SUPREME COURT OF THE
STATE OF WASHINGTON

NO. 80251-3

VERNON BRAATEN

Respondent,

v.

BUFFALO PUMPS, INC., et al.

Petitioners.

SUPREME COURT OF THE
STATE OF WASHINGTON

NO. 80076-6

JOSEPH A. SIMONETTA and JANET E. SIMONETTA,

Respondents,

v.

VIAD CORP.,

Petitioner.

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I. INTRODUCTION

Schroeter, Goldmark & Bender ("SGB") has represented more than 1,000 Washington residents who have contracted asbestos-related diseases, has filed complaints relating to those diseases, and currently represents over one hundred such residents. Since the early 1990's, SGB has represented almost 200 clients based on mesothelioma, a disease whose only established cause is asbestos exposure. For example, SGB represents Mrs. James Morgan, whose husband, a long time pipe-fitter at Puget Sound Naval Shipyard, died last week of mesothelioma. The decision in this appeal may well impact that and other clients' claims. As such, SGB, on behalf of itself and its clients, has an interest in the outcome of this appeal, and believes that this amicus brief will be useful to the Court.[1]

One primary issue in this appeal is the existence of a duty for negligence and product liability purposes. Washington courts use a variety of sources including "legislative facts" to determine the existence of such duties. In Estate of Templeton v. Daffern, 98 Wn. App. 677, 687, 990 P.2d 968 (2000), the Court of Appeals explained:

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[1] SGB has previously filed an amicus curiae brief in three analogous situations. Green v. A.P.C. Co., 136 Wn.2d 87, 960 P.2d 912 (1998), Lunsford v. Saberhagen Holding, Washington Court of Appeals, Division I, 139 Wn. App. 334, 160 P.3d 1089 (2007), and Rochon v. Kimberly Clark, Washington Court of Appeals Division I, No. 58579-7-1.

> Whether a defendant owes a common law duty of reasonable care is a question of law.[39] It is to be answered generally, "without reference to the facts or parties in a particular case, "[40] in part by "tak[ing] notice of 'legislative facts'--social, economic, and scientific facts that 'simply supply premises in the process of legal reasoning.'" [41] Other considerations include "logic, common sense, justice, policy, and precedent"; [42] earlier "constitutional, legislative, and judicial expressions of public policy";[43] and a "balancing of interests" that well may compete.[44]

(Footnotes omitted.) Washington courts derive these "legislative facts" from sources including case law, law review articles, and government documents. Wyman v. Wallace, 94 Wn.2d 99, 102-105, 615 P.2. 452 (1980). Such legislative facts concerning the incidence of mesothelioma, its strong connection with asbestos even in small amounts, and scientific information on mesothelioma, can be found in sources such as Washington Court records, published opinions, and National Institute for Occupational Safety and Health ("NIOSH") publications.[2]

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[2] See (A) NIOSH Safety and Health Topic: Occupational Respiratory Disease Surveillance Table 7-1. Malignant mesothelioma: Number of deaths by sex, race, and age, and median age at death, U.S. residents age 15 and over, 1999 (http://www.cdc.gov/niosh/topics/surveillance/ords/NationalStatistics/Highlights/table07-01 MM01).html); (B) Table 7-4. Malignant mesothelioma: Number of deaths, mortality rates (per million population), and years of potential life lost (YPLL) by state, U.S. residents age 15 and over, 1999 (http://www.cdc.gov/niosh/topics/surveillance/ords/NationalStatistics/Highlights/table07-04(MM04).html); (C) Report to Congress on Workers' Home Contamination Study Conducted Under The Workers' Family Protection Act (29 U.S.C. 671a), September, 1995, DHHS (NIOSH) Publication No. 95-123 (http://www.cdc.gov/niosh/95-123.html) ("Workers' Contamination Study"); and (D) Work-Related Lung Disease (WoRLD) Surveillance System (http://www2a.cdc.gov/drds/WorldReportData/FigureTableDetails.asp?FigureTable ID=207).

II. ARGUMENT

A. *Braaten* and *Simonetta* Correctly Determined Duty Under Washington Negligence Law.

This Court in Hunsley v. Giard, 87 Wn.2d 424, 435, 553 P.2d 1096 (1976) relied on Dean Prosser's discussion of the factors which determine whether a court should find a duty for negligence purposes:

> In the decision whether or not there is a duty, many factors interplay: the hand of history, our ideas of morals and justice, the convenience of administration of the rule, and our social ideas as to where the loss should fall. (Emphasis added.)

These factors are relevant to the task of:

> balancing the interest of the injured party to compensation against the view that a negligent act should have some end to its legal consequences.

Id. (emphasis added.) Later Supreme Court cases characterized relevant factors as (1) logic, (2) common sense, (3) justice, (4) policy, and (5) precedent. Snyder v. Med. Serv. Corp., 145 Wn.2d 233, 243, 35 P.3d 1158 (2001); Hartley v. State, 103 Wn.2d 769, 779, 698 P.2d 77 (1985).

Foreseeability is not among the factors expressly listed by this Court as a bases for determining duty, but foreseeability is relevant to a number of those factors such as "justice", "policy", and "our social ideas as to where the loss should fall." That is why this Court, while indicating

that foreseeability alone does not create a duty[3], has repeatedly held that foreseeability is relevant to the determination of whether a duty is owed. For example, this Court recently stated that foreseeability is part of the question of law of whether a municipality owes a duty in a particular situation:

> Whether a municipality owes a duty in a particular situation is a question of law, *Hansen v. Friend*, 118 Wn.2d 476, 479, 824 P.2d 483 (1992), and generally includes a determination of whether the incident that occurred was foreseeable. *DOBBS, supra*, § 229, at 582-83; *King v. City of Seattle*, 84 Wn.2d 239, 248, 525 P.2d 228 (1974) (holding that "foreseeability of the risk of harm to the plaintiff is an element of the duty question");

Keller v. City of Spokane, 146 Wn.2d 237, 243, 44 P.3d 845 (2002) (emphasis added). See King v. Seattle, 84 Wn.2d 239, 248, 525 P.2d 228 (1974); Shepherd v. Mielke, 75 Wn. App. 201, 205, 877 P.2d 220 (1994). See also Bailey v. Forks, 108 Wn.2d 262, 266, 737 P.2d 1257 (1987) in which a four judge plurality stated: "[t]he concept of duty turns on foreseeability and pertinent policy considerations." (Emphasis added.)

Of equal importance, several of this Court's cases determining duty in a negligence context can only be explained as involving a consideration of foreseeability. In Harbeson v. Parke-Davis, Inc., 98

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[3] See Schooley v. Pinch's Deli Market, Inc., 134 Wn.2d 468, 474, 951 P.2d 749 (1998); Hansen v. Friend, 118 Wn.2d 476, 487, 824 P.2d 483 (1992).

Wn.2d 460, 471-73, 656 P.2d 483 (1983), this Court held that, "parents have a right to prevent the birth of a defective child and health care providers a duty correlative to that right." The primary basis for the duty was recent medical developments that made foreseeable whether a child was likely to suffer from a variety of genetic defects. Id.

In Kaiser v. Suburban Transp. Sys., 65 Wash.2d 461, 398 P.2d 14, 401 P.2d 350 (1965), this Court found a duty against a doctor in favor of a third person who was injured by the doctor's bus driver patient when the doctor failed to warn the patient of the side effects of a drug which resulted in the patient losing consciousness while driving a bus and injuring a third party who was a passenger. 65 Wn.2d at 464-65. This Court based the finding of duty, at least in part, on the foreseeability of the danger by the doctor. Id. See also Petersen v. State, supra, 100 Wn.2d at 421, 427-28, 671 P.2d 230 (1983) (relying, inter alia, on Kaiser).

It would be both unjust and against public policy to hold that a manufacturer of valves such as Crane Co. ("Crane") or pumps such as IMO (Delaval Turbine Company) ("IMO"), which contained asbestos as

designed and sold, had no duty to warn about the known dangers of asbestos contained in their products.[4] Indeed, Crane gave such a warning:

> [a]ttached to certain industrial valves that informed the user that asbestos-containing materials were contained within the valve. That warning read as follows: Caution-Contains Asbestos Packing or Gaskets."

CP 1310. Unfortunately, Crane's warning first appeared "in the mid-1980's." Id. That was too late for most users of its valves and was many years after Crane and the other manufacturers in Braaten were or should have been aware of the dangers of asbestos in their products.

The Court of Appeals well described the public policy issues involved as well as "the manufacturers' knowledge of the dangers of the use of their own product":

> As a matter of policy, it is logical and sensible to place some duty to warn on the manufacturer, who is in the best position to foresee the specific danger involved in the use of a product. Here, the asbestos manufacturers had a duty to warn about the general dangers of inhaling asbestos fibers, but the manufacturers of the pumps, turbines, and valves

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[4] The Court of Appeals in Braaten v. Saberhagen Holdings, 137 Wn. App. 32, 38, 151 P.3d 1010 (2007), correctly read the record and pointed out that:

> Buffalo Pumps sold pumps with asbestos packing and gaskets for use in Navy ships from 1943 to 1989. Crane's bronze, iron, and steel valves all included asbestos packing and gaskets; asbestos sheet packing was described in the Crane catalog as "superior." Yarway acknowledged that asbestos was the "only insulation product available to withstand temperature" on Navy ships. Although some of their machines could operate using no insulation or nonasbestos insulation, it was highly likely that a valve, pump, or turbine sold to the Navy would contain or be used in conjunction with asbestos.

> also had a duty to warn about maintenance procedures for their products that would release those dangerous fibers into the air.
>
> The record supports a duty to warn sufficient to survive summary judgment. A trier of fact could conclude that the manufacturers knew or should have known that exposure to released asbestos fibers was a hazard involved in the use of their products. Contrary to the manufacturers' framing of the issue, their duty was not to warn of dangers associated with a third party's product, but of dangerous aspects of their own product: namely, that using their products as intended would very likely result in asbestos exposure.

137 Wn. App. at 49 (emphasis added.)

The Court of Appeals in Simonetta v. VIAD, 137 Wn. App. 15, 151 P.3d 1019 (2007) also correctly found a duty even though the product without the subsequently added asbestos insulation was not hazardous. First, relying both on the Restatement (2d) of Torts and long accepted Washington law, the Court explained:

> [a] manufacturer can also be found negligent for failure to give adequate warning of the hazards involved in the use of the product which are known, or in the exercise of reasonable care should have been known, to the manufacturer." *Novak v. Piggly Wiggly Puget Sound Co.*, 22 Wn. App. 407, 412, 591 P.2d 791 (1979), *see also Restatement (Second) of Torts* § 388 (1965).

137 Wn. App. at 21. Secondly, the Court of Appeals correctly cited testimony in the record by Charles Cushing and Jerry Lauderdale which provided substantial evidence that VIAD would have known that its

evaporators required insulation and that, during the periods in question, such insulation would have both been asbestos-containing and would have posed harm to workers such as Mr. Simonetta. 137 Wn. App. at 22.

Contrary to the arguments of the manufacturers and their amici, it is neither unusual nor inappropriate for a manufacturer of a product to warn of a danger associated with the use of another product in conjunction with the manufacturer's product. Common examples available for those of us who are homeowners or television watchers include the following:

1. The operating instruction to the Weber Gas Ignition Outdoor Grill warns that if you use any flammable liquids in starting that grill, you will likely suffer serious injury or death:

LIGHTING

DANGER

Open lid before lighting. Do not use any flammable liquids such as starting fluid, gasoline, alcohol or any form of self-lighting charcoal at any time, including when manually lighting. Failure to do so will cause serious bodily injury or death.[5]

2. The Material Safety Data Sheet for Clorox Bleach, put out by the Clorox Company explains that if you use Clorox with vinegar or toilet bowl cleaners, you will produce a hazardous gas such as chlorine:

[5] Copy attached as Appendix 1.

VII Reactivity Data

Stable under normal use and storage conditions. Strong oxidizing agent. Reacts with other household chemicals such as toilet bowl cleaners, rust removers, vinegar, acids or ammonia containing products to produce hazardous gases, such as chlorine and other chlorinated species. Prolonged contact with metal may cause pitting or discoloration.[6]

3. The maker of Levitra, an erectile dysfunction tablet, explains in its TV advertisements that bad health effects occur to men who are using nitrates if they take Levitra.[7]

B. *Braaten* And *Simonetta* Correctly Determined Duty Under Washington Product Liability Common Law.

Teagle v. Fischer & Porter Company, 89 Wn.2d 149, 570 P.2d 438 (1977), was relied upon by both the Braaten and Simonetta opinions. Teagle was the first case by this court adopting "the strict liability theory of Restatement (Second) of Torts § 402A (1965)" in the context of warnings. 89 Wn.2d at 154-155. As with Braaten, Teagle involved a situation in which a product – a "flowrator" – became dangerous because of the lack warnings concerning its use in conjunction with a particular kind of gasket – "Viton O-rings" – when used with ammonia.

In Teagle, this Court held that the flowrator's manufacturer had a duty to warn about the damage of using Viton O-rings with ammonia

[6] Copy attached as Appendix 2.

[7] Copy of excerpts of Levitra discussion in Physicians Desk Reference attached as Appendix 3.

although the manufacturer neither manufactured nor supplied the Viton O-rings or the ammonia:

> In addition, appellant knew that Viton O-rings were incompatible with ammonia, yet it did nothing more than recommend the use of Buna O-rings. It did not warn of the dangers which could result from using Viton O-rings with ammonia. The lack of this warning, by itself, would render the flowrator unsafe.

89 Wn.2d at 156.[8] Indeed this Court affirmed summary judgment against the manufacturer of the flowrator.

This Court has also held in the asbestos injury context that under § 402A, manufacturers are strictly liable for failing to give adequate warnings. See Van Hout v. Celotex Corp., 121 Wn.2d 697, 704, 853 P.2d 908 (1993). That duty extended to users of a manufacturer's product and Mr. Braaten was such a foreseeable user. Lunsford v. Saberhagen Holdings, 125 Wn.App. 784, 793, 106 P.3d 808 (2005); Braaten, 137 Wn.App. at 46. Teagle thus provides substantial support per the Braaten court's ruling despite the factual distinction noted by the Court of Appeals.

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[8] As completely explained by the Braaten court:

> Despite the fact that the use of Viton rings and ammonia in the flowrater was entirely the choice of Teagle's employer, the court held the flowrater manufacturer liable for not warning that the use of those products in conjunction with the flowrater made it dangerous. Without proper warnings, the product was defective when used as intended, regardless of the fact that a third-party's product used in conjunction with the flowrater was the precipitating cause of the malfunction and resulting injury.

The public policy set forth in the comments to § 402A also support the finding of a duty under the facts. Comment C to Restatement (Second) § 402A, as quoted and relied upon in Braaten, states:

> "On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper person to afford it are those who market the products."

That part directly supports a duty under the facts of this case.

The court in Simonetta also properly followed Washington law when it held:

> Even though the evaporator left the factory without insulation, it was defective. It had to be encapsulated in insulation for use, yet included no warning about the risk of exposure to a known danger, which would result from disturbing the insulation during ordinary use and necessary maintenance on the units.

That analysis is supported by Teagle which the Simonetta court found "persuasive" rather than controlling. It also is supported by the comments to § 402A, and by Wright v. Stang Manufacturing Co., 54 Cal.App.4th 1218, 1222, 63 Cal.Rptr. 2d 422 (1997).

C. Post *Braaten And Simonetta* Claims Will Not Flood The Courts With Inappropriate Tort Claims; Rather, The Claims Are Ones Which The Tort System Shall Properly Adjudicate.

Several defendants or amici have suggested that the Braaten and Simonetta decisions in the Court of Appeals will flood the courts in Washington with non-citizen "claims" for asbestos injury. See Crane Petition. SGB's experience in the year before and year after those decisions is inconsistent with that argument. Braaten and Simonetta were both decided on January 29, 2007. SGB is one of only several law firms in Washington currently handling asbestos litigation. In the twelve months before January 29, 2007, SGB filed 10 asbestos injury or death cases in Washington courts against one or more of the Braaten or Simonetta defendants. Five involved plaintiffs or decedents who had mesothelioma, three involved lung cancer, and two involved serious asbestosis.[9] Nine of the 10 cases involved shipyard or Navy exposure and all of the cases involved Washington residents.

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[9]
- Allen v. IMO Industries Inc., et al (Cause No. 06-2-17809-2SEA), Filed: 5/30/06; Lung Cancer; PSNS
- Mundy v.IMO Industries Inc., et al (Cause No. 06-2-14464-3SEA), Filed 5/2/06; Mesothelioma; Navy
- Exton for Okabe v. Ingersoll-Rand Co. (Cause No. 06-2-21268-1SEA), Filed 6/30/06; Lung Cancer; PSNS
- Korb v.ACL et al; Korb v. EJB et al (Cause No. 06-2-09607-0 SEA/ 06-2-09608-8 SEA), Filed 3/20/06; Mesothelioma; PSNS
- Baxter v. ACL et al (Cause No. 06-2-21504-4SEA), Filed 7/5/06; Asbestosis ; Crown Zellerbach

In the twelve months following Braaten and Simonetta, SGB filed 11 asbestos injury or death cases against one or more of the Braaten and Simonetta defendants. Ten of the cases filed were mesothelioma cases and one was a lung cancer and asbestos case. Nine of the cases involved Navy or shipyard asbestos exposure, and again, all of the cases were Washington residents.[10] That data, all of which is from complaints on file in King County Superior Court, does not include any cases from non-

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• Small for Raudebaugh v. ACL et al (Cause No. 06-2-16928-0SEA), Filed 5/19/06; Mesothelioma; SeaTac Shipbuilding
• Thomas v. ACL et al (Cause No. 06-2-23613-1SEA), Filed 7/21/06; Mesothelioma; PSNS
• Larson v. ACL et al (Cause No. 06-2-08613-9SEA), Filed 3/10/06; Lung Cancer; PSNS; Lockheed, Navy
• Dinan v.ACL et al; Dinan v. IMO et al; Dinan v. Goulds Pumps et al (Cause No. 06-2-17553-1SEA; 06-2-18327-4SEA; 06-2-31122-1SEA), Filed 5/26/06; 6/5/06; 9/26/06; Asbestosis; PSNS
• Kimball for Kimball v. ACL (Cause No. 06-2-05502-1SEA), Filed 2/10/06; Mesothelioma; Spouse PSNS worker.

[10] • Simpson v. Todd Shipyards Corp. et al (Cause No. 07-2-10599-9SEA), Filed 3/29/07; Mesothelioma; Child of insulator
• Ivanoff for Nyman v. Allis Chamlers et al (Cause No. 07-2-31420-2SEA), Filed 9/26/2007; Mesothelioma; Western Wash., Papermill
• Ackerman v. Bondex Intl et al (Cause No. 07-2-33402-5SEA), Filed 10/16/07; Mesothelioma; Industrial Electrician Western Wash
• Abbay v. Afton Pumps et al; Abbay v. Cla-Val Co. et al (Cause No. 07-2-36537-1SEA/ 07-2-36540-1 SEA), Filed 11/16/07; Mesothelioma; PSNS
• Morganv. Agco Corp et al (Cause No. 07-2-28464-8 SEA), Filed 8/29/07; Mesothelioma; PSNS
• Crawford v. ACL et al; Crawford v. Elliott (Cause No. 07-2-30076-7SEA/ 07-2-30078-3SEA), Filed 9/14/07; Mesothelioma; PSNS
• Williams for Dodson v. ACL et al; Williams for Dodson v. Elliott (Cause No. 07-2-25811-6SEA/ 07-2-25810-8SEA), Filed 8/7/07; Mesothelioma; PSNS
• Justice v. Alfa Laval et al (Cause No. 07-2-30057-1SEA), Filed 9/14/07; Mesothelioma; PSNS
• Honsowetz for Thompson v. CBS (Cause No. 07-2-15745-0SEA/ 07-215744-1SEA), Filed 5/14/07; Asbestosis & Lung Cancer; PSNS
• Richmond v. ACL et al; Richmond v. Elliott (Cause No. 07-2-35314-3SEA/ 07-2-35312-1SEA), Filed 11/2/07; Mesothelioma; PSNS
• Anderson v. Armstrong Intl et al (Cause No. 07-2-40128-8SEA), Filed 12/20/07; Mesothelioma; PSNS

Washington residents. It shows no increase at all that could reasonably be attributed to those decisions. What the information does show from one law firm in only two years is about 20 Washington residents who died or are dying from asbestos-related cancer after working aboard ships containing, among other things, valves, pumps and other machinery manufactured by the Braaten and Simonetta defendants which contained or were insulated with asbestos.

This information also illustrates the data referenced at footnote 2 herein, showing that each year several thousand United States workers die from asbestos-related cancer. Washington courts are not being cluttered with asbestos claims of unimpaired workers; rather, these cases involve dying or dead workers. SGB suggests it is precisely these sort of claims that are a proper subject of the Washington tort system. These equipment manufacturers who used or knew about asbestos were in a good position to instruct or warn workers about products that, years later, killed the workers. That is what "duty" in negligence and product liability should be about.

Those numbers exclude one mesothelioma case in 2006 and three mesothelioma cases in 2007, in which SGB is serving only as local counsel. All four of those cases also involved Washington residents.

III. CONCLUSION

SGB requests that Braaten and Simonetta be affirmed.

RESPECTFULLY SUBMITTED this 8th day of February, 2008.

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APPENDIX 1

PERFORMER TOUCH-N-GO®

TOUCH-N-GO IGNITION

Owner's Manual

⚠DANGER

If you smell gas:

1. **Shut off gas to the appliance.**
2. **Extinguish any open flame.**
3. **Open lid.**
4. **If odor continues, immediately call your gas supplier or your fire department.**

⚠WARNING

1. **Do not store or use gasoline or other flammable vapors and liquids in the vicinity of this or any other appliance.**
2. **An LP tank not connected for use shall not be stored in the vicinity of this or any other appliance.**

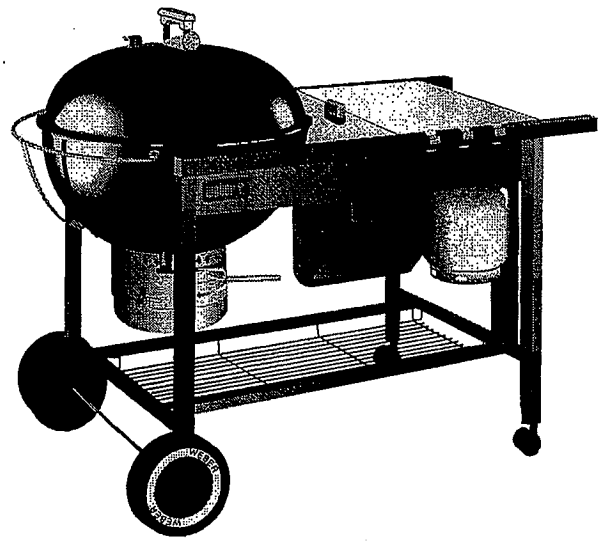
⚠WARNING: Follow all leak check procedures carefully in this manual prior to barbecue operation. Do this even if barbecue was dealer assembled.

NOTICE TO INSTALLER: These instructions must be left with the owner and the owner should keep them for future use.

THIS GAS APPLIANCE IS DESIGNED FOR OUTDOOR USE ONLY.

⚠WARNING: Do not try to light this appliance without reading "Lighting" instructions section of this manual.

Gas Ignition



YOU MUST READ THIS OWNERS GUIDE BEFORE OPERATING YOUR GAS IGNITION GRILL

MEMBER NPGA National PROPANE GAS Association

DESIGN CERTIFIED

55015 02/03/02

Operating Instructions

Lighting

⚠DANGER

Open lid before lighting. Do not use any flammable liquids such as starting fluid, gasoline, alcohol or any form of self-lighting charcoal at any time, including when manually lighting. Failure to do so will cause serious bodily injury or death.

⚠WARNING: Check hose before each use of barbecue for nicks, cracking, abrasions or cuts. If the hose is found to be unserviceable do not use barbecue. Replace using only Weber factory authorized replacement parts. Order from Weber-Stephen Products Co., Customer Service Center, or authorized dealer.

1) Open lid.

2) Clear any ashes from the bowl by moving the control rod side to side. Figure 1.

⚠CAUTION: Be sure that burner slots are free of any ash or obstructions before lighting.

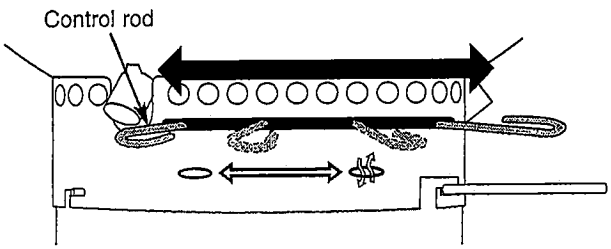


Figure 1

3) Open bottom bowl vents. Figure 2.

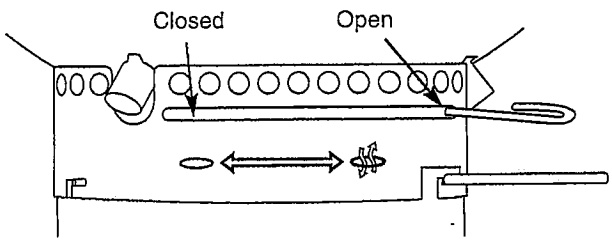


Figure 2

4) Position filled Char-Baskets over burner. Figure 3.

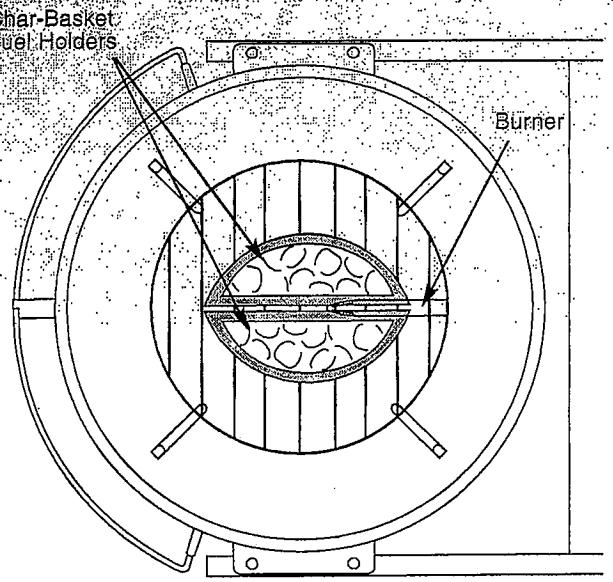


Figure 3

5) Turn gas supply ON (counterclockwise) at LP tank.

⚠WARNING: Do not lean over open barbecue while lighting.

6) Push igniter button until burner ignites.

⚠CAUTION: Flame may be difficult to see on a bright day.

⚠CAUTION: Your LP tank connection is equipped with an excess flow device. If it activates it reduces the flow of gas to the burner. If this should occur turn OFF the LP tank and turn the test valve OFF. Wait 5 minutes for the gas to clear. Then turn ON the LP tank and slowly turn the test valve ON and try to ignite again.

⚠WARNING: If burner fails to ignite, turn tank valve handwheel OFF. Wait five minutes for gas to clear and follow Manual Lighting Instructions.

7) Turn gas supply OFF after charcoal has started to burn *(approximately 3-5 min.)*.

Note - If you are cooking using the Indirect method, separate your Char-Baskets after turning gas supply OFF. Wear barbecue mitts and use long-handled tongs.

8) You can begin cooking when briquets have a light coating of grey ash (approx. 25-30 minutes).

APPENDIX 2

The Clorox Company
1221 Broadway
Oakland, CA 94612
Tel. (510) 271-7000

Material Safety Data Sheet

I Product:	CLOROX REGULAR-BLEACH
Description:	CLEAR, LIGHT YELLOW LIQUID WITH A CHARACTERISTIC CHLORINE ODOR

Other Designations	Distributor	Emergency Telephone Nos.
Clorox Bleach EPA Reg. No. 5813-50	Clorox Sales Company 1221 Broadway Oakland, CA 94612	For Medical Emergencies call: (800) 446-1014 For Transportation Emergencies Chemtrec (800) 424-9300

II Health Hazard Data

DANGER: CORROSIVE. May cause severe irritation or damage to eyes and skin. Vapor or mist may irritate. Harmful if swallowed. Keep out of reach of children.

Some clinical reports suggest a low potential for sensitization upon exaggerated exposure to sodium hypochlorite if skin damage (e.g., irritation) occurs during exposure. Under normal consumer use conditions the likelihood of any adverse health effects are low.

Medical conditions that may be aggravated by exposure to high concentrations of vapor or mist: heart conditions or chronic respiratory problems such as asthma, emphysema, chronic bronchitis or obstructive lung disease.

FIRST AID:

Eye Contact: Hold eye open and rinse with water for 15-20 minutes. Remove contact lenses, after first 5 minutes. Continue rinsing eye. Call a physician.

Skin Contact: Wash skin with water for 15-20 minutes. If irritation develops, call a physician.

Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, call a physician. Do not give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If breathing is affected, call a physician.

III Hazardous Ingredients

Ingredient	Concentration	Exposure Limit
Sodium hypochlorite CAS# 7681-52-9	6.15%	Not established
Sodium hydroxide CAS# 1310-73-2	<1%	2 mg/m$^{3;1}$ 2 mg/m$^{3;2}$

[1]ACGIH Threshold Limit Value (TLV) - Ceiling

[2]OHSA Permissible Exposure Limit (PEL) – Time Weighted Average (TWA)

None of the ingredients in this product are on the IARC, NTP or OSHA carcinogen lists.

IV Special Protection and Precautions

No special protection or precautions have been identified for using this product under directed consumer use conditions. The following recommendations are given for production facilities and for other conditions and situations where there is increased potential for accidental, large-scale or prolonged exposure.

Hygienic Practices: Avoid contact with eyes, skin and clothing. Wash hands after direct contact. Do not wear product-contaminated clothing for prolonged periods.

Engineering Controls: Use general ventilation to minimize exposure to vapor or mist.

Personal Protective Equipment: Wear safety glasses. Use rubber or nitrile gloves if in contact liquid, especially for prolonged periods.

KEEP OUT OF REACH OF CHILDREN

V Transportation and Regulatory Data

DOT/IMDG/IATA - Not restricted.

EPA - SARA TITLE III/CERCLA: Bottled product is not reportable under Sections 311/312 and contains no chemicals reportable under Section 313. This product does contain chemicals (sodium hydroxide <0.2% and sodium hypochlorite <7.35%) that are regulated under Section 304/CERCLA.

TSCA/DSL STATUS: All components of this product are on the U.S. TSCA Inventory and Canadian DSL.

VI Spill Procedures/Waste Disposal

Spill Procedures: Control spill. Containerize liquid and use absorbents on residual liquid; dispose appropriately. Wash area and let dry. For spills of multiple products, responders should evaluate the MSDS's of the products for incompatibility with sodium hypochlorite. Breathing protection should be worn in enclosed, and/or poorly ventilated areas until hazard assessment is complete.

Waste Disposal: Dispose of in accordance with all applicable federal, state, and local regulations.

VII Reactivity Data

Stable under normal use and storage conditions. Strong oxidizing agent. Reacts with other household chemicals such as toilet bowl cleaners, rust removers, vinegar, acids or ammonia containing products to produce hazardous gases, such as chlorine and other chlorinated species. Prolonged contact with metal may cause pitting or discoloration.

VIII Fire and Explosion Data

Flash Point: None

Special Firefighting Procedures: None

Unusual Fire/Explosion Hazards: None. Not flammable or explosive. Product does not ignite when exposed to open flame.

IX Physical Data

Boiling point	approx. 212°F/100°C
Specific Gravity (H_20=1)	~ 1.1 at 70°F
Solubility in Water	complete
pH	~11.4

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DATA SUPPLIED IS FOR USE ONLY IN CONNECTION WITH OCCUPATIONAL SAFETY AND HEALTH DATE PREPARED 05/05

APPENDIX 3

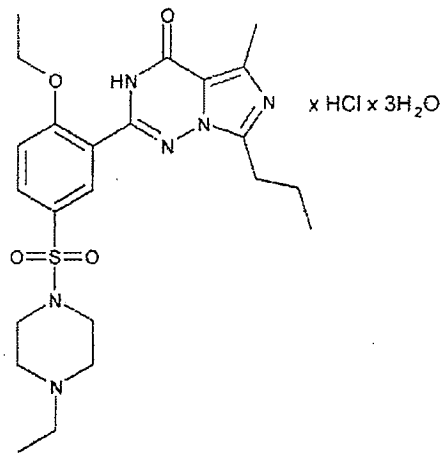
LEVITRA®
(vardenafil HCl)
TABLETS

08918646. R.4 10/07

DESCRIPTION

LEVITRA® is an oral therapy for the treatment of erectile dysfunction. This monohydrochloride salt of vardenafil is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5).

Vardenafil HCl is designated chemically as piperazine, 1-[[3-(1,4-dihydro-5-methyl-4-oxo-7-propylimidazo[5,1-*f*][1,2,4]triazin-2-yl)-4-ethoxyphenyl]sulfonyl]-4-ethyl-, monohydrochloride and has the following structural formula:



Vardenafil HCl is a nearly colorless, solid substance with a molecular weight of 579.1 g/mol and a solubility of 0.11 mg/mL in water. LEVITRA is formulated as orange, round, film-coated tablets with "BAYER" cross debossed on one side and "2.5", "5", "10", and "20" on the other side corresponding to 2.5 mg, 5 mg, 10 mg, and 20 mg of vardenafil, respectively. In addition to the active ingredient, vardenafil HCl, each tablet contains microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide, yellow ferric oxide, and red ferric oxide.

CLINICAL PHARMACOLOGY

Mechanism of Action

Penile erection is a hemodynamic process initiated by the relaxation of smooth muscle in the corpus cavernosum and its associated arterioles. During sexual stimulation, nitric oxide is released from nerve endings and endothelial cells in the corpus cavernosum. Nitric oxide activates the enzyme guanylate cyclase resulting in increased synthesis of cyclic guanosine monophosphate (cGMP) in the smooth muscle cells of the corpus cavernosum. The cGMP in turn triggers smooth muscle relaxation, allowing increased blood flow into the penis, resulting in erection. The tissue concentration of cGMP is regulated by both the rates of synthesis and degradation via phosphodiesterases (PDEs). The most abundant PDE in the

Patients should be advised to contact the prescribing physician if new medications that may interact with LEVITRA are prescribed by another healthcare provider.

Physicians should advise patients to stop use of all PDE5 inhibitors, including LEVITRA, and seek medical attention in the event of sudden loss of vision in one or both eyes. Such an event may be a sign of non-arteritic anterior ischemic optic neuropathy (NAION), a cause of decreased vision, including permanent loss of vision, that has been reported rarely post-marketing in temporal association with the use of all PDE5 inhibitors. It is not possible to determine whether these events were related directly to the use of PDE5 inhibitors or to other factors. Physicians should also discuss with patients the increased risk of NAION in individuals who have already experienced NAION in one eye, including whether such individuals could be adversely affected by use of vasodilators such as PDE5 inhibitors (see **POST-MARKETING EXPERIENCE, Ophthalmologic**).

Physicians should advise patients to stop taking PDE5 inhibitors, including LEVITRA, and seek prompt medical attention in the event of sudden decrease or loss of hearing. These events, which may be accompanied by tinnitus and dizziness, have been reported in temporal association to the intake of PDE5 inhibitors, including LEVITRA. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors or to other factors (see **ADVERSE REACTIONS**).

Physicians should discuss with patients the potential cardiac risk of sexual activity for patients with preexisting cardiovascular risk factors.

The use of LEVITRA offers no protection against sexually transmitted diseases. Counseling of patients about protective measures necessary to guard against sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV), should be considered.

Physicians should inform patients that there have been rare reports of prolonged erections greater than 4 hours and priapism (painful erections greater than 6 hours in duration) for LEVITRA and this class of compounds. In the event that an erection persists longer than 4 hours, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

Drug Interactions

Effect of other drugs on LEVITRA

In vitro studies: Studies in human liver microsomes showed that vardenafil is metabolized primarily by cytochrome P450 (CYP) isoforms 3A4/5, and to a lesser degree by CYP2C9. Therefore, inhibitors of these enzymes are expected to reduce vardenafil clearance (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

In vivo studies: Cytochrome P450 Inhibitors

Cimetidine (400 mg b.i.d.) had no effect on vardenafil bioavailability (AUC) and maximum concentration (C_{max}) of vardenafil when co-administered with 20 mg LEVITRA in healthy volunteers.

Erythromycin (500 mg t.i.d.) produced a 4-fold increase in vardenafil AUC and a 3-fold increase in C_{max} when co-administered with LEVITRA 5 mg in healthy volunteers (see **DOSAGE AND ADMINISTRATION**). It is recommended not to exceed a single 5 mg dose of LEVITRA in a 24-hour period when used in combination with erythromycin.

Ketoconazole (200 mg once daily) produced a 10-fold increase in vardenafil AUC and a 4-fold increase in C_{max} when co-administered with LEVITRA (5 mg) in healthy volunteers. A

5-mg LEVITRA dose should not be exceeded when used in combination with 200 mg once daily ketoconazole. Since higher doses of ketoconazole (400 mg daily) may result in higher increases in C_{max} and AUC. a single 2.5 mg dose of LEVITRA should not be exceeded in a 24-hour period when used in combination with ketoconazole 400 mg daily (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

HIV Protease Inhibitors:

Indinavir (800 mg t.i.d.) co-administered with LEVITRA 10 mg resulted in a 16-fold increase in vardenafil AUC, a 7-fold increase in vardenafil C_{max} and a 2-fold increase in vardenafil half-life. It is recommended not to exceed a single 2.5 mg LEVITRA dose in a 24-hour period when used in combination with indinavir (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

Ritonavir (600 mg b.i.d.) co-administered with LEVITRA 5 mg resulted in a 49-fold increase in vardenafil AUC and a 13-fold increase in vardenafil C_{max}. The interaction is a consequence of blocking hepatic metabolism of vardenafil by ritonavir, a highly potent CYP3A4 inhibitor, which also inhibits CYP2C9. Ritonavir significantly prolonged the half-life of vardenafil to 26 hours. Consequently, it is recommended not to exceed a single 2.5 mg LEVITRA dose in a 72-hour period when used in combination with ritonavir (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

Other CYP3A4 inhibitors: Although specific interactions have not been studied, other CYP3A4 inhibitors, including grapefruit juice would likely increase vardenafil exposure.

Other Drug Interactions: No pharmacokinetic interactions were observed between vardenafil and the following drugs: glyburide, warfarin, digoxin, Maalox, and ranitidine. In the warfarin study, vardenafil had no effect on the prothrombin time or other pharmacodynamic parameters.

Effects of LEVITRA on other drugs

In vitro studies:

Vardenafil and its metabolites had no effect on CYP1A2, 2A6, and 2E1 (Ki >100 μM). Weak inhibitory effects toward other isoforms (CYP2C8, 2C9, 2C19, 2D6, 3A4) were found, but Ki values were in excess of plasma concentrations achieved following dosing. The most potent inhibitory activity was observed for vardenafil metabolite M1, which had a Ki of 1.4 μM toward CYP3A4, which is about 20 times higher than the M1 C_{max} values after an 80 mg LEVITRA dose.

In vivo studies:

Nitrates: The blood pressure lowering effects of sublingual nitrates (0.4 mg) taken 1 and 4 hours after vardenafil and increases in heart rate when taken at 1, 4 and 8 hours were potentiated by a 20 mg dose of LEVITRA in healthy middle-aged subjects. These effects were not observed when LEVITRA 20 mg was taken 24 hours before the NTG. Potentiation of the hypotensive effects of nitrates for patients with ischemic heart disease has not been evaluated, and concomitant use of LEVITRA and nitrates is contraindicated (see **CLINICAL PHARMACOLOGY, Pharmacodynamics, Effects on Blood Pressure and Heart Rate when LEVITRA is Combined with Nitrates; CONTRAINDICATIONS**).

Nifedipine: Vardenafil 20 mg, when co-administered with slow-release nifedipine 30 mg or 60 mg once daily, did not affect the relative bioavailability (AUC) or maximum concentration (C_{max}) of nifedipine, a drug that is metabolized via CYP3A4. Nifedipine did not alter the

plasma levels of LEVITRA when taken in combination. In these patients whose hypertension was controlled with nifedipine, LEVITRA 20 mg produced mean additional supine systolic/diastolic blood pressure reductions of 6/5 mmHg compared to placebo.

Alpha-blockers:

Blood pressure effects in patients on stable alpha-blocker treatment:

Two clinical pharmacology studies were conducted in patients with benign prostatic hyperplasia (BPH) on stable-dose alpha-blocker treatment for at least four weeks.

Study 1: This study was designed to evaluate the effect of 5 mg vardenafil compared to placebo when administered to BPH patients on chronic alpha-blocker therapy in two separate cohorts: tamsulosin 0.4 mg daily (cohort 1, n=21) and terazosin 5 or 10 mg daily (cohort 2, n=21). The design was a randomized, double blind, cross-over study with four treatments: vardenafil 5 mg or placebo administered simultaneously with the alpha-blocker and vardenafil 5 mg or placebo administered 6 hours after the alpha-blocker. Blood pressure and pulse were evaluated over the 6-hour interval after vardenafil dosing. For BP results see Table 2. One patient after simultaneous treatment with 5 mg vardenafil and 10 mg terazosin exhibited symptomatic hypotension with standing blood pressure of 80/60 mmHg occurring one hour after administration and subsequent mild dizziness and moderate lightheadedness lasting for 6 hours. For vardenafil and placebo, five and two patients, respectively, experienced a decrease in standing systolic blood pressure (SBP) of >30 mmHg following simultaneous administration of terazosin. Hypotension was not observed when vardenafil 5 mg and terazosin were administered 6 hours apart. Following simultaneous administration of vardenafil 5 mg and tamsulosin, two patients had a standing SBP of <85 mmHg; two and one patient (vardenafil and placebo, respectively) had a decrease in standing SBP of >30 mmHg. When tamsulosin and vardenafil 5 mg were separated by 6 hours, two patients had a standing SBP <85 mmHg and one patient had a decrease in SBP of >30 mmHg. There were no severe adverse events related to hypotension reported during the study. There were no cases of syncope.

Table 2: Mean (95% C.I.) maximal change from baseline in systolic blood pressure (mmHg) following vardenafil 5 mg in BPH patients on stable alpha-blocker therapy (Study 1)

Alpha-Blocker		Simultaneous dosing of Vardenafil 5 mg and Alpha-Blocker, Placebo-Subtracted	Dosing of Vardenafil 5 mg and Alpha-Blocker Separated by 6 Hours, Placebo-Subtracted
Terazosin 5 or 10 mg daily	Standing SBP	-3 (-6.7, 0.1)	-4 (-7.4, -0.5)
	Supine SBP	-4 (-6.7, -0.5)	-4 (-7.1, -0.7)
Tamsulosin 0.4 mg daily	Standing SBP	-6 (-9.9, -2.1)	-4 (-8.3, -0.5)
	Supine SBP	-4 (-7.0, -0.8)	-5 (-7.9, -1.7)

Blood pressure effects (standing SBP) in normotensive men on stable dose tamsulosin 0.4 mg following simultaneous administration of vardenafil 5 mg or placebo, or following administration of vardenafil 5 mg or placebo separated by 6 hours are shown in Figure 3. Blood pressure effects (standing SBP) in normotensive men on stable dose terazosin (5 or 10 mg) following simultaneous administration of vardenafil 5 mg or placebo, or following administration of vardenafil 5 mg or placebo separated by 6 hours, are shown in Figure 4.