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that reasonably supports the conclusion that a product creates an unreasonable risk of serious injury or death. Previously, the reporting obligation for unregulated products only arose when available information indicated that the product in question was defective and created a substantial product hazard because of the pattern of the defect, the severity of the risk of injury, the number of products distributed in commerce, etc. The effect of the 1990 amendment is discussed in detail in the Commission's interpretative rule relating to the reporting of substantial product hazards at 16 CFR part 1115.

(2) The new substantive reporting requirements of section 15(b)(3) support the conclusion that Congress intended section 37 to capture product-related accident information that has not been reported under section 15(b). Between the time a firm learns of an incident or problem involving a product that raises safety-related concerns and the time that a lawsuit involving that product is resolved by settlement or adjudication, the firm generally has numerous opportunities to evaluate whether a section 15 report is appropriate. Such evaluation might be appropriate, for example, after an analysis of product returns, the receipt of an insurance investigator's report, a physical examination of the product, the interview or deposition of an injured party or an eyewitness to the event that gave rise to the lawsuit, or even preparation of the firm's responses to plaintiff's discovery requests. Even if a manufacturer does not believe that a report is required prior to the resolution of a single lawsuit, an obligation to investigate whether a report is appropriate may arise if, for example, a verdict in favor of the plaintiff raises the issue of whether the product in question creates an unreasonable risk of death or serious injury.

(3) In contrast, the application of section 37 does not involve the discretionary judgment and subjective analyses of hazard and causation associated with section 15 reports. Once the statutory criteria of three settled or adjudicated civil actions alleging grievous injury or death in a two year period are met, the obligation to report under section 37 is automatic. For this reason,

the Commission regards section 37 as a 'safety net' to surface product hazards that remain unreported either intentionally or by inadvertence. The provisions in the law limiting such reports to cases in which three or more lawsuits alleging grievous injury or death are settled or adjudicated in favor of plaintiffs during a two year period provide assurance that the product involved presents a sufficiently grave risk of injury to warrant consideration by the Commission. Indeed, once the obligation to report under section 37 arises, the obligation to file a section 15 report concurrently may exist if the information available to the manufacturer meets the criteria established in section 15(b) for reporting.

(4) Section 37 contains no specific record keeping requirements. However, to track and catalog lawsuits to determine whether they are reportable, prudent manufacturers will develop and maintain information systems to index and retain lawsuit data. In the absence of a prior section 15 report, once such systems are in place, such manufacturers will be in a position to perform a two-fold analysis to determine whether the information contained in such systems is reportable under either section 15(b) or 37. A manufacturer might conclude, for example, that the differences between products that are the subject of different lawsuits make them different models or that the type of injury alleged in one or more of the suits is not grievous bodily injury. Based on this analysis, the manufacturer might also conclude that the suits are thus not reportable under section 37. However, a reporting obligation under section 15 may exist in any event if the same information reasonably supports the conclusion that the product(s) contain a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death.

## § 1116.8 Determination of particular model.

(a) The obligation rests with the manufacturer of a product to determine whether a reasonable basis exists to conclude that a product that is the subject of a settled or adjudicated lawsuit is sufficiently different from other

similar products to be regarded as a 'particular model' under section 37 because it is "distinctive." To determine whether a product is "distinctive", the proper inquiry should be directed toward the degree to which a product differs from other comparable products in one or more of the characteristics enumerated in section 37(e)(2) and §1116.2(c) of this part. A product is "distinctive" if, after an analysis of information relating to one or more of the statutory characteristics, a manufacturer, acting in accordance with the customs and practices of the trade of which it is a member, could reasonably conclude that the difference between that product and other items of the same product class manufactured or imported by the same manufacturer is substantial and material. Information relevant to the determination of whether a product is a "particular model" includes:

- (1) The description of the features and uses of the products in question in written material such as instruction manuals, description brochures, marketing or promotional programs, reports of certification of products, specification sheets, and product drawings.
- (2) The differences or similarities between products in their observable physical characteristics and in components or features that are not readily observable and that are incorporated in those products for safety-related purposes:
- (3) The customs and practices of the trade of which the manufacturer is a member in marketing, designating, or evaluating similar products.
- (4) Information on how consumers use the products and on consumer need or demand for different products, such as products of different size. In analyzing whether products are different models, differences in size or calibration afford the basis for distinguishing between products only if those differences make the products distinctive in functional design or function.
- (5) The history of the manufacturer's model identification and marketing of the products in question;
- (6) Whether variations between products relate solely to appearance, ornamentation, color, or other cosmetic features; such variations are not ordi-

narily sufficient to differentiate between models.

- (7) Whether component parts used in a product are interchangeable with or perform substantially the same function as comparable components in other units; if they are, the use of such components does not afford a basis for distinguishing between models.
- (8) Retail price. Substantial variations in price arising directly from the characteristics enumerated in section 37(e)(2) for evaluating product models may be evidence that products are different models because their differences are distinctive. Price variations imposed to accommodate different markets or vendors are not sufficient to draw such a distinction.
- (9) Manufacturer's designation, model number, or private label designation. These factors are not controlling in identifying "particular models".
- (10) Expert evaluation of the characteristics of the products in question, and surveys of consumer users or a manufacturer's retail customers.
- (b) The definition of "consumer product" expressly applies to components of consumer products. Should a component manufacturer be joined in a civil action against a manufacturer of a consumer product, the section 37 reporting requirements may apply to that manufacturer after a combination of three judgments or settlements involving the same component model during a two year period, even though the manufacturer of the finished product is exempt from such reporting because the lawsuits do not involve the same particular model of the finished consumer product. The same proposition holds true for common components used in different consumer products. If the manufacturer of such a component is a defendant in three suits and the requisite statutory criteria are met, the reporting obligations apply.
- (c) Section 37 expressly defines the reporting obligation in terms of the particular model of a product rather than the manner in which a product was involved in an accident. Accordingly, even if the characteristic of a product that caused or resulted in the deaths of grievous injuries alleged in three or more civil actions is the same

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in all of the suits, the requirement to report under section 37 would arise only if the same particular model was involved in at least three of the suits. However, the existence of such a pattern would strongly suggest that the obligation to file a report under section 15(b) (2) or (3) (15 U.S.C. 2064(b) (2) or (3)) exists because the information reasonably supports the conclusion that the product contains a defect that could present a substantial risk of injury to the public or creates an unreasonable risk of serious injury or death.

(d) Section 37 does not require that the same category of injury be involved in multiple lawsuits for the reporting obligation to arise. As long as a particular model of a consumer product is the subject of at least three civil actions that are settled or adjudicated in favor of the plaintiff in one of the statutory two year periods, the manufacturer must report, even though the alleged category of injury and the alleged causal relationship of the product to the injury in each suit may differ.

## § 1116.9 Confidentiality of reports.

- (a) Pursuant to section 6(e) of the Consumer Product Safety Act (15 U.S.C. 2055(e)) no member of the Commission, no officer or employee of the Commission, and no officer or employee of the Department of Justice may publicly disclose information furnished to the Commission under section 37(c)(1) and section 37(c)(2)(A) of the Act, except that:
- (1) An authenticated copy of a section 37 report furnished to the Commission by or on behalf of a manufacturer may, upon written request, be furnished to the manufacturer or its authorized agent after payment of the actual or estimated cost of searching the records and furnishing such copies; or
- (2) Any information furnished to the Commission under section 37 shall, upon written request of the Chairman or Ranking Minority Member of the Committee on Commerce, Science, and Transportation of the Senate or the Committee on Energy and Commerce of the House of Representatives or any subcommittee of such committee, be provided to the Chairman or Ranking Minority Member for purposes that are

related to the jurisdiction of such committee or subcommittee.

(b) The prohibition contained in section 6(e) (15 U.S.C. 2055(e)) against the disclosure of information submitted pursuant to section 37 only applies to the specific items of information that a manufacturer is required to submit under section 37(c)(1) and to statements under section 37(c)(2)(A) relating to the possibility or existence of an appeal of a reported judgment adverse to a manufacturer. Section 6(e)(1) does not, by its terms, apply to information that the manufacturer voluntarily chooses to submit pursuant to section 37(c)(2)(B). Thus, disclosure of such information is governed by the other provisions of section 6 of the CPSA (15 U.S.C. 2055) and by the interpretative rules issued by the Commission (16 CFR parts 1101 and 1015). For example, if a manufacturer includes information otherwise reportable under section 15 as part of a section 37 report, the Commission will treat the information reported pursuant to section 15 as "additional information" submitted pursuant to section 37(c)(2)(B). Generally, any issue of the public disclosure of that information will be controlled by the relevant provisions of section 6(b), including section 6(b)(5) relating to the disclosure of substantial product hazard reports, and section 6(a) relating to the disclosure of confidential or trade secret information. However, to the extent the section 15 report reiterates or references information reported under section 37, the confidentiality provisions of section 6(e) still apply to the reiteration or reference. In addition, interpretative regulations issued under section 6(b) of the Act establish that disclosure of certain information may be barred if the disclosure would not be fair in the circumstances. 16 CFR 1101.33. Accordingly, issues of releasing additional information submitted pursuant to section 37 will also be evaluated under the fairness provisions of section 6(b). Should the Commission receive a request for such information or contemplate disclosure on its own initiative, the manufacturer will be given an opportunity to present arguments to the Commission why the information should not be disclosed, including, if appropriate, why disclosure