**[J-52A-2019 and J-52B-2019]**
**IN THE SUPREME COURT OF PENNSYLVANIA**
**EASTERN DISTRICT**

**SAYLOR, C.J., BAER, TODD, DONOHUE, DOUGHERTY, WECHT, MUNDY, JJ.**

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| IN RE: RISPERDAL LITIGATION<br>JONATHAN SAKSEK,<br><br>Appellant<br><br>v.<br><br>JANSSEN PHARMACEUTICALS, INC.,<br>JOHNSON & JOHNSON COMPANY,<br>JANSSEN RESEARCH AND<br>DEVELOPMENT, LLC,<br><br>Appellees | : | No. 22 EAP 2018<br><br>Appeal from the Judgment of Superior Court entered on November 13, 2017 at No. 576 EDA 2015 (reargument denied January 16, 2018) affirming the Judgment entered on February 12, 2015 in the Court of Common Pleas , Philadelphia County, Civil Division at No. 00183 February Term, 2014, No. 296 March Term, 2010<br><br>ARGUED: May 16, 2019 |
| IN RE: RISPERDAL LITIGATION<br>JOSHUA WINTER,<br><br>Appellant<br><br>v.<br><br>JANSSEN PHARMACEUTICALS, INC.,<br>JOHNSON & JOHNSON COMPANY,<br>JANSSEN RESEARCH AND<br>DEVELOPMENT, LLC,<br><br>Appellees | : | No. 23 EAP 2018<br><br>Appeal from the Judgment of Superior Court entered on November 13, 2017 at No. 590 EDA 2015 (reargument denied January 16, 2018) affirming the Judgment entered on February 10, 2015 in the Court of Common Pleas , Philadelphia County, Civil Division at No. 01170 March Term, 2014, 296 March Term, 2010<br><br>ARGUED: May 16, 2019 |

**OPINION**

**JUSTICE DONOHUE** **DECIDED: November 20, 2019**

In this consolidated appeal, Appellants Jonathan Saksek ("Saksek") and Joshua Winter ("Winter") challenge the ruling of the Superior Court affirming the trial court's grant of summary judgment in favor of Appellees Janssen Pharmaceuticals, Inc., Johnson & Johnson Company, and Janssen Research and Development, LLC (collectively, "Janssen"). Saksek and Winter are two of a large number of men who have filed suit against Janssen alleging that they developed gynecomastia (enlarged breasts in men) as a result of their ingestion of Risperdal, an antipsychotic drug manufactured by Janssen. In 2014, Janssen filed two motions for summary judgment, which, although nominally directed at Saksek's and Winter's cases, were couched in terms directed at all of the Risperdal plaintiffs – seeking a global ruling that all claims accrued for statute of limitations purposes no later than October 31, 2006, when Janssen changed the Risperdal label to reflect a greater association between gynecomastia and Risperdal. The trial court ruled that all Risperdal-gynecomastia claims, including those of Saksek and Winter, accrued no later June 31, 2009. The Superior Court disagreed, ruling that all such claims accrued no later than Janssen's preferred date (October 31, 2006). Concluding that the Superior Court erred in granting summary judgment at all in Saksek's and Winter's cases, we vacate its decision and remand to the trial court for further proceedings consistent with this decision.

## I. RELEVANT BACKGROUND

### A. Risperdal

Risperdal®, also known in its generic form as risperidone, is a second-generation antipsychotic prescription medication. It is manufactured and sold by Janssen Pharmaceuticals, Inc., a wholly owned and independently managed subsidiary of

Johnson & Johnson Company. The federal Food and Drug Administration ("FDA") first approved Risperdal in 1993 for certain adult uses, like schizophrenia. At the time that Risperdal was prescribed to Saksek and Winter, it was for an "off label" use because the FDA had not approved its use either for children generally or for any condition from which they were suffering. The FDA subsequently approved Risperdal for a number of other diseases and patient populations, including in 2003 for bipolar disorder in adults, in 2006 for irritability associated with autistic disorder in children and adolescents aged 5-16 years, and in 2007 for schizophrenia in adolescents aged 13-17 years and bipolar disorder in children and adolescents aged 10-17.

Gynecomastia is an endocrine disorder that is characterized by "swelling of the breast tissue in boys or men, caused by an imbalance of the hormones estrogen and testosterone." *Enlarged Breasts in Men (Gynecomastia)*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/gynecomastia/symptoms-causes/syc-20351793 (last visited Oct. 28, 2019). Janssen does not dispute that Risperdal sometimes causes hyperprolactinemia, an elevation of prolactin, a hormone secreted by the pituitary gland. Prolactin sometimes suppresses testosterone, which in turn boosts estrogen, both of which may result in the development of breast tissue. *Stange v. Janssen Pharmaceuticals, Inc.*, 179 A.3d 45, 54-55 (Pa. Super. 2018).

In the prescribing insert (sometimes referred to as the drug's "label") for Risperdal prior to 2006 (during the time when Saksek and Winter were taking the drug), there was no mention of hyperprolactinemia or gynecomastia in either its 'WARNINGS" or "ADVERSE REACTIONS" sections. In the "PRECAUTIONS" section, the label provided as follows:

> Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. . . . Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients.

Saksek's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 4 at 7. In a section entitled "Other Events Observed During the Pre-Marketing Evaluation of Risperdal," gynecomastia was identified as an endocrine disorder and a "rare" adverse event. *Id.* at 19.

When the FDA approved Risperdal for pediatric use in October 2006, the label was changed to provide:

> Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.
>
> * * *
>
> Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin elevating compounds.
>
> * * *
>
> In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorder treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.3% of Risperdal-treated patients.

*Id.* Ex. 6 at 15, 24.

### B. The Saksek and Winter Claims

Saksek was born in 1987. He grew up in and continues to reside in Hazelton, Pennsylvania. In 1998, at age 11, his psychiatrist prescribed Risperdal in connection with diagnoses for attention deficit hyperactivity disorder and bipolar disorder. Janssen's

Motion for Summary Judgment (Saksek), 8/18/2014, Ex. 1 at 5. He discontinued the use of Risperdal in 2004. *Id.* On February 4, 2014, Saksek filed a short-form complaint, *id.* Ex. 2, which in turn incorporated by reference a master long-form complaint developed and amended over time by the plaintiffs in the mass-tort litigation.[1] *Id.* Ex. 11. The master long-form complaint asserts twelve claims based on state common law, products liability and deceptive trade practices,[2] all based upon the allegation that Janssen failed to warn plaintiffs and their prescribers about the risks associated with Risperdal. *Id.* In a "Plaintiff's Fact Sheet" attached as an exhibit to the long-form complaint, Saksek reported that in 2001 through 2002, he became aware, through "visual observation," of increased breast size, extreme weight gain, and psychological and emotional distress. *Id.* Ex. 1 at 7.

Winter was born in May 1980 in Harrisburg, Pennsylvania and continues to reside there. In 1997, Winter began taking Risperdal to control anger management issues. Janssen's Motion for Summary Judgment (Winter), 8/18/2014, Ex.1 at 4. He stopped using Risperdal in 1998. *Id.* In his short-form complaint, Winter represented that he suffered from weight gain and diabetes while taking Risperdal. *Id.* Ex. 5 at 2-4. In his "Plaintiff's Fact Sheet," Winter reported that in 1998, he perceived, through "self-

[1] Saksek's and Winter's complaints were consolidated as part of the *In re: Risperdal Litigation* mass tort programs in the Court of Common Pleas of Philadelphia County.

[2] While these claims have statutes of limitations of varying lengths and although both Winter and Saksek took Risperdal when they were minors, neither of them contests that, absent tolling by the discovery rule, all of their claims would be untimely given the dates of the filing of their complaints in relation to the dates on which they turned eighteen. *See Fancsali v. Univ. Health Center of Pittsburgh*, 761 A.2d 1159, 1164 (Pa. 2000) ("[T]he period within which a minor's action must be commenced is measured not from the time the cause of action accrues, but from the time he or she turns eighteen.").

observation," that he was experiencing breast development and psychological and emotional distress. Janssen's Motion for Summary Judgment (Winter), 8/18/2014, Ex.1 at 6.

In connection with the filing of their complaints, both Saksek and Winter submitted affidavits swearing that, inter alia, (1) they filed their complaints after being informed by their mothers who had viewed a television commercial in 2013 describing the relationship between gynecomastia and Risperdal; (2) they are not medical professionals and did not know anything about Risperdal other than that it had been prescribed to them; (3) they followed their doctors' instructions in taking Risperdal; (4) no doctor told them or their parents that their breast growth and weight gain could have been caused by anything to which they were exposed or ingested; (5) no doctor ever told them or their parents that Risperdal was the cause of their breast growth and weight gain; and (6) they now understood that their breast growth is referred to as gynecomastia, a term they had never heard of until shortly before signing their affidavits. Saksek's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 3; Winter's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 3.

**C. Janssen's Partial Motions for Summary Judgment**

On May 19, 2014, Janssen filed a motion for partial summary judgment on the issue of the statute of limitations on a global basis (without naming any individual plaintiffs). Therein, Janssen asked the trial court to enter an order holding, inter alia, that all plaintiffs were on constructive and/or inquiry notice of a potential connection between Risperdal use and gynecomastia by no later than October 31, 2006, and that for any gynecomastia injury prior to October 31, 2006 any applicable tort or product liability

statute of limitations began to run no later than October 31, 2006. Janssen's Motion for Partial Summary Judgment as to the Affirmative Defense of the Statute of Limitations, 5/19/2015, Proposed Order. The parties fully briefed this global motion, but the trial court did not issue a ruling.

On August 18, 2014, Janssen filed motions for summary judgment in the *Winter* and *Saksek* cases. Janssen incorporated by reference the arguments in its global summary judgment motion into these motions. Janssen's Motion for Summary Judgment (Winter), 8/18/2014, at 8 n.10; Janssen's Motion for Summary Judgment (Saksek), 8/18/2014, at 8 n.9. In its moving papers, Janssen contended that both plaintiffs were placed on inquiry notice of their potential Risperdal claim by no later than October 31, 2006 as a result of the drug's label change. On January 13, 2015, the trial court entered an order and opinion granting Janssen's motion for summary judgment in the *Winter* case, ruling in the opinion that any claim filed after June 31, 2009 must be dismissed on statute of limitations grounds based upon the cumulative effect of medical literature, newspaper articles and attorney advertising present by that point in time. *Winter v. Janssen Pharmaceuticals, Inc.*, 2015 WL 4578416, at *8 (Pa.Com.Pl. Jan. 13, 2015). On January 31, 2015, the trial court also granted Janssen's motion for summary judgment in the *Saksek* case, referring in its accompanying opinion that it was doing so for the reasons set forth in its *Winter* opinion. In a new case management order, the trial court placed approximately twenty percent of all cases on the Risperdal master docket in suspense, indicating that if "the appellate courts affirm this [c]ourt's analysis in *Winter* regarding the accrual date for Risperdal claims under Pennsylvania's discovery rule," then summary

judgment would be entered in all of the suspended cases on statute of limitations grounds. Case Management Order #10, 9/22/2015, at 1-2.

On appeal, a three-judge panel of the Superior Court affirmed in principal part.[3] The intermediate appellate court agreed that the entry of summary judgment against Winter and Saksek was appropriate, but moved the accrual for causes of action related to Risperdal back from June 31, 2009 to October 31, 2006 – the date on which Janssen changed the Risperdal label to reflect, inter alia, the relative rates for gynecomastia in pediatric clinical trials. *In re: Risperdal Litig.*, 2017 WL 5256400, at *6 (Pa. Super. Nov. 13, 2017). The Superior Court held that the 2006 label change sufficiently tied the usage of Risperdal to the incidence of gynecomastia such that Winter and Saksek should have known of their injuries and the relationship between those injuries and Risperdal. *Id.*

This Court granted discretionary review to consider whether summary judgment should have been granted in Janssen's favor on statute of limitations grounds. *In re: Risperdal Litigation*, 189 A.3d 376 (Pa. 2018). An appellate court may reverse a grant of summary judgment if there has been an error of law or an abuse of discretion. *Fine v. Checcio*, 870 A.2d 850, 857 n.3 (Pa. 2005). "[S]ummary judgment is appropriate only in those cases where the record clearly demonstrates that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." *Atcovitz v. Gulph Mills Tennis Club, Inc.*, 812 A.2d 1218, 1221 (Pa. 2002); Pa.R.C.P. 1035.2(1). The trial court must take all facts of record and reasonable inferences therefrom in a light most favorable to the non-moving party. *Toy v. Metropolitan Life Ins. Co.*, 928 A.2d 186, 195 (Pa. 2007). In so doing, the trial court must resolve all doubts as to the existence of

[3] Judge Fitzgerald concurred only in the result.

a genuine issue of material fact against the moving party, and, thus, may only grant summary judgment "where the right to such judgment is clear and free from all doubt." *Summers v. Certainteed Corp.*, 997 A.2d 1152, 1159 (Pa. 2010). Because the issue presented requires us to decide whether there are genuine issues of material fact is a question of law, our standard of review is de novo and our scope of review is plenary. *Fine*, 870 A.2d at 857 n.3.

## II. THE ARGUMENTS OF THE PARTIES

Saksek and Winter argue that the record does not provide any basis for concluding, as a matter of law, that they knew or should have known with the exercise of reasonable diligence that the condition they were experiencing was not the product of excessive weight gain, but rather was the result of the abnormal growth of female breast tissue caused by their ingestion of Risperdal. Saksek/Winter's Brief at 15. They contend that gynecomastia was not described to them when they were prescribed Risperdal or warned that its ingestion could result in gynecomastia. *Id.* at 14. Neither boy had any reason to believe that they were not experiencing a buildup of fatty tissue but rather were suffering from an endocrine disorder caused by a drug they took for entirely different reasons (psychotic disorders). *Id.* Since neither of them had any medical background, they had no understanding of changes to hormone levels as a result of prolactin changes, or of the possibility (much less the likelihood) that the development of permanent female breasts in boys could be the result. *Id.* at 15.

Conversely, Janssen contends that Saksek and Winter both allege that they developed gynecomastia more than ten years before they filed suit. Janssen's Brief at 17. Janssen argues that Pennsylvania's discovery rule has been interpreted by this Court

narrowly, permitting the tolling of the statute of limitations only if a reasonable person exercising reasonable diligence could not have determined the cause of his or her injury. *Id.* at 12. According to Janssen, not only did Saksek and Winter not exercise reasonable diligence, they exercised no diligence at all. *Id.* Janssen insists that Saksek and Winter may prevail only if this Court replaces its long-established objective standard for application of the discovery rule with a subjective one tolling the statute of limitations until a plaintiff has individualized knowledge of his or her injury and its precise cause. *Id.* at 13. As a result, Janssen argues that this Court should affirm the Superior Court's determination that the accrual date for all Risperdal-related gynecomastia claims is October 31, 2006, the date of the label change. *Id.* at 27.

## III. APPLICABLE LAW

Saksek's and Wilson's actions were dismissed based upon their alleged failure to file them in a timely manner. Limitations periods are computed from the time the cause of action accrued. 42 Pa.C.S. § 5502(a). Generally, "a cause of action accrues, and thus the applicable limitations period begins to run, when an injury is inflicted." *Wilson v. El-Daief*, 964 A.2d 354, 361 (Pa. 2009). "Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action." *Fine*, 870 A.2d at 857.

The discovery rule is an exception that tolls the statute of limitations when an injury or its cause is not reasonably knowable. *Id.* The discovery rule will toll the applicable statute until a plaintiff could reasonably discover the cause of his action, including in circumstances where the connection between the injury and the conduct of another are not readily apparent. *Wilson*, 964 A.2d at 361. Pennsylvania's reasonable diligence

standard is objective; the question is not what the plaintiff actually knew of the injury or its cause, but "what he might have known by exercising the diligence required by law." *Gleason v. Borough of Moosic*, 15 A.3d 479, 485 (Pa. 2011). Although objective, the objective reasonable diligence standard is "sufficiently flexible ... to take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question," *Fine*, 870 A.2d at 858 (citing *Crouse v. Cyclops Industries*, 745 A.2d 606, 611 (Pa. 2000)), and, as such, "is to be applied with reference to individual characteristics." *Wilson*, 964 A.2d at 366.

The requirement of reasonable diligence is not an absolute standard but, rather, is "what is expected from a party who has been given reason to inform himself of the facts upon which his right of recovery is premised." *Id.* at 858. This Court has stressed that "there are very few facts which diligence cannot discover, but there must be some reason to awaken inquiry and direct diligence in the channel to which it would be successful." *Fine*, 870 A.2d at 858. In determining whether reasonable diligence has been exercised, a court must determine whether the plaintiff exhibited "those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interests and the interests of others." *Id.* Because this determination typically involves many fact determinations, it is normally for the jury to decide it. *Gleason*, 15 A.3d at 485 (quoting *Fine*, 870 A.2d at 859).

Pennsylvania's formulation of the discovery rule represents a more narrow approach than is mandated in some other jurisdictions, as it places a greater burden on plaintiffs because the "commencement of the limitations period is grounded on 'inquiry notice' that is tied to 'actual or constructive knowledge of at least some form of significant

harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause.'" *Nicolaou v. Martin*, 195 A.3d 880, 893 (Pa. 2018) (quoting *Gleason*, 15 A.3d at 484). However, this Court has expressly declined to hold, as a matter of law, that a layperson may be charged with knowledge greater than that which was communicated to her by the medical professionals who provided treatment and diagnosis. *Wilson*, 964 A.2d at 365.

## IV. ANALYSIS

### A. October 2006 Accrual Date

As indicated, discovery rule determinations are fact-intensive inquiries that should typically be left for juries to decide, and summary judgment is appropriately granted only in cases where reasonable minds would not differ in finding that the plaintiff knew or should have known, based upon the exercise of reasonable diligence, of his injury and its cause. *Gleason*, 15 A.3d at 485 (quoting *Fine*, 870 A.2d at 859). The certified record here provides no substantial basis for such a finding in these two consolidated cases. To the contrary, other than the pleadings and briefs filed by the parties, the evidence in the certified record consists primarily of the "Plaintiff's Fact Sheets" prepared by Winter and Saksek and the affidavits they each filed. Because Janssen's goal was to obtain a **global** accrual date of October 31, 2006 for all Risperdal-related claims, Janssen filed the two motions for summary judgment at issue here before any case-specific discovery occurred.[4] As such, although these cases involve malformations of their bodies, the

[4] In their responses to Janssen's motions for summary judgment, Saksek and Winter described the motions as "premature" and noted that our Superior Court has recognized that motions for summary judgment should not be considered until the adverse party has had a full opportunity to develop a claim or defense after all relevant discovery has

certified record contains no pictures of Winter or Saksek, including none that depict the nature or extent of those malformations – evidence that could be essential to a determination of the reasonableness of their actions (or lack thereof) in response thereto. Perhaps even more importantly, the certified record contains no medical records regarding the interactions between Winter and/or Saksek and their treating physicians, and no depositions of Winter, Saksek, their parents, or any of their treating physicians (none of whom, apparently, diagnosed either of them with gynecomastia until at least 2013).

Despite the absence of any evidence in support, the Superior Court found that "Appellants repeatedly acknowledged that they developed gynecomastia in 1998 [Saksek] and 2002 [Winter]." *In re: Risperdal Litig*., 2017 WL 5256400 at *5. These "repeated acknowledgements" presumably included answers set forth in their "Plaintiff's Fact Sheets" to the effect that each began to observe swelling of their breasts and increased weight gain at or around the time that they were ingesting Risperdal, and a statement in their responses to Janssen's summary judgment motions to the effect that "[t]his case is about [Winter/Saksek, young men] who ingested [Janssen's] drug, Risperdal, and developed large, female-like breasts as a result …" These are not, however, binding admissions with respect to what Winter and Saksek knew back in 2002

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occurred. *See, e.g.*, Saksek's Response in Opposition to Motion for Summary Judgment, 8/18/2014, at 4 n.3 (citing *Anthony Biddle Contrs. v. Preet Allied Am. St., L.P.*, 28 A.2d 916, 928 (Pa. Super. 2011) and *Burger v. Owens Illinois, Inc.*, 966 A.2d 611, 618 (Pa. Super. 2009)). Neither Saksek nor Winter, however, asked the trial court to deny summary judgment based upon the allegedly premature nature of Janssen's filings.

and 1998 (respectively), namely that either of them knew at those times that they had "developed gynecomastia."[5]

The Superior Court conflates what Winter and Saksek know **now**, having subsequently been diagnosed with gynecomastia, with what they knew in 2002 and 1998. The Superior Court likewise appears to assume that Winter and Saksek either knew or should have known that their breast growth was an outward manifestation of an endocrine disorder known as gynecomastia (thus triggering a duty to investigate its underlying cause). Importantly, the Superior Court fails to distinguish between knowledge of the **physical condition** of large breasts and the critical knowledge of an **injury**, gynecomastia. The Superior Court assumes Winter's and Saksek's knowledge of the latter (gynecomastia).

There is no evidence of record to support such an assumption. Moreover, there is significant evidence of record in the affidavits of Winter and Saksek to support an

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[5] Relatedly, the trial court found that paragraph 173 of the long-form complaints (incorporated into the filed short-form complaints) included a judicial admission by Winter and Saksek that they should have known of the link between Risperdal and gynecomastia no later than October 2009. *Winter*, 2015 WL 4578416, at *9 & n.7 (citing paragraph 173 of the Second Amended Master Long-Form Complaint as alleging that Janssen "deliberately withheld [information concerning the link between Risperdal and gynecomastia] from prescribing physicians and the public **until at least October 2006**, when it appeared in the label for Risperdal and/or Invega") (emphasis in original). The trial court reasoned that "[l]ogically, if the information was 'hidden from the public until at least October 2006,' the information must have been available after October 2006; otherwise, the insertion of a specific time, October 2006, was superfluous." *Id.*

We do not agree that paragraph 173 constitutes a judicial admission. "[A]n admission is not conclusively binding as a judicial admission unless the testimony is clear and unequivocal[.]" *Greater Val. Terminal Corp. v. Goodman*, 176 A.2d 408, 410 (Pa. 1962). The paragraph states only that Janssen had knowledge of the relationship between Risperdal and gynecomastia prior to October 2006, which it disclosed in October 2006. The paragraph does not convey that Winter or Saksek actually received the information on the revised label, either in October 2006 or at any time thereafter.

alternative possibility. At all relevant times, weight gain was a reported risk of Risperdal. Saksek's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 4 at 16; *id.* Ex. 6 at 23. In their affidavits, both Winter and Saksek reported that they experienced significant weight gain while on Risperdal. Winter's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 3 at 2; Saksek's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 3 at 2. Winter and Saksek both contend that weight gain provided a normal and reasonable explanation for the breast growth – both understood that their enlarged breasts reflected the addition of fatty tissue in their breasts, a condition that would alleviate itself over time when they were able to lose the increased weight. Winter/Saksek Brief at 29.

Their affidavits provide further support for this explanation. Both attested that they had never heard of the term "gynecomastia" and their physicians had never discussed the condition with them or suggested that the ingestion of Risperdal (or any other drug) could cause the growth of female breast tissue in males. To the contrary, both Winter and Saksek attested that they had no specialized medical or scientific training and thus had no understanding of how the endocrine system worked. As such, they had no idea that an endocrine system disorder could result in the growth of female breast tissue in males – the entire concept was foreign to them. Both further indicated that over time they were under the care of physicians who they relied upon to provide treatment and medical advice, none of whom ever diagnosed them with gynecomastia.

In his dissenting opinion, Chief Justice Saylor takes a contrary view with regard to Saksek's and Winter's awareness of weight gain while taking Risperdal, arguing that it should have put Saksek and Winter on inquiry notice sufficient to require them to consult

with their physicians regarding gynecomastia. Dissenting Op. at 2-4. While it may (or may not) have been useful for treatment purposes for Saksek and Winter to ask their physicians whether their weight gain was caused by Risperdal or some other cause (e.g., overeating), it is not at all clear, and the Chief Justice does not explain, how their weight gain put either of them on inquiry notice of a possible causal link between their ingestion of Risperdal and the development of a pathological endocrine condition resulting in the growth of female breast tissue. As indicated above, supra at 14, weight gain was at all relevant times listed on the Risperdal label as a known side effect of ingestion of the drug, and thus even if it is assumed that Saksek and Winter linked the weight gain to the drug, this would not in any way be indicative of any other more serious abnormality. To the contrary, it could be argued that knowledge of weight gain as a side effect tempered inquiry into other explanations for the physical changes to their bodies.

At bottom, the Chief Justice effectively posits that if an individual experiences **one** potential (but not unexpected) side effect from consuming a drug, he or she is therefore placed on inquiry notice for **every other potential side effect** that could possibly result from consumption of that same drug (even one, like gynecomastia, which the pre-2006 label recognized as a "rare adverse event"). No case law from any jurisdiction supports this contention. The only case cited by the Dissent, *Ridenour v. Boehringer Ingelheim Pharm., Inc.*, 679 F.3d 1062 (8th Cir. 2012), provides no such support. In that case, the plaintiff began experiencing compulsive behaviors and asked his physician if there was a possible relationship between those compulsive behaviors and his ingestion of Mirapex. *Id.* at 1066. The court ruled that the plaintiff's question placed him on inquiry notice of a possible claim against the manufacturer of Mirapex for causing his compulsive behaviors

(the precise condition he understood himself to be experiencing). *Id.* In the present case, even if Saksek and/or Winter understood there to be an association between Risperdal and weight gain (the condition they themselves acknowledged that they were experiencing), no reason exists to explain how this circumstance would, as a matter of law, have placed them on inquiry notice with respect to an entirely different side effect of Risperdal – gynecomastia, a pathological endocrine condition that neither Saksek or Winter even knew existed at the time that they were prescribed Risperdal.[6] At best, the argument developed by the Dissent is one for Janssen to posit to a jury for its consideration.

Saksek's and Winter's lack of medical training is significant. In another case on the *In re: Risperdal Litigation* master docket, *Murray v. Janssen Pharmaceuticals, Inc.*, 180 A.3d 1235 (Pa. Super. 2018), Janssen argued that a physician could not have

[6] In this regard, the Chief Justice suggests that because both weight gain and gynecomastia may result in an enlargement of male breasts, if Saksek and/or Winter had consulted with physicians regarding their weight gain, then perhaps their gynecomastia could have been diagnosed at that time. Dissenting Op. at 3-4. In their fact sheets, however, both Saksek and Winter identified multiple physicians with whom they consulted for their medical needs during and after the periods of time when they were prescribed Risperdal. Saksek, for example, listed four physicians who provided medical care for his ADD, ADHD and bipolar disorder during and after the time that he was prescribed Risperdal, and three additional physicians who provided him with primary care during the relevant time periods. Janssen's Motion for Summary Judgment (Saksek), 8/18/2014, Ex. 1 at 7-8. In their affidavits, both Saksek and Winter testified that none of their doctors ever diagnosed them as having gynecomastia or suggested that their breast growth could have been caused by Risperdal. These facts, taken together and in the light most favorable to Saksek and Winter as the non-moving parties, establish for summary judgment purposes that both plaintiffs were under the supervision and care of physicians while taking Risperdal and that none of these physicians diagnosed them as suffering from gynecomastia. See *Nicolaou,* 195 A.3d at 893 (citing *Wilson*, 964 A.2d at 365) (while inquiry notice does not require knowledge of "the full extent of the injury," nevertheless "a layperson is only charged with the knowledge communicated to him or her by the medical professionals who provided treatment and diagnosis").

diagnosed the plaintiff as suffering from gynecomastia caused by the ingestion of Risperdal based upon viewing a photograph. *Id.* at 1242. Janssen insisted that a physician's examination of a patient "is essential to distinguish between gynecomastia – enlarged breasts due to the presence of breast tissue, and pseudo-gynecomastia – enlarged breasts due to the accumulation of fat tissue[.]" *Id.* Janssen argued that a photograph could not be relied upon to determine "the cause of enlargement." *Id.* This contention at least suggests that Janssen agrees that breast enlargement may be explained by weight gain (pseudo-gynecomastia) as an alternative to the existence of a pathological endocrine disorder (gynecomastia) resulting in the growth of female breast tissue in males. With no specialized medical knowledge or training, it is unlikely (at best) that either Winter or Saksek could have, solely through self-examination, reached any conclusion that their conditions resulted from the growth of female breast tissue rather than fatty tissue, particularly where they testified in their affidavits that they had no understanding that the growth of female breast tissue in males was even a possibility as a result of ingesting a drug.

As explained hereinabove, the discovery rule tolls the running of the applicable statute of limitation until the plaintiff discovers, through the exercise of reasonable diligence, that he is injured and that the injury has been caused by another party's conduct. *Wilson*, 964 A.2d at 361. Importantly, however, the mere experience of a physical condition does not trigger any obligation to actively seek out further information, including whether it is the result of another person's conduct. As this Court made clear in *Fine*, "there must be some reason to awaken inquiry and direct diligence in the channel to which it would be successful. This is what is meant by reasonable diligence." *Fine*,

870 A.2d at 858; *see also id.* (stating that reasonable diligence is "what is expected from a party who has been given reason to inform himself of the facts upon which his right of recovery is premised."). If, as Winter and Saksek contend, they believed that their condition was merely the result of weight gain rather than a pathological endocrine disorder caused by the conduct of another, then the requirement to exercise due diligence may never have been awakened. If so, then Winter and Saksek had no legal obligation to seek an alternative explanation for the condition – including, as the Superior Court insisted, a requirement to seek medical advice concerning their breast growth. *In re: Risperdal Litig.*, WL 5256400, at *6. To the contrary, having no reason to believe that they were suffering from an abnormal pathological condition, they thus arguably had no reason to consult with their physicians regarding a potential diagnosis.

We do not suggest that Janssen's contention that Winter and Saksek were aware of their injuries in 2002 and 1998 is incorrect. Rather, we conclude only that given that the evidentiary record here is entirely undeveloped, and given that in summary judgment proceedings all facts of record and reasonable inferences therefrom must be construed in the light most favorable to the non-moving party, Janssen was not entitled to summary judgment as a matter of law with respect to application of the discovery rule. It is for the jury to decide the material issues of fact remaining for resolution.

We likewise disagree with the Superior Court's determination that the landscape for discovery changed by October 31, 2006 when Janssen changed the Risperdal label to report the results of clinical trials which reported the incidence of gynecomastia in 2.3% of Risperdal-treated patients. The Superior Court found that "by that date, 'reasonable minds would not differ in finding that' Appellants knew, or should have known, of their

injuries and the cause of those injuries by this point." *Id.* Again, however, the certified record does not support this conclusion, for several reasons.

First, the argument presumes that Winter and Saksek were aware of and should have appreciated that their breast growth was caused by the conduct of another when they first experienced breast growth. In other words, this argument suggests that Winter and Saksek should have been seeking to identify the cause of their condition, including through examination of the drug label for Risperdal, rather than believe their condition was adequately explained as a normal byproduct of excessive weight gain. Moreover, Winter stopped taking Risperdal in 1998 and Saksek did so in 2004. As a result, neither were still taking Risperdal at the time of the label change in 2006.[7] No evidence in the certified record explains how either would have even known that the label for a drug they were no longer taking had changed. The record does not reflect that under this circumstance, their doctors would have had a reason to provide them with updated labels.

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[7] The trial court rejected the date of the label change (October 31, 2006) as the accrual date for Risperdal-related gynecomastia claims on the following basis:

> Viewing the facts in the light most favorable to [Winter], it is possible that immediately after he noticed his injuries, [Winter] conducted a diligent search into the cause of his injuries, was unable to find evidence of the link between his injuries and his Risperdal use, and by 2006 his diligent search had become stale. When viewed in the light most favorable to [Winter], it would be unreasonable to expect him to have continued checking the Risperdal label until October 2006 even though he stopped taking Risperdal in 1998. Put another way, the October 2006 change to the Risperdal label may have been, standing alone, insufficient to have awakened [Winter's] inquiry concerning the link between Risperdal and his injuries.

*Winter*, 2015 WL 4578416, at *6.

Even if they had, for some unexplained reason, sought access to the updated label, the certified record does not demonstrate how they would have known where to obtain it.

Moreover, if they had gained access to the updated label, it is questionable whether either of them could have, given their lack of medical training, understood the complex and specialized discussion of the relevant clinical trials. The revised 2006 label arguably did not provide any of the basic terms and information necessary to understand the label's review of the clinical trials, including, for instance, what specifically gynecomastia is, that it is caused by an endocrine disorder, or even that the 2.3% incidence of gynecomastia revealed by the trials was statistically significant, higher than had been expected, or greater than the incidence of the disorder in the general population. Winter's and Saksek's lack of medical training made it unlikely that their review of the 2006 label would have provided them with any relevant information about their potential claims.

Finally, even if Winter and Saksek had consulted with their physicians regarding the contents of the 2006 revised label, the certified record contains no evidence to support the conclusion that their physicians would have told them that the label confirmed a causal link between Risperdal and gynecomastia. To the contrary, in deposition testimony attached as an exhibit to Winter's and Saksek's responses to the motions for summary judgment, a Janssen causation expert emphatically denied that the 2006 label established any such causal link and further opined that the incidence of gynecomastia in Risperdal-taking patients could be explained by mere coincidence:

> Q: Let me ask you, how would you interpret it? Can you agree with me that based on what I just read that Risperdal is associated with gynecomastia?

A: No. No. No. No. What you just read to me is that in a population of children and in adolescents taking risperidone, that 2.3 percent of those patients were found to have gynecomastia. And I posit based on the medical literature that, you know, if you just do a cross-sectional surveys of adolescent boys, you will find that between, you know, as low as 4 percent and as high as - in the literature, you know, 65, 66 percent of boys will have gynecomastia. If you look at your own expert's testimony, Dr. Goldstein in his blog, he estimates it at 90 percent.

So the fact of the matter is you have a population of patients that are going to have pubertal gynecomastia and they just happen to be taking Risperdal. And they go through puberty and they develop gynecomastia, you cannot really make the association that the risperidone caused the gynecomastia. This in most instances is going to be just simply pubertal gynecomastia.

Q. Come on, Dr. Braunstein. A doctor that reads this is going to come away with, you know, 2.3 percent of risperidone-treated patients - that's evidence of causation; isn't it?

A. No.

Q. That's evidence of an association, would you agree?

A. No more than my example of drinking coffee and later dying.

Winter's Response in Opposition to Motion for Summary Judgment, 8/18/2014, Ex. 9 at 70-71.

The contents of the label are consistent with this testimony, as it provides that Risperdal may elevate prolactin levels and is "associated with higher prolactin levels than other antipsychotic agents," and also that various endocrine disorders, including gynecomastia, "have been reported in patients receiving prolactin-elevating compounds." *Id.* Ex. 6 at 15. The label does not, however, indicate that the ingestion of Risperdal may cause gynecomastia. If Janssen's causation expert, based upon his review of the 2006 label, did not conclude that said label reflected a causal link, then it cannot be said,

contrary to the Superior Court's determination, that "reasonable minds would not differ in finding that" Winter and Saksek knew or should have known that their injuries were caused by their ingestion of Risperdal based upon Janssen's issuance of the 2006 revised label.

Again, Janssen may certainly argue to the jury that the 2006 label change would have established for Winter and Saksek knowledge of the injury and its cause if they had exercised more vigorous diligence. We conclude only that on this record, Janssen was not entitled to summary judgment as a matter of law, as material issues of fact remain for a jury's determination.

**B. June 30, 2009 Accrual Date**

Janssen's motions for summary judgment were based entirely on the evidentiary predicate that the accrual date for Winter's and Saksek's causes of action was no later than October 2006.[8] The trial court rejected this accrual date. Instead of ending its inquiry with the denial of the pending motion for summary judgment, the trial court, sua sponte, developed an alternative basis for summary judgment based on an accrual date of no later than June 30, 2009. On appeal, the Superior Court disagreed with the trial court's rejection of the 2006 accrual date and noted without analysis that the record supported both the 2006 and 2009 accrual dates, the latter being irrelevant given its decision. *In re: Risperdal Litig.*, 2017 WL 5256400, at *6 n.8.

[8] *See* Janssen's Motion for Summary Judgment (Saksek), 8/18/2014, at 13 ("[I]n sum, [Saksek] brought his suit almost nine years after he reached the age of eighteen, more than eleven years after he learned of his alleged injuries, and more than seven years after the latest date on which he should be charged with constructive knowledge or inquiry notice of the purported cause of his injuries, October 31, 2006.").

The trial court concluded that Winter's and Saksek's claims accrued no later than June 30, 2009 based upon the environment created by the cumulation of medical journal articles, media reports, and an instance of lawyer advertising. *Winter*, 2015 WL 4578416, at *8. As part of the environment, the trial court identified three "high volume, national, medical publications"[9] dating from 2003-2004 that "reference a link between Risperdal use and increased prolactin production, as well as the fact that increased prolactin production may result in gynecomastia." *Id.* at 7.[10] [11]

With respect to media reports, the trial court referenced various newspaper articles and television news broadcasts that it represented contained disclosures of "Risperdal causing adolescent boys to develop breasts." *Winter*, 2015 WL 4578416, at *7. According to the trial court, publicity of the connection between Risperdal and gynecomastia began in 2001, with three articles appearing in the Miami Herald.[12] The

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[9] Donna A. Wirshing et al., *Update On Atypicals: Practical Tips To Manage Common Side Effects*, 2 Current Psychiatry 49-57 (2003); *Choice Of An Antipsychotic*, 45 The Medical Letter 102-04 (2003); Peter M. Haddad & Angelika Wieck, *Antipsychotic-Induced Hyperprolactinemia: Mechanisms, Clinical Features And Management*, 64 Drugs 2291, 2292, 2296, 2298-2300 (2004).

[10] Here again, the trial court presupposes that Winter and Saksek were aware that their breast enlargement was an injury (gynecomastia) rather than a physical condition resulting from weight gain.

[11] Winter and Saksek argue that these articles discuss the relationship between Risperdal and gynecomastia only in general terms and do not provide any detailed analysis to support a causal connection between them. Winter's Brief at 43-46. Winter and Saksek further contend that in 2004 Janssen "poisoned the proverbial well" on this issue in the scientific community by commissioning and publishing an article that concluded, falsely, that there was no significant correlation between high prolactin levels and gynecomastia. *Id.* at 44.

[12] *Foster Kids Describe Drugs' Effects Prescribed Psychiatric Medications Made "Everything a Blur" for One Girl*, Miami Herald (April 23, 2001) at 1A, http://poundpuplegacy.org/node/33599 (last visited October 28, 2019); *Shocking Tale*

trial court next reported that in 2004 Janssen sent "Dear Doctor" letters to prescribing physicians concerning certain potentially fatal complications relating to the ingestion of Risperdal, which resulted in articles in four major newspapers.[13] *Id.* While the Dear Doctor letters were unrelated to any correlation between Risperdal and gynecomastia, the four articles mentioned the link in a single sentence. Then, in 2008, the New York Post and the Philadelphia Inquirer published articles that "mentioned the link between Risperdal and gynecomastia."[14] Later in 2008, Fox Television and CBS Evening News

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*Fails to Register*, Miami Herald (April 24, 2001) at 1B, http://nl.newsbank.com/nlsearch/we/Archives?p_action=doc&p_docid=0EBC6E5CEB1C58B4&p_docnum=1&s_dlid=DL01190805163555003 73&s_ecproduct=SBK-W3&s_ecprodtype=NORENEW&s_trackval=&s_siteloc=MH&s_referrer=&s_subterm=Subscription%20until%3A%2008%2F12%2F2019&s_docsbal=&s_subexpires=08%2F12%2F2019&s_docstart=3&s_docsleft=0&s_docsread=3&s_username=switalec&s_accountid=AC01190725163413028 98&s_upgradeable=no, (last visited October 28, 2019); *Investigation Urged on Antipsychotic Drugs Given to Disabled Floridians*, Miami Herald, (May 11, 2001) at 23A, http://nl.newsbank.com/nl-search/we/Archives?p_actiondoc&p_docid=0EBF52C804F9D5A1&p_docnum=1&s_dlid=DL01190805163 12004604&s_ecproduct=SBK-W3&s_ecprodtype=NORENEW&s trackval=&s_siteloc=MH&s_referrer=&s_subterm=Subscription%20until%3A%2008%2F12%2F2019&s_docsbal=Docs%20remaining%3A%201&s_subexpires=08%2F12%2F2019&s_docstart=3&s_docsleft=1&s_docsread=2&s_username=switalec&s_accountid=AC01190725163413028 98&s_upgradeable=no (last visited October 28, 2019).

[13] *Warning on Schizophrenia Drug*, New York Times (July 25, 2004) at 117, https://www.nytimes.com/2004/07/25/us/warning-on-schizophrenia-drug.html (last visited October 28, 2019); *Maker of Schizophrenia Medicine Clarifies Risks*, Washington Post (July 25, 2004), https://www.washingtonpost.com/archive/politics/2004/07/25/maker-of-schizophrenia-medicine-clarifies-risks/0f06be62-0dbb-412b-af7d-6f21314120be/?utm_term=.e18b8a5ca72f (last visited October 28, 2019); *Drug Firm Admits Misleading Claims,* Charleston Newspapers *(July 25, 2004) at 8; Medicine Maker Admits Deception It Downplayed Possibly Fatal Safety Risks,* Kansas City Star (July 25, 2004), https://kansascity.newsbank.com/doc/news/104140855AD42619?search_terms (last visited October 28, 2019).

[14] *Medicaid Kids in Psych-Rx $urge*, N.Y.Post (February 3, 2008) at 7, https://nypost.com/2008/0203/medicaid-kids-in-psych-rx-urge (last visited October 28, 2019); Karl Stark, *Tarnished View of Wonder Drugs*, Philadelphia Inquirer, February 17,

discussed a possible link between Risperdal and gynecomastia, and on June 15, 2009, counsel for Winter and Saksek uploaded a video on an internet platform (YouTube) discussing the issue.[15] *Id.* at 8. Based on this publicity, the trial court concluded that "by June 30, 2009, [Winter's] inquiry should have been awakened," and that "as a matter of law, the discovery rule can only toll the statute of limitation until a maximum date of June 30, 2009 for plaintiffs who ingested Risperdal prior to October 2006." *Id.*

Before proceeding to analysis of the trial court's contentions, we note that only some of the media reports cited by the trial court are included in the certified record on appeal. The New York Post and the Philadelphia Inquirer articles published in 2008, the cited Fox and CBS television shows, and the YouTube video were referenced by Janssen in a footnote regarding lawyer advertising in its global motion for partial summary judgment (on which the trial court did not issue a ruling). Janssen's Motion for Partial Summary Judgment as to the Affirmative Defense of the Statute of Limitations, 5/19/2015, at 22 n.27. Because Janssen incorporated by reference the arguments in its global summary judgment motion into its motions for summary judgment in the Winter and Saksek cases, Janssen's Motion for Summary Judgment (Winter), 8/18/2014, at 8 n.10, Janssen's Motion for Summary Judgment (Saksek), 8/18/2014, at 8 n.9, these items are fairly considered to be in the certified record here. However, the three Miami Herald articles, see supra note 12, and the four articles related to the "Dear Doctor" letters, supra

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2008 at E01, https://www.inquirer.com/philly/business/20080217_Tarnished_View_of_Wonder_Drugs.html (last visited October 28, 2019).

[15] Sheller PC, Risperdal®: Has your son experienced breast growth while taking this drug? Youtube (uploaded June 25, 2009), http://www.youtube.com/watch?v=L_wj6-LINIg (last visited October 28, 2019).

note 13, were not part of either the global record or the summary judgment records of Winter or Saksek. The identification of these seven articles is the apparent result of sua sponte research conducted by the trial court, which, having rejected October 31, 2006 as the final accrual date, proceeded to fashion its own alternative accrual date.

In a footnote, the trial court indicated that "a court may take judicial notice of press releases[,] news articles and published analyst reports in determining what the market knew," citing to a single decision of a federal district court. *Id.* at *7 n.9 (citing *Landow v. Wachovia Securities, LLC*, 966 F.Supp.2d 106, 119 (E.D.N.Y. 2013)) (in case involving, inter alia, allegations of financial fraud, federal district court took judicial notice of certain court filings and media reports "not for the truth of the matters asserted therein, but rather to establish the fact that the information in those materials was publicly available"). We note that in taking judicial notice, it is unclear whether the trial court considered the requirements of Rule 201 of the Pennsylvania Rules of Evidence, entitled "Judicial Notice of Adjudicative Facts."[16] For example, Rule 201(b)(1) directs that judicial notice may be

[16] Rule 201 provides as follows:

> Rule 201. Judicial Notice of Adjudicative Facts
>
> (a) Scope. This rule governs judicial notice of an adjudicative fact only, not a legislative fact.
>
> (b) Kinds of Facts That May Be Judicially Noticed. The court may judicially notice a fact that is not subject to reasonable dispute because it:
>
> > (1) is generally known within the trial court's territorial jurisdiction; or
> >
> > (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.
>
> (c) Taking Notice. The court:

taken of an adjudicative fact if it is not subject to reasonable dispute that the fact is generally known within the trial court's jurisdiction. Relevant to summary judgment in these cases, whether the facts judicially noticed by the trial court were generally known goes to the heart of the inquiry notice issue. [17]

Moreover, it is unclear under our rules whether a trial court may take judicial notice of certain facts and then grant summary judgment to the moving party on those same facts. Pursuant to Rules 1035.1–1035.5 of the Pennsylvania Rules of Civil Procedure, the "record" for purposes of motions for summary judgment consists of the pleadings,

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> (1) may take judicial notice on its own; or
>
> (2) must take judicial notice if a party requests it and the court is supplied with the necessary information.
>
> (d) Timing. The court may take judicial notice at any stage of the proceeding.
>
> (e) Opportunity to Be Heard. On timely request, a party is entitled to be heard on the propriety of taking judicial notice and the nature of the fact to be noticed. If the court takes judicial notice before notifying a party, the party, on request, is still entitled to be heard.
>
> (f) Instructing the Jury. The court must instruct the jury that it may, but is not required to, accept as conclusive any fact judicially noticed.

Pa.R.E. 201.

[17] The propriety of judicial notice aside, the trial court did not, and could not, discuss whether Winter and/or Saksek had any reasonable access to these media reports. Because the evidence in this regard is non-existent, it is not even clear whether Winter and/or Saksek had access to the internet or the skill to search effectively, especially since the articles typically lacked certain terms (e.g., gynecomastia or breast growth) that would have been useful in constructing searches designed to locate them. The record also does not establish that, at the relevant points in time, these articles could have been accessed without subscriptions to the publications in question. The Court ascertained, in connection with its efforts to gain access (for citation purposes) to certain of the websites listed supra, that paid subscriptions are currently required for two of the Miami Herald articles in footnote 12 and the Kansas City Star article in footnote 13.

depositions, answers to interrogatories, admissions, affidavits, and reports signed by an expert witness that would, if filed, comply with Rule 4003.5(a)(1), whether or not the reports have been produced in response to interrogatories. Pa.R.C.P. 1035.1–1035.5. These rules do not indicate that a trial court may also take judicial notice of other facts and thus consider them part of the record when ruling on a motion for summary judgment. The manner in which the trial court proceeded and the information it considered have not been challenged,[18] however, and we will not decide the issue here. We thus review the merits.

The media reports relied on by the trial court do not discuss any causal link between the ingestion of Risperdal and gynecomastia sufficient to place Winter and Saksek on notice of their claims against Janssen. None of the nine cited newspaper articles reference gynecomastia in their titles, and only one of the nine even uses the term in the text. Five of the nine do not refer to breast growth at all, but rather only the development of lactating breasts in boys, a condition never reported by Winter or Saksek. Finally, and perhaps most importantly, the articles only mention breast growth and/or

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[18] In a reply brief, Saksek and Winter note that the seven articles are not in the certified record on appeal, indicating that the "trial court found them through independent research." Saksek/Winter Reply Brief at 15 n.1; see also Saksek/Winter Brief at 47 (The trial court sua sponte referenced these articles in its opinion, presumably based on independent research.").

On this point, we note, parenthetically, that Rule 2.9(C) of the Pennsylvania Code of Judicial Conduct provides "[a] judge shall not investigate facts in a matter independently, and shall consider only the evidence presented and any facts that may properly be judicially noticed." Comment 6 to Rule 2.9(C) makes clear that electronic media, i.e., the internet, is a prohibited source of independent research of facts.

This case does not implicate an analysis of any potential violation of this Rule. Instead, we use this opportunity to caution the bench against resorting to this practice.

lactation anecdotally, typically referring to a single boy (or a "handful" of boys) suffering from the side effects of ingesting Risperdal at issue here.

As indicated, the trial court also referred to two television news shows and a YouTube video. One of the television news shows was a Fox News broadcast on November 20, 2008.[19] At the end of the broadcast there was a short segment introduced as follows: "Thousands of children are taking them, dozens have died as a result of side effects. So, should doctors stop prescribing antipsychotic drugs to children. A new warning from a government panel[.]" Janssen's Motion for Partial Summary Judgment as to the Affirmative Defense of the Statute of Limitations, 5/19/2015, Ex. AA at 8. The segment included a brief interview with a young woman who complained that Risperdal caused her to gain "so much weight" that it affected her moods and made her depressed. *Id.* at 9. A short interview with Attorney Stephen Sheller (now counsel for Saksek and Winter) followed. Attorney Sheller was introduced by the show's host as "a lawyer in Philadelphia who represents patients damaged by antipsychotic drugs, including these boys who had to have mastectomies because they grew breasts on Risperdal." *Id.* Attorney Sheller did not address the subject of his introduction, instead commenting only that antipsychotic drugs are "a good profit center for the drug industry" and that the FDA has conflicts of interest that protect the drug companies at the expense of public health. *Id.*

The YouTube video referenced by the trial court contains a lawyer advertisement by Attorney Sheller. Without question it links the ingestion of Risperdal with the incidence

[19] Unlike with the Fox News program, Janssen did not attach a transcript of the CBS News program to its global motion for summary judgment. The website cited by Janssen (and set forth in the trial court's opinion) indicates that the video is no longer available.

of gynecomastia. As it was uploaded on June 25, 2009 and the trial court set June 30, 2009 as the final accrual date for all Risperdal-related gynecomastia claims, this video was apparently the straw that broke the camel's back for the trial court, such that any potential plaintiff's "inquiry should have been awakened." *Winter*, 2015 WL 4578416, at *8.

The trial court's contention was that the cumulative effect of the above-discussed medical journal articles and media reports gave rise to inquiry notice. According to the trial court, "the link between Risperdal and gynecomastia was so widely discussed in the mainstream media, and in medical journals, that by June 30, 2009 anyone exercising reasonable diligence would have discovered the existence of his or her claims against Janssen. *Id.* In making this argument, the trial court adopted the reasoning of three federal district court decisions, each of which determined that the level of publicity regarding causal links between a particular drug and a particular injury was such that a potential plaintiff should have been put on notice of his or her claim. *See In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2012 WL 3205620 (E.D. Pa. Aug. 7, 2012) (federal district court found that a reasonable person would have been on notice to investigate possible link between heart attack already suffered and the drug Advandia after New England Journal of Medicine concluded that there was a 43% increased risk of myocardial infarction, multiple national health associations issued warnings for patients to consult with physicians, and the FDA required a black box label, all resulting in massive mainstream media coverage); *In re Vioxx Products Liab. Litig.*, 522 F.Supp.2d 799 (E.D. La. 2007) (after a large patient study associated ingestion of the drug Vioxx with significantly increased risks of serious cardiovascular thrombotic events, the FDA

required a revised label, the manufacturer withdrew the drug from the market, which resulted in an "avalanche of media coverage" penetrating local markets nationwide, which the federal district court found was sufficient to put potential plaintiffs on notice); *Burrell v. Astraeneca LP*, 2010 WL 3706584, at *1 (Del. Super. Sept. 20, 2010) (based upon information published in medical and lay sources regarding a link between the drug Seroquel and diabetes, a label change and two "Dear Doctor" letters specifically alerting the medical community of the label change, the federal district court ruled that plaintiffs were on notice as of the date of their diagnosis with diabetes).

Unlike in these cases, we cannot conclude, as a matter of law, that the present case involves the degree of publicity required to place Winter or Saksek on notice of the relationship between their injury and its cause. In *In re Avandia*, the American College of Cardiology, the American Diabetes Association, and the American Heart Association all issued statements advising diabetes patients to contact their physicians. *In re Avandia*, 2012 WL 3205620, at *3. The FDA required a prominent "black box warning" to be included on the drug label. *Id.* The district court, in setting the accrual date at the end of 2007, found that local and national media had successfully reported to the general public, citing statistics indicating that by November 2007 Avandia prescriptions had fallen by 54%. *Id.* at *4. In the Vioxx litigation, the district court likewise found that when the manufacturer pulled the drug from the market, an "immediate media blitz" followed which penetrated both national and local markets. *In re Vioxx*, 522 F.Supp.2d at 801. The district court described the situation as "the largest and most-publicized prescription drug withdrawal in this country's history." *Id.* at 803. In *Burrell,* the drug manufacturer had to issue not just one but two "Dear Doctor" letters alerting the medical community of the

label change that identified the link between Seroquel and diabetes. *Burrell,* 2010 WL 3706584, at *6.

It may fairly be questioned as to whether the national attention regarding the link between Risperdal and gynecomastia compares favorably with the extent of media coverage in the *In re Avandia*, *In re Vioxx* and *Burrell* cases. In the present cases, the trial court referenced three medical journal articles (all published in 2003-2004), nine newspaper articles (spread over eight years), two television news programs in 2008, and a YouTube video. However, the FDA did not require a black box warning on the Risperdal label, no national health organizations issued warnings to physicians and patients, no statistics regarding decreases in prescriptions have been cited in support of the extent of the media coverage into local markets, there was no national media "blitz," and Janssen did not issue any "Dear Doctor" letters advising prescribing physicians of the 2006 label change.

This is not to say that the publicity (including the medical journal articles) cited by the trial court in this case was insufficient to place Winter and Saksek on notice (at any particular point in time) that their ingestion of Risperdal was the cause of their gynecomastia or that their enlarged breasts were in fact the result of the growth of female breast tissue and not mere overall weight gain. Rather, we conclude only that reasonable minds could differ, thus requiring that the factual issues relating to Janssen's statute of limitations defense must be submitted to a jury for resolution.

Finally, the scope of the distribution and information linking Risperdal to gynecomastia in the medical journal articles, media reports and lawyer advertising does not cumulatively, as a matter of law, lead to the conclusion that Saksek and Winter were

put on inquiry notice sufficient to establish a June 30, 2009 accrual date for their causes of action.

We therefore hold that the Superior Court erred in affirming the trial court's grant of summary judgment in favor of Janssen. Genuine issues of material fact remain with respect to Janssen's statute of limitations defense. We remand these two cases to the trial court for further proceedings consistent with this decision.

Reversed and remanded.

Justices Baer, Todd, Dougherty, Wecht and Mundy join the opinion.

Justice Baer files a concurring opinion in which Justice Donohue joins.

Chief Justice Saylor files a dissenting opinion.