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Joan Claybrook, President

January 6, 1999

Minnie Baylor-Henry, R.Ph., J.D.  
Director, Division of Drug Marketing, Advertising,  
and Communications  
Food and Drug Administration  
Rm. 17B20 HFD-40  
5600 Fishers Lane  
Rockville, MD 20857

Dear Ms. Baylor-Henry:

Enclosed is an extremely misleading direct-to-consumer (DTC) advertisement that lacks fair balance for the dangerous diabetes drug troglitazone (Rezulin), made by Parke Davis, a division of Warner Lambert, of Morris Plains, NJ. This ad, with the good news and promotional information in Spanish but the official labeling with warnings and risks in English, appeared in the December 1998 *El Tiempo Latino* a publication distributed with newspapers in cities with large Spanish speaking populations that is promoted as "The Magazine for All Hispanics."

*El Tiempo Latino* has a total average circulation of 1,139,568 and 397,713 copies are distributed in California alone. A list of newspapers in which *El Tiempo Latino* is distributed and its circulation is enclosed for your reference. Also enclosed is an English language translation of the advertisement.

At the end of the ad consumers are instructed in Spanish to ". . . read the important information which appears on the back," referring to a brief summary of the full professional product labeling or package insert. However, the brief summary is not in Spanish but in English. It is our opinion that this ad violates provisions of the Federal Food, Drug and Cosmetic Act and Food and Drug Administration (FDA) advertising regulations by being misleading and lacking in fair balance.

Many Spanish speaking Americans have excellent bilingual language skills and are fluent in both Spanish and English. However, the interpretation of the brief summary (a drug's professional product labeling) that must accompany DTC print ads by regulation can be difficult to understand even for those consumers whose first language is English. The brief summary contains some risk information that is

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Ralph Nader, Founder

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important for consumers but it is written for health professionals, in dense technical jargon, and assumes a high level of medical knowledge on the part of the reader.

The December issue of *El Tiempo Latino* does contain an ad for another prescription drug, this time with consumer directed text and the required brief summary and both are in English. The troglitazone ad appears to be directed primarily at Spanish speaking only consumers who are only presented with the alleged benefits of troglitazone and no balancing risk information in Spanish with which to make an informed decision about using this drug.

The careful choice of words by Parke Davis in the ad's Spanish language text minimizes the risks of troglitazone by telling consumers:

*In a few cases, Rezulin has been associated with serious hepatic problems, which generally are reversible, although in a few cases have resulted in insufficient hepatic function and death. Your doctor can advise you in regard to the new recommendations for hepatic monitoring with Rezulin, which require routine blood tests.*

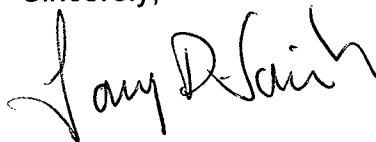
The box warning contained in troglitazone's English language brief summary, though in technical language, informs consumers in bold type "**... rare cases of hepatic failure, leading to death or liver transplant, have been reported. Injury has occurred after both short- and long-term troglitazone treatment.**" The brief summary goes on to say that 11 blood tests are required during the first year of treatment with the drug, rather than simply that "routine blood tests" are required.

The FDA must immediately ban the distribution of this dangerously misleading ad. Because vital risk information about troglitazone has been hidden from the Spanish speaking public, Parke Davis must be required to run corrective ads in all publications in which this ad has appeared. The corrective ad must run for the same period of time that this misleading ad appeared in the publication. The corrective ad must clearly inform Spanish speaking diabetics--in Spanish--of the potentially life-threatening liver toxicity associated with this drug.

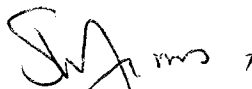
Ultimately, the FDA must address the multitude of problems that have been seen with DTC drug ads, such as this ad for troglitazone, by finalizing, and vigorously enforcing, regulations that directly address these unique problems of DTC advertising as the Agency promised to do 15 years ago.

We look forward to the FDA's prompt action on this critical public health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Larry D. Sasich". The signature is written in a cursive style with a large initial "L".

Larry D. Sasich, Pharm.D., M.P.H., FASHP  
Public Citizen's Health Research Group

A handwritten signature in black ink, appearing to read "Sidney M. Wolfe". The signature is written in a cursive style with a large initial "S".

Sidney M. Wolfe, M.D.  
Director  
Public Citizen's Health Research Group

REZULIN,<sup>®</sup> UNA

VEZ AL DÍA,

PODRÍA

CAMBIAR LA

FORMA

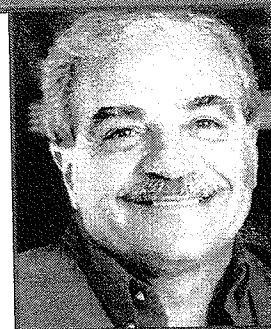
EN QUE

SU MÉDICO

TRATA LA

DIABETES TIPO 2.

"MI MÉDICO  
ME RECETÓ  
REZULIN  
Y ME DIJO  
QUE PODRÍA  
REDUCIR  
MI DOSIS  
DIARIA DE  
INSULINA."



"SÓLO TENGO  
QUE TOMAR  
REZULIN  
UNA VEZ  
AL DÍA,  
LO QUE  
ME SIMPLIFICA  
MUCHO LA  
VIDA."

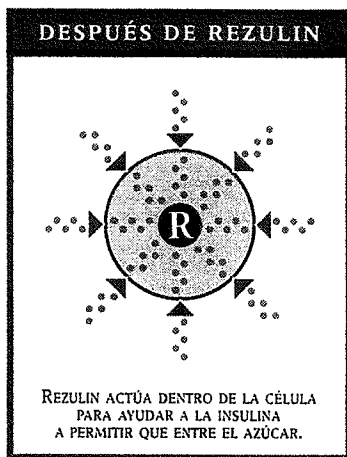
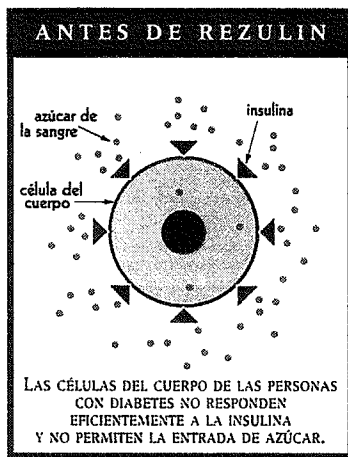


"AHORA  
FINALMENTE  
TENGO  
CONTROLADO  
EL AZÚCAR  
DE MI  
SANGRE,  
REZULIN ME  
ESTÁ DANDO  
RESULTADOS."



## REZULIN®: MEJORA EL CONTROL DE LA DIABETES TIPO 2.

Rezulin (troglitazone), una píldora para la diabetes que se toma una sola vez por día ayuda al cuerpo a utilizar su propia insulina para mejorar el control del azúcar de la sangre. Rezulin puede ser usado en pacientes no bien controlados con dieta y ejercicio solamente, o con píldoras orales de sulfonilureas o con insulina.



**Puede reducir y quizás eliminar la necesidad de inyectarse insulina.** Debido a que Rezulin mejora la utilización de la insulina, podría hacer una diferencia si el tratamiento de su diabetes tipo 2 incluye inyecciones de insulina. Con Rezulin, es posible que usted pueda reducir la dosis de insulina o el número de inyecciones que se administra. Quizás podría eliminar las inyecciones por completo.

**Aumenta la eficacia de muchos medicamentos orales.** Es posible que su médico descubra que Rezulin proporciona un mejor control del azúcar en la sangre cuando se agrega a un régimen de píldoras para la diabetes que contienen una sulfonilurea, tal como Amaryl®, Glucotrol XL®, Glynase® PresTab®, \*glipizide, o glyburide.

**Pregúntele a su médico si usted se beneficiará tomando Rezulin.** Rezulin puede ofrecerle a millones de personas con diabetes tipo 2 opciones de tratamiento útiles. Por favor, tenga en cuenta que los pacientes con diabetes tipo 1 no deben tomar Rezulin. Como es el caso con todos los medicamentos disponibles en la actualidad para tratar la diabetes tipo 2, Rezulin se ha asociado a efectos colaterales. Si bien éstos no son por lo general

serios, usted debe hablar de estas posibilidades con su médico. En casos poco frecuentes, Rezulin se ha asociado a problemas hepáticos serios, que por lo general son reversibles, si bien en casos muy poco frecuentes han llevado a la insuficiencia hepática y a la muerte. Su médico le puede aconsejar con respecto a las nuevas recomendaciones de monitorización hepática con Rezulin, que requieren pruebas de sangre de rutina. Los efectos colaterales más comunes descritos en los estudios médicos fueron similares a los observados con un placebo (una tableta sin medicamento) e incluyen los siguientes: infección (placebo 22% vs. Rezulin 18%), dolor de cabeza (placebo 11% vs. Rezulin 11%), y dolor (placebo 14% vs. Rezulin 10%). Hable con su médico de inmediato si llega a tener náusea, vómitos, dolor de estómago, cansancio, falta de apetito, orina de color oscuro, o coloración amarillenta de la piel (ictericia), ya que estas manifestaciones podrían ser signos o síntomas de un problema del hígado. Siga todas las recomendaciones que su médico le haga con respecto a dieta, ejercicio y pérdida de peso. Como corresponde con cualquier medicamento, dígame a su médico o profesional de atención a la salud acerca de cualquier otro medicamento que esté tomando. Si su tratamiento incluye Rezulin y píldoras de una sulfonilurea, existe la posibilidad de tener un aumento de peso controlable. Si usted es una mujer premenopáusicas que ya no ovula, debe tener presente que el tratamiento con Rezulin puede causar que se reinicie la ovulación, lo que crearía un riesgo de embarazo.

**Más de 1.000.000 de personas han comenzado a tomar Rezulin para mejorar el control de su diabetes.** Y esta cifra continúa aumentando. La mejor manera de averiguar si a usted le beneficiaría tomar Rezulin es consultando a su médico. Para mayor información, vea la importante información que aparece en la parte posterior, y llame sin cargo telefónico al número:

**1-888-900-TYPE2**

UNA VEZ AL DÍA  
**REZULIN®**  
TROGLITAZONE

**PREGÚNTELE A SU MÉDICO  
CÓMO REZULIN ES DIFERENTE.**

Por favor vea la importante información que aparece al dorso.

\* Amaryl es una marca de comercio registrada de Hoechst Marion Roussel; Glucotrol XL es una marca de comercio registrada de Pfizer, Inc.; Glynase and PresTab son marcas de comercio registradas de Pharmacia & Upjohn.

English translation of Rezulin ad done by pharmacists at The West Texas Regional Poison Control Center, El Paso, TX.

**Page One**

*(Headline):*

**REZULIN, ONCE A DAY, COULD CHANGE THE WAY YOUR DOCTOR TREATS TYPE 2 DIABETES.**

*(Photo captions, counter-clockwise)*

**Man: My doctor prescribed Rezulin and told me that I could reduce my daily dose of insulin.**

**Woman #1: I only have to take Rezulin once a day, which really makes my life easier.**

**Woman #2: Now I finally have my blood sugar level under control; Rezulin has given me results.**

**Page Two**

*(Header):*

**REZULIN: ENHANCES CONTROL OF TYPE 2 DIABETES.**

Rezulin (troglitazone), a pill for diabetes that is taken only once a day, helps the body utilize its own insulin to enhance the control of blood sugar. Rezulin can be used by patients (who have not been able to control their diabetes well through diet and exercise only)(?), with oral sulfonylureas, or with insulin.

*(Illustrations, left to right)*

**Box 1**

*(header):* BEFORE REZULIN

*(counter-clockwise):* blood sugar, cell in a body, insulin

*(caption):* THE CELLS OF A PERSON WITH DIABETES DO NOT RESPOND EFFICIENTLY TO INSULIN AND DO NOT PERMIT SUGAR TO ENTER.

**Box 2**

*(header):* AFTER REZULIN

*(caption):* REZULIN ACTS WITHIN THE CELL TO HELP INSULIN PERMIT SUGAR TO ENTER.

**You can reduce and possibly eliminate the need to inject insulin.** Because Rezulin enhances the utilization of insulin, this could make a difference if your Diabetes Type 2 treatment includes insulin injections. With Rezulin, it's possible that you can reduce your insulin dose or the number of required injections. It could also be possible to completely eliminate the injections.

**Increases the efficacy of many oral medications.** It is possible that your doctor will find that Rezulin provides better control of blood sugar levels when added to a regimen of other pills being taken for diabetes which contain a sulfonilurea such as Amaryl, Glucotrol XL, Glynase, PresTab, glipizide, or glyburide.

**Ask your doctor if you would benefit from taking Rezulin.** Rezulin can offer millions of people with diabetes type 2 useful treatment options. Please take into consideration that patients with diabetes type 1 should not take Rezulin. As is the case with all medications currently available to treat diabetes type II, Rezulin is known to cause side effects. Although these are not generally serious, you should talk about the possibility of these side effects with your doctor. In a few cases, Rezulin has been associated with serious hepatic problems, which generally are reversible, although in a few cases have resulted in insufficient hepatic function and death. Your doctor can advise you in regard to the new recommendations of hepatic monitoring with Rezulin, which require routine blood tests. The most common side effects found in medical studies were similar to those observed under a placebo (an inactive pill) and include the following: Infection (placebo 22% vs. Rezulin 18%), headache (placebo 11% vs. Rezulin 11%), and pain (placebo 14% vs. Rezulin 10%). Talk to your doctor immediately if you experience nausea, vomiting, stomachache, fatigue, loss of appetite, dark-colored urine, or a yellowish coloring to your skin (jaundice), since these manifestations could be signs or symptoms of liver problems. Follow all of your doctor's instructions with regard to diet, exercise, and weight loss. As with any medication, tell your doctor or healthcare professional about any other medications you are taking. If your treatment includes Rezulin and pills of a sulfonilurea, there is a possibility of weight gain which is controllable. If you are a pre-menopausal woman who no longer ovulates, you should keep in mind that Rezulin treatment could cause ovulation to occur, which would create a risk for pregnancy.

**More than 1,000,000 people have begun to take Rezulin to better control their diabetes.** And this figure continues to grow. The best way to determine if you would benefit from taking Rezulin is to talk to your doctor. For further information, read the important information which appears on the back of this page, and call toll free:  
**1-888-900-TYPE 2**

**ONCE A DAY**

**REZULIN**

**TROGLITAZONE**

**ASK YOUR DOCTOR  
ABOUT THE REZULIN DIFFERENCE**

Please read the important information which appears on the back.





STATE	NEWSPAPER	VISTA CIRCULATION	DISTRIBUTION DAY
<b>ARIZONA</b> 11,597	Arizona Republic	11,597	Friday
<b>CALIFORNIA</b> 397,713	<ul style="list-style-type: none"> <li>•Alhambra Post/Wave 22,687 Saturday</li> <li>•City Terrace Tribune/Wave 12,600 Saturday</li> <li>•East Los Angeles Tribune/Wave 30,334 Saturday</li> <li>•El Sereno News Herald/Wave 5,250 Saturday</li> <li>The Fresno Bee 76,500 Saturday</li> <li>Hanford Sentinel 13,958 Saturday</li> <li>•Highland Park News/Wave 12,850 Saturday</li> <li>•Huntington Park Press/Wave 10,488 Saturday</li> <li>•Lincoln Heights News Herald/Wave 6,725 Saturday</li> <li>•Los Angeles Daily News 46,084 Tuesday</li> <li>•Maywood Press/Wave 12,116 Saturday</li> <li>•Mt. Washington Star Review/Wave 2,735 Saturday</li> <li>•Monterey Park Progress/Wave 15,488 Saturday</li> <li>Porterville Recorder 11,706 Monday</li> <li>San Francisco Direct 30,000</li> <li>•San Pedro News Pilot 12,283 Saturday</li> <li>•South Gate Press/Wave 6,227 Saturday</li> <li>Tulare Advance-Register 8,014 Monday</li> <li>•Ventura County Star 29,850 Saturday</li> <li>Visalia Times-Delta 21,928 Monday</li> <li>Watsonville Register-Pajaronian 9,890 Monday</li> </ul>		
<b>FLORIDA</b> 128,000	<ul style="list-style-type: none"> <li>Miami Herald-El Nuevo Herald 90,000 Sunday</li> <li>Tampa Tribune 38,000 Tuesday</li> </ul>		
<b>ILLINOIS</b> 24,500	Chicago Direct	24,500	
<b>NEW MEXICO</b> 52,497	<ul style="list-style-type: none"> <li>Albuquerque Tribune 28,364 Saturday</li> <li>Santa Fe New Mexican 24,133 Monday</li> </ul>		
<b>NEW YORK * *</b> 100,184	<ul style="list-style-type: none"> <li>El Diario/La Prensa 53,000 Sunday</li> <li>The Jersey Journal 25,684 Saturday</li> <li>El Nuevo Hudson 21,500 Saturday</li> </ul>		
<b>TEXAS</b> 398,914	<ul style="list-style-type: none"> <li>Austin American-Statesman 28,782 Saturday</li> <li>Brownsville Herald 18,639 Sunday</li> <li>Dallas Morning News 59,530 Sunday</li> <li>El Paso Times 54,556 Tuesday</li> <li>El Paso Other/Direct 1,660</li> <li>Harlingen Valley Morning Star 25,590 Sunday</li> <li>Houston Direct 23,500 Sunday</li> <li>Laredo Times 24,055 Sunday</li> <li>San Antonio Express-News 150,466 Monday</li> <li>San Antonio Other/Direct 2,000</li> <li>Waco Tribune Herald 10,136 Sunday</li> </ul>		
<b>WASHINGTON, D.C.</b> 26,163	El Tiempo Latino	26,163	Friday

**TOTAL AVERAGE CIRCULATION**

**1,139,568**

9/1/98

• LA ADI Circulation 225,717  
 \*\*NY ADI