

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