

an agency because somebody is waiting for her Social Security check or a guy is waiting for an FHA loan and the agency gives me some song and dance, I try to let them know I'm not gonna take any of their crap," he says. "At times, I tell them I've discussed this problem with the senator. Sometimes, it isn't true."

A former jewelry store owner and Chamber of Commerce honcho from Norwich, Conn., Israelite is Dodd's pipeline to many of the state's small-business owners. Harry Jackson, a lifelong Republican who is the City Council president in Norwich, recalls how difficult it was to get a meeting with officials from the Environmental Protection Agency when the city wanted to build a new firehouse on federal land. "Stan got us in there after just one phone call," says Jackson, who ultimately built the firehouse.

#### THINGS HAPPENED.

Don Daren says Israelite was a lifesaver in 1981, when a state-based paper distributor was trying to secure a \$900,000 umbrella loan from the Connecticut Development Authority. Daren, who owns the Arrow Paper Supply and Food Co., says it was going to take forever for the CDA to process his loan papers so he could buy a new warehouse. "Stanley told them [CDA officials] my problem, and things happened right away," says Daren, whose business has grown from 36 workers then to nearly 200 today. "He has his own constituency. People like Stanley."

Ideally, says veteran Hartford Courant political columnist Don Noel, senators like Dodd would use their clout on Capitol Hill to fix bureaucracies and make them more consumer friendly—eliminating the need for taxpayer-financed ombudsmen like Israelite. But since that goal seems unattainable, Noel figures that Israelite plays a vital role. "If you have something you need the senator to do for you, if anyone can do it, Stanley can," he says.

Israelite admits that he is motivated by a desire to help re-elect Dodd. But he adds: "Part of what drives me is knowing that there's someplace where somebody can go when they are not getting anywhere."

#### GENERIC ZANTAC

• Mr. FAIRCLOTH. Mr. President, during the debate on an amendment offered by my colleague from Arkansas, Senator PRYOR, with regard to GATT patent extensions, there were representations made about the availability of a generic form of Zantac. The Senate has expressed its support for Judiciary Committee hearings on this important issue. The chairman of that committee has committed to hold a hearing on February 27, 1996.

Some supporters of the generic drug companies claim that the hearings will delay marketing of generic Zantac. This is not true. In fact, due to other outstanding patent issues with regard to Zantac, it is unclear when a generic form of Zantac will be available, but it will be at least several months and likely to be after September 1996. Therefore, hearings held in early 1996 will permit more than sufficient time to resolve this question well before September 1996.

Mr. President, I ask to have printed in the RECORD a detailed background paper on the patent issues relating to Zantac.

The material follows:

#### BACKGROUND ON THE IMPACT OF GATT PATENT EXTENSIONS ON POTENTIAL AVAILABILITY OF GENERIC ZANTAC® (RANITIDINE HYDROCHLORIDE)

Even if the U.S. had not implemented the General Agreement on Tariffs and Trade (GATT), based on the generic applications submitted to date, no generic form of Zantac could have been legally marketed on December 5, when the basic patent was scheduled to expire prior to the implementation of GATT. Because of other outstanding patent issues with regard to Zantac, it is unclear when a generic form of Zantac will be available, but it will be at least several months and is likely to be after September 1996.

Glaxo Wellcome has two product patents with respect to ranitidine hydrochloride, which exists in two forms, referred to as form 1 and Form 2. All of the Zantac sold by Glaxo Wellcome worldwide has been Form 2. The Form 2 product patent expires on June 4, 2002. It bars the marketing of generic versions of Form 2 or any product that contains Form 2. In September 1993, the validity of the Form 2 patent was upheld in federal district court against a challenge by a generic company. That decision was affirmed on appeal.

The basic patent was scheduled to expire on December 5, 1995, but was changed by the GATT implementing law to July 25, 1997. The basic patent bars the marketing of generic versions of both Form 1 and Form 2. For various reasons it may be more difficult to manufacture Form 1 ranitidine in a pure form in commercial quantities over time. Even when the basic patent expires, before a company can market a generic form 1 ranitidine, they must demonstrate that their Form 1 product is bioequivalent to Zantac and does not violate the remaining Form 2 patent.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch/Waxman Act) provides expedited procedures for generic drugs to enter the market and for the resolution of outstanding patent issues. Under these procedures, a company seeking approval for a generic drug may file an Abbreviated New Drug Application (ANDA) with the FDA. The ANDA must contain one of the following certifications with respect to each relevant patent on the pioneer drug: (I) patent information has not been filed with the FDA, (II) the patent has expired, (III) the patent will expire on a date specified, or (IV) the patent is invalid or won't be infringed.

If the ANDA contains a paragraph III certification listing the patent expiration date, the FDA is precluded from making the ANDA effective prior to that date. If the generic company seeks to market a drug before the expiration of any relevant patents, the ANDA must contain a paragraph IV certification that the patents are invalid or won't be infringed, and the generic company must notify the patent owner. Unless the patent owner sues for infringement within 45 days of being notified, the FDA can approve the ANDA.

If the patent owner does sue within 45 days, FDA cannot make the ANDA effective immediately. To protect generics from undue delay during litigation, the Act provides that the FDA can make the ANDA effective after 30 months from the date the patent holder is notified of the ANDA filing or when there is a final court ruling that the patent is invalid or not infringed, whichever is earlier.

All ANDA applicants seeking to market generic ranitidine hydrochloride prior to 2002 have lawsuits pending against them asserting violations of one or more patents. Because of the 30 month provision, the pending litigation affects the earliest date that ge-

neric ranitidine hydrochloride could be marketed by any of these companies.

Even if the FDA were not precluded by the Hatch/Waxman Act from making ANDAs effective prior to the expiration of the full patent term for brand name drugs, September 1996 is the earliest date under the Hatch/Waxman Act procedures that Form 1 generic ranitidine hydrochloride could be marketed by any of these companies unless there is a final court ruling earlier that the basic patent is invalid or that the generic product does not infringe any Glaxo Wellcome patents.

Because a trial court decision is not considered final if an appeal is taken, it is unlikely that a final court ruling will occur prior to September 1996. In a prior patent infringement case against Novopharm with respect to the validity of the Form 2 patent, the trial court ruled in Glaxo Wellcome's favor in September 1993. Novopharm appealed the same month, but the appeal was not decided for 19 months, in April 1995. The appeals court upheld the earlier decision in favor of Glaxo Wellcome.●

#### WELFARE 2015

• Mr. MOYNIHAN. Mr. President, since the publication of Michael Young's "The Rise of Meritocracy" in 1957, a book written from the perspective of Great Britain in the year 2034, there has not been so brilliant an exercise in this format than Jason DeParle's "Welfare, End of" in yesterday's New York Times Magazine, looking back from the year 2015. It foresees a social disaster that will follow the repeal of title IV-A of the Social Security Act, Aid to Families with Dependent Children, in this the 104th Congress. Mr. DeParle speculates that President Clinton will look back upon this as one of the greatest regrets of his Presidency.

Mr. President, I ask that the article be printed in the RECORD.

The article follows:

[From the New York Times Magazine, Dec. 17, 1995]

WELFARE, END OF—THE EVENTS THAT LED TO ITS DEMISE IN 1995, AND THE STRIKING CONSEQUENCES IN THE YEARS SINCE.

(By Jason DeParle)

The following interactive encyclopedia entry looks back from the year 2015. References to events before December 1995 are real; subsequent developments may become so all too quickly.

#### SUMMARY

For 60 years, until 1995, the United States Government ran a social program technically called Aid to Families with Dependent Children, and commonly known as welfare. The program, which provided cash grants to indigent families, was abolished as part of a bipartisan deal that reduced Federal spending and transferred power to state governments. At the time of its demise, welfare was a thoroughly discredited program—often accused of causing long-term poverty rather than helping people survive it.

A handful of critics accurately predicted that ending welfare would bring rising numbers of "street families," just as the closing of mental hospitals had produced "street people" in the 1970's and 80's. But most welfare abolitionists argued that the poor would be better off without the program. They would have been astonished to learn that today, in 2015, the program they reviled as "welfare" is often described nostalgically as

the last thread of the "Federal safety net." This entry summarizes the consequences of abolishing welfare, and the odd political dynamics that led to its end.

#### THE STATES

Though it grew into a potent symbol of social decay, the A.F.D.C. program was established amid little controversy, as a sidelight of the Social Security Act. It was intended to provide small pensions to indigent widows, instead of placing their children in orphanages. But the program changed during a period of explosive growth in the late 1960's, as millions of never-married women joined the rolls. If the program's public face was once that of a West Virginia miner's widow, it then became that of a young black woman in an urban ghetto. There were about 14 million women and children receiving benefits when the program ended, with the average family of three getting about \$370 a month.

Initially, those who warned of social catastrophe seemed alarmist. In abolishing welfare, Congress gave the states annual lump-sum payments, called block grants, to assist the poor virtually any way they saw fit. The states were barred from aiding families for more than five years, but most set much shorter limits. By later standards, the sizes of the first block grants were generous, and difficult as it is now to imagine, the late 1990's seemed a golden age of state experimentation.

In 1997, Mississippi contracted with church groups to run its relief programs; within a few years the teen-age pregnancy rate dropped 10 percent. Vermont placed a two-year limit on benefits but offered subsidized jobs to those who were still unemployed. Tennessee took a tougher tack, imposing a strict 18-month cutoff with no further aid. But in the late 1990's, Tennessee had a 3 percent unemployment rate, and most mothers found at least part-time work. While millions of poor families still led hand-to-mouth existences, they always had; local control, whatever its problems, was not unambiguously worse.

Then came the 1999 recession. Faced with declining revenues and rising aid requests, states slashed their payments; the mother of two who had received \$370 in 1995 was now getting \$180 a month. With families crossing borders in search of aid, the "race to the bottom" ensued, with each state trying to be as tough as its neighbors. Just months after Texas barred payments to legal immigrants, for instance, the other border states followed. As an entitlement, the old A.F.D.C. system promised, a check to any qualifying family within 45 days; waiting lists now grew as long as two years. As many as a million families who have received aid under the Federal system now received nothing.

Though the economy recovered in subsequent years, state spending did not. As the number of neglected children skyrocketed, the child welfare system snapped. In 1995, there were approximately 460,000 children in foster-care programs; a decade later, the number approached one million. As the numbers grew, the Federal Government began a 10-city experiment to test the performance of orphanages—an idea first broached by former House Speaker Newt Gingrich.

The experiment earned high marks, but Congress balked at its cost. A year at the latter-day Boys' Towns cost more than a year at Harvard, and lawmakers refused to keep financing them.

#### THE PEOPLE

The end of welfare was accompanied by major cuts in food, housing and medical programs. And it came when the wages of low-skilled workers were already in a free fall because of global competition. So it is not surprising that poor people have seen their

standard of living decline, while their numbers are rapidly increasing. Until 1995, for instance, all poor children in America had health insurance under a program called Medicaid. The successor state programs have largely devoted their resources to the elderly, leaving about half the nation's poor children uninsured.

Not all former recipients have fared poorly. As many as a quarter of the five million A.F.D.C. families found and retained full-time work. For them, the end of welfare worked much as it was intended—as a prompt to greater self-reliance. They received considerable publicity in the late 1990's as welfare abolitionists tried to rebut charges that the cuts had been cruel. A coalition of conservative groups sponsored the "Million Mothers March," a day of speeches and prayer by former recipients to celebrate their new lives. While their earnings remained quite modest—often little more than they had received on welfare—many mothers praised the psychic rewards of serving as "positive role models."

Far more numerous are those in a second category: "cyclers," who have alternated between short-term employment and charitable aid. The cycling phenomenon was first identified in the mid-1980's by researchers at Harvard University who hoped to see expanded Government aid. Part of the cyclers' continuing problem has been economic: whether they work as telemarketers, cosmetologists, cashiers or clerks, they are typically the last hired and first fired.

But even in good times, the chaos of many low-income homes spills onto the job. Broke-down cars, sick relatives and a lack of child care are perennial problems—indeed, a 2007 study by the Children's Defense Fund found that dozens of mothers were arrested each year for locking their children in cars as they worked. Sociologists estimate that since welfare ended, about half the former population has fallen into this pattern of sporadic work with little hope for advancement.

At the same time, about 25 percent of the A.F.D.C. families—that is, more than a million of them—have fallen into utter destitution. The public now sees them lining up at shelters, stealing into abandoned buildings and begging on street corners. At the time of abolition, half the welfare mothers lacked a high-school diploma, and in inner cities as many as one in three had histories of some drug or alcohol abuse; a subsequent study by the Rockefeller Foundation emphasized how many remained deeply disturbed. It found that by 2005, three-fourths of the families entering shelters were those of welfare mothers who had exhausted their lifetime eligibility.

The Rockefeller study, "Repeating Mistakes," compared the 1995 law ending welfare with the 1960's move that deinstitutionalized the mentally ill. Schizophrenics were supposed to find community-based programs; welfare recipients were entrusted to state agencies. In neither case did the local safety net appear. Like the 1980's street people, the homeless families of the early 21st century enjoyed a brief period of Hollywood vogue. Meryl Streep won an Oscar in 2006 for her portrayal of a destitute woman.

But one again, charity chic faded.

The end of welfare also brought unintended consequences in the area of morality. The abolitionists had hoped to spur a return to work, marriage and responsibility. But for some of the poorest women, the loss of aid had the opposite effect. Some became more reliant on abusive boyfriends, and reports of domestic violence rose. Abortion rates hit record levels and so did arrests for prostitution, leading several cities to decriminalize the practice in specified red-light zones.

#### POLITICS

Antipathy for the dole is as old as the country itself, but it gained a sudden new potency in the mid-1990's, just before the program's demise. Oddly enough, it was President William Jefferson Clinton, a Democrat, who set the new forces into motion. In his 1992 campaign, he famously promised to "end welfare as we know it" by imposing time limits and work requirements. When he later failed to promote his plan, the Republicans pushed his rhetoric to a conclusion he had not envisioned.

Clinton's initial plan for ending welfare had included new training, universal health care and job guarantees. But the actual end meant only that. And a President who had pledged to expand the income and medical security of all Americans wound up presiding over an unprecedented contraction of the safety net.

In his recent memoirs, the ex-President describes his handling of the issue as "one of my greatest regrets." He acknowledges that his party's defeat in the 1994 elections left him reluctant to spend political capital on the welfare poor. His own plan had included the toughest work requirements any President had ever proposed. But by the fall of 1995 Clinton had joined those dismissing it as weak, apologizing in an interview: "I wasn't pleased with it either."

At the same time, Clinton argues in his memoirs that he was genuinely surprised that the subsequent state-based system collapsed so quickly. Throughout 1995 he had looked skeptically at his own aides' predictions that poverty would rise sharply. But the memoirs do recount one moment of doubt. On the day before Thanksgiving 1995, Clinton served dinner at a homeless shelter in Washington, where, as he explained at the time, he was distributed to see that "the fastest growing group of homeless people in our country are young women and their young children."

Looking back 20 years later, Clinton confessed something he did not disclose that day at the shelter. Standing in the serving line, a month before welfare's end, he feared that he had just got a glimpse of America's future. ●

#### UNANIMOUS-CONSENT AGREEMENT—CONFERENCE REPORT ON H.R. 1530

Mr. MACK. Madam President, I ask unanimous consent that when the Senate resumes consideration of the Defense authorization conference report at 9:30 a.m. on Tuesday, December 19, that there be 3 hours for debate equally divided in the usual form, with the Democratic time in the morning divided as follows:

Senator NUNN, 45 minutes; Senator BYRD, 15 minutes; Senator GLENN, 30 minutes; Senator BRYAN, 15 minutes.

I further ask unanimous consent that at 2:15 p.m., on Tuesday, there be time for the following Senators:

Senator DORGAN, 10 minutes; Senator EXON, 15 minutes; Senator KENNEDY, 5 minutes; Senator LEVIN, 10 minutes; Senator DASCHLE, 10 minutes; Senator THURMOND or his designee, 1 hour.

I further ask that following the disposition of, or yielding back of time, the following Senators have 20 minutes under their control:

Senator LEAHY, Senator THURMOND, Senator NUNN, Senator WARNER.