the industry. This will be a difficult task but it is a worthwhile endeavor for the American people.

Even during this session of Congress, some have proposed changes to our nation's drug discovery laws. There has, for example, been some discussion about changing one of the most controversial provisions of the 1984 law—the so-called Bolar Amendment. Section 271(e) of the Title 35, contains language to overturn a 1984 Federal Circuit Court of Appeals ruling in the case of Roche v. Bolar Pharmaceutical Co., which held that conducting the tests required to secure approval of generic copies of pioneer drugs constituted patent infringement. Section 271(e)(1) establishes an exception to patent infringement laws to authorize generic pharmaceutical companies to conduct testing on patent approved pharmaceutical products for purpose of filing an abbreviated new drug application.

Recently, the application of section 271(e)(1) has been a matter of some controversy in an on-going legal battle between two pioneer drug firms, one company holding existing patent protection and FDA product approval and the other company asserting its own patent rights and seeking pioneer rather than generic approval from FDA. While ultimately the courts must decide whether this is a case of patent infringement, it is clear that this is not merely a simple, garden variety patent infringement case because it also raises the question of precisely what type activities that section 271(e)(1) should allow, and should not allow, in the context of developing not only generic drugs but new drugs and biologicals that they potentially compete directly with.

While I do not take a position on the merits of the actual patent rights in dispute in the current Amgen v. Hoechst Marion Roussel litigation, I must say this case is of some concern to me, especially with regard to court's initial findings which are not consistent with, and broaden, Congress' intent in enacting 271(e).

I do believe Congress would be wise to reassess the breadth of section 271(e)(1) in light of this and a number of court decisions since 1984 that have tended to expand the scope of this provision. One case in particular is the 1990 Supreme Court decision in Lilly v. Medtronic.

My position on these questionable decisions has been clear for some time. I was, in fact, a signatory to an amicus brief in the Lilly case that argued for a somewhat narrower interpretation of 271(e)(1) than has evolved in the courts.

One proposal worthy of serious consideration is to more clearly limit the applicability of 271(e)(1) to exclude testing and other activities necessary for approval of NDAs and BLAs from the patent infringement exemption. Of course, the 271(e)(1) question is only one of many issues that will undoubtedly be proper for further discussion in the next Congress.

Some are concerned about whether drugs that were already in FDA review at the time of enactment of Hatch–Waxman (the ''pipeline drugs'') have received adequate and fair patent protections in view of subsequent delays that were encountered. Congress should undertake complete review of this proposal during our study of Waxman–Hatch next year, as I believe the evidence will show that there are inequalities we should take steps to remediate.

Others are concerned about the application of the 180 day generic drug exclusivity rule in the aftermath of the Mova decision. Indeed, some are advocating report language that will give FDA new leeway to adopt a ''first-to-succeed'' in patent litigation approach rather than the ''first-to-file'' an ANDA that the courts have found.

Frankly, I have concerns about the current outcome whereby some ANDA applicants appear to be handsomely rewarded by pioneer firms for not selling generic competitors.

Still others advocate in the spirit of international harmonization adopting the European rule of a 10 year marketing exclusivity period for all new drugs. And others point out that the advent of the new GATT-required 20 year from filing patent term may change the traditional incentives in coordinating PTO and FDA approvals.

It is time, some argue, to do away completely with current rule by which only 5 years of patent life may be restored to compensate time lost at FDA and only if the effective patent term does not exceed 14 years. Some would also like to revise the rule that limits patent restoration for time lost during the IND phase in a for each 2-days lost, 1-day restored ratio.

On the generic side of the industry, there is concern that as NDA approvals speed up due to user fees, generic approvals continue to lag and take much longer than NDAs. There is also great frustration about what some describe as challenges to the bioequivalence of generic products that are more a delaying and harassing tactic than a bona fide scientific dispute.

And then, there are those in the generic industry who believe that FDA's Orange Book, which records the patents in effect for FDA approved drugs, should be renamed as the ''Evergreen Book''!

So there are many issues that merit consideration as we reassess the adequacy of the laws pertaining to the generic and pioneer sectors of the pharmaceutical industry.

Our focus should be on ascertaining what steps we can take that will most benefit the American people in terms of providing incentives both for the development of new drugs and the production of competitively priced generic products. This has and will continue to require a delicate balance. There is an inherent tension between the twin goals discovering the next generation of drugs while at the same time providing generic versions of today's medications.

My goal is to reconcile these somewhat conflicting but wholly meritorious goals in the interest of the American people, and I look forward to working with my colleagues in the House and Senate on this complex issue next year.

TRIBUTE TO ALLEN GARTNER

Mr. LEAHY. Mr. President, Allen Gartner is one of Vermont's real citizen treasures. He was recently honored by the Rutland Region Chamber of Commerce on their 100th anniversary. I ask unanimous consent that a letter I