



## Legislation Details (With Text)

|                        |   |                     |   |                    |   |
|------------------------|---|---------------------|---|--------------------|---|
| <b>File #:</b>         | Res 1915-2001   | <b>Version:</b>     | * | <b>Name:</b>       | The Greater Access to Affordable Pharmaceuticals Act of 2001. |
| <b>Type:</b>           | Resolution  | <b>Status:</b>      |   | <b>In control:</b> | Filed   |
|                        |   |                     |   |                    | Committee on State and Federal Legislation                    |
| <b>On agenda:</b>      | 5/23/2001   |                     |   |                    |   |
| <b>Enactment date:</b> |   | <b>Enactment #:</b> |   |                    |   |
| <b>Title:</b>          | Resolution calling upon the United States Congress to adopt, and the President to sign, the Greater Access to Affordable Pharmaceuticals Act of 2001. |                     |   |                    |   |
| <b>Sponsors:</b>       |   |                     |   |                    |   |
| <b>Indexes:</b>        |   |                     |   |                    |   |
| <b>Attachments:</b>    |   |                     |   |                    |   |

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| 5/23/2001  | *    | City Council | Introduced by Council       |        |
| 5/23/2001  | *    | City Council | Referred to Comm by Council |        |
| 12/31/2001 | *    | City Council | Filed (End of Session)      |        |

Res. No. 1915

..Title

Resolution calling upon the United States Congress to adopt, and the President to sign, the Greater Access to Affordable Pharmaceuticals Act of 2001.

By the Speaker (Council Member Vallone) and Council Members Provenzano, Miller, Malave-Dilan, Eisland, Michels, Moskowitz and Nelson; also Council Members Espada, Fisher, Foster, Koslowitz, Marshall, Pinkett, Reed and Robles.

Whereas, Media reports, federal regulators, and consumer advocates have charged that current laws governing the relationship between name brand pharmaceuticals and generic drugs are subject to abuses which allow brand-name drug manufacturers to delay the approval of lower-cost generic versions, often for years; and

Whereas, The 1984 Hatch-Waxman Act, which governs prescription drug patents, was, according to reported statements of one of its authors, Senator Waxman, designed to increase competition between brand-name drugs and generic alternatives; and

Whereas, Loopholes in the Hatch-Waxman Act's patent provisions have, according to federal regulators and legislators, allowed drug companies to unilaterally block the marketing of generic drugs, or collude with the makers of generic alternatives - in either case resulting in the name-brand manufacturer maintaining a monopoly on the drug; and

Whereas, One example of the use of current law to stifle competition, according to media reports, can be found in a recent federal lawsuit filed by 15 states' attorneys general which alleges that one major pharmaceutical company which sued its generic competitor for patent violations, abused the Hatch-Waxman Act by paying the generic company/defendant an \$89 million settlement to keep the cheaper generic drug off the shelves for an additional period of time; and

Whereas, The Federal Trade Commission in April of this year, began a widespread investigation into other anti-competitive practices by brand-name drug manufacturers, including similar settlements between brand-name manufacturers and generic manufacturers, to examine whether drug companies are manipulating the law to delay the marketing of generic drugs; and

Whereas, Under current law, when a generic drug manufacturer institutes a challenge to the name-brand manufacturer's patent in order to win the right to begin marketing a generic version, if the name-brand manufacturer files suit against the challenge, it is automatically entitled to a 30 month delay, during which time the generic drug cannot be marketed, which, according to media reports, has led to frivolous actions by brand-name manufacturers in order to delay competition; and

Whereas, Senators Charles Schumer of New York, and John McCain of Nevada, have introduce Senate Bill 807, entitled the Greater Access to Affordable Pharmaceuticals Act of 2001; and

Whereas, Among other changes to the current laws, this legislation would do away with the automatic 30 month wait awarded to brand-name drug manufacturers who file suit against the patent challenges of generic competitors, instead forcing the brand-name manufacturers to obtain a preliminary injunction in order to stop the marketing of the generic drug; and

Whereas, The proposed legislation would require brand-name manufacturers to list all of a drug's patents and certify that the list is complete,

and would allow generic competitors to go into court to seek a declaratory judgment as to the validity of any of the brand-name patents, apparently in an effort to prevent drug manufacturers from waiting until the expiration of one patent on a brand-name drug, to use another patent in an effort to extend the period during which the brand-name manufacturer is protected from competition; and Whereas, The legislation's sponsors and supporters claim that by removing the current law's obstacles to fair competition between brand-name and generic drugs, consumers could save more than \$70 billion over the next ten years, because trends in prices under the current law show the average prescription drug costs over 330% more than the average generic drug -- a disparity which is increasing; now, therefore, be it Resolved, That the Council of the City of New York calls upon the United States Congress to adopt, and the President to sign, the Greater Access to Affordable Pharmaceuticals Act of 2001.