

Take Steps to Protect Your Online Reputation

BY SHERRY BOSCHERT

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MONTEREY, CALIF. – Have you searched for your name on the Internet? Your patients have.

“Your patients are Googling you,” and some of them probably are rating your performance as a doctor on one of the many physician-rating sites or generic rating sites, Dr. Clifford Warren Lober said.

Here’s the problem: The patients most likely to rate you are those who are livid at you, or those who think you walk on water. And it’s not just patients who are posting comments about you, but previous patients, ex-employees, former spouses, or anyone else who knows you, said Dr. Lober, a dermatologist and attorney in Kissimmee, Fla.

Online comments may be made anonymously, persist for years on the Internet, be accessed by anyone with a computer, and be replicated on other Web sites beyond the original. If you discover comments about you that you think are harmful to your reputation, your attempts to remedy the situation may backfire and instead “optimize” the content by bringing more attention to the posted statement, amplifying its negativity, he said.

Legal remedies are few and complicated. “There is a morass of legal de-

fenses and privileges that protect the offending person,” Dr. Lober said.

So how best to manage your online reputation? One strategy is to minimize the impact of negative online information through search-engine optimization, he suggested.

In practice, this means blitzing the Web with your own content to crowd out comments by others. “You want to occupy the first three pages of the rating

sites” and the search-engine results pages if possible, Dr. Lober said, adding that most people don’t look beyond the first three pages of results.

This can be done by establishing multiple Web sites, each with numerous internal page links, external high-traffic links, significant content on each of your home pages, and other features that make these the sites that show up when someone searches your name.

Establishing a deep social network presence helps, too. Create accounts on Facebook, Twitter, LinkedIn, ZoomInfo, Connectbeam, Yahoo Profile, Google Profile, MSN Profile, Wetpaint, Naymz, Jigsaw, Ning, and others, he suggested. Ideally, get on sites that feature RSS (Really Simple Syndication) feeds so that information posted on one site transfers to others.

Other prongs in this strategy include

ROTARIX (Rotavirus Vaccine, Live, Oral)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

ROTARIX® is indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) when administered as a 2-dose series [see *Clinical Studies (14.3) of full prescribing information*]. ROTARIX is approved for use in infants 6 weeks to 24 weeks of age.

4 CONTRAINDICATIONS

4.1 Hypersensitivity: A demonstrated history of hypersensitivity to any component of the vaccine. Infants who develop symptoms suggestive of hypersensitivity after receiving a dose of ROTARIX should not receive further doses of ROTARIX.

4.2 Gastrointestinal Tract Congenital Malformation: History of uncorrected congenital malformation of the gastrointestinal tract (such as Meckel’s diverticulum) that would predispose the infant for intussusception. **4.3 Severe Combined Immunodeficiency Disease:** Infants with Severe Combined Immunodeficiency Disease (SCID) should not receive ROTARIX. Postmarketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered live, oral rotavirus vaccines and later identified as having SCID [see *Adverse Reactions (6.2)*].

5 WARNINGS AND PRECAUTIONS

5.1 Gastrointestinal Disorders: Administration of ROTARIX should be delayed in infants suffering from acute diarrhea or vomiting. Safety and effectiveness of ROTARIX in infants with chronic gastrointestinal disorders have not been evaluated.

[See *Contraindications (4.2)*.] **5.2 Altered Immunocompetence:**

Safety and effectiveness of ROTARIX in infants with known primary or secondary immunodeficiencies, including infants with human immunodeficiency virus (HIV), infants on immunosuppressive therapy, or infants with malignant neoplasms affecting the bone marrow or lymphatic system have not been evaluated. **5.3 Shedding and Transmission:** Rotavirus shedding in stool occurs after vaccination with peak excretion occurring around day 7 after dose 1. Live rotavirus shedding was evaluated in 2 studies among a subset of infants at day 7 after dose 1. In these studies, the estimated percentages of recipients of ROTARIX who shed live rotavirus were 25.6% (95% Confidence Interval [CI]: 10.2, 41.1) and 26.5% (95% CI: 15.5, 37.5), respectively. Transmission of virus was not evaluated. There is a possibility that the live vaccine virus can be transmitted to non-vaccinated contacts. The potential for transmission of vaccine virus following vaccination should be weighed against the possibility of acquiring and transmitting natural rotavirus. **5.4 Intussusception:** Following administration of a previously licensed oral live rhesus rotavirus-based vaccine, an increased risk of intussusception was observed. The risk of intussusception with ROTARIX was evaluated in a safety study (including 63,225 infants) conducted in Latin America and Finland. No increased risk of intussusception was observed in this clinical trial following administration of ROTARIX when compared with placebo. [See *Adverse Reactions (6.1)*.] In postmarketing experience, cases of intussusception have been reported in temporal association with ROTARIX [see *Adverse Reactions (6.2)*]. **5.5 Post-Exposure Prophylaxis:** Safety and effectiveness of ROTARIX when administered after exposure to rotavirus have not been evaluated.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. As with any vaccine, there is the possibility that broad use of ROTARIX could reveal adverse reactions not observed in clinical trials. Solicited and unsolicited adverse events, serious adverse events and cases of intussusception were collected in 7 clinical studies. Cases of intussusception and serious adverse events were collected in an additional large safety study. These 8

clinical studies evaluated a total of 71,209 infants who received ROTARIX (N = 36,755) or placebo (N = 34,454). The racial distribution for these studies was as follows: Hispanic 73.4%, white 16.2%, black 1.0%, and other 9.4%; 51% were male.

Solicited Adverse Events: In 7 clinical studies, detailed safety information was collected by parents/guardians for 8 consecutive days following vaccination with ROTARIX (i.e., day of vaccination and the next 7 days). A diary card was completed to record fussiness/irritability, cough/runny nose, the infant’s temperature, loss of appetite, vomiting, or diarrhea on a daily basis during the first week following each dose of ROTARIX or placebo. Adverse events among recipients of ROTARIX and placebo occurred at similar rates (Table 1).

Table 1. Solicited Adverse Events Within 8 Days Following Doses 1 and 2 of ROTARIX or Placebo (Total Vaccinated Cohort)

	Dose 1		Dose 2	
	ROTARIX N = 3,284	Placebo N = 2,013	ROTARIX N = 3,201	Placebo N = 1,973
	%	%	%	%
Fussiness/irritability ^a	52	52	42	42
Cough/runny nose ^b	28	30	31	33
Fever ^c	25	33	28	34
Loss of appetite ^d	25	25	21	21
Vomiting	13	11	8	8
Diarrhea	4	3	3	3

Total vaccinated cohort = all vaccinated infants for whom safety data were available.

N = number of infants for whom at least one symptom sheet was completed.

^aDefined as crying more than usual.

^bData not collected in 1 of 7 studies; Dose 1: ROTARIX N = 2,583; placebo N = 1,897; Dose 2: ROTARIX N = 2,522; placebo N = 1,863.

^cDefined as temperature $\geq 100.4^{\circ}\text{F}$ ($\geq 38.0^{\circ}\text{C}$) rectally or $\geq 99.5^{\circ}\text{F}$ ($\geq 37.5^{\circ}\text{C}$) orally.

^dDefined as eating less than usual.

Unsolicited Adverse Events: Infants were monitored for unsolicited serious and non-serious adverse events that occurred in the 31-day period following vaccination in 7 clinical studies. The following adverse events occurred at a statistically higher incidence (95% CI of Relative Risk excluding 1) among recipients of ROTARIX (N = 5,082) as compared with placebo recipients (N = 2,902): irritability (ROTARIX 11.4%, placebo 8.7%) and flatulence (ROTARIX 2.2%, placebo 1.3%).

Serious Adverse Events (SAEs): Infants were monitored for serious adverse events that occurred in the 31-day period following vaccination in 8 clinical studies. Serious adverse events occurred in 1.7% of recipients of ROTARIX (N = 36,755) as compared with 1.9% of placebo recipients (N = 34,454). Among placebo recipients, diarrhea (placebo 0.07%, ROTARIX 0.02%), dehydration (placebo 0.06%, ROTARIX 0.02%), and gastroenteritis (placebo 0.3%, ROTARIX 0.2%) occurred at a statistically higher incidence (95% CI of Relative Risk excluding 1) as compared with recipients of ROTARIX.

Deaths: During the entire course of 8 clinical studies, there were 68 (0.19%) deaths following administration of ROTARIX (N = 36,755) and 50 (0.15%) deaths following placebo administration (N = 34,454). The most commonly reported cause of death following vaccination was pneumonia, which was observed in 19 (0.05%) recipients of ROTARIX and 10 (0.03%) placebo recipients (Relative Risk: 1.74, 95% CI: 0.76, 4.23).

Intussusception: In a controlled safety study conducted in Latin America and Finland, the risk of intussusception was evaluated in 63,225 infants (31,673 received ROTARIX and 31,552 received placebo). Infants were monitored by active surveillance including independent, complementary methods (prospective hospital surveillance and parent reporting at scheduled study visits) to identify potential cases of intussusception within 31 days after vaccination and, in a subset of 20,169 infants (10,159 received ROTARIX and 10,010 received placebo), up to one year after

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issuing press releases by using Internet publication sites, establishing one or more blogs in your name, and using pay-per-click advertising.

Sound overwhelming? Innovative entrepreneurs thought that it might, so a number of Internet reputation-management companies have formed to do some of this work for you – for a fee, of course. These include companies like Reputation Repair & Management, Internet Reputation Management, and ReputationDefender, Dr. Lober said.

If, instead, you want to try to get a specific offensive statement removed from

the Web, seek legal counsel to guide you, he advised.

First, the statement must be determined to meet the legal definition of defamation. If it does, the next step is to determine if the person who wrote it is covered by any one of several standard legal defenses. If that's not an issue, check the terms and conditions listed by the Internet service provider (ISP) of the site where the comment appeared, to see if the ISP made any promises or assurances about the content on the site. If you contact the ISP, it may take the comment down.

Normally, ISPs are immune from lawsuits over statements made by others on its service; they resemble telephone companies more than newspapers in that respect, he said.

You or your lawyer can request that the courts issue a subpoena to try to compel the person who made the statement (even for an anonymous poster) to remedy the situation, but this process is time consuming and expensive, and the person who posted the comment may be difficult to locate, Dr. Lober cautioned.

And if you sue, then the defendant

may try to frame your action as a SLAPP (strategic litigation against public participation) suit intended to muzzle critics and restrict freedom of speech.

Some states have anti-SLAPP laws that could leave you paying the defendant's attorney fees and costs, and make you vulnerable to a countersuit by the defendant.

Better to try to "manage" your online reputation than to try to legally defend it, he suggested.

Dr. Lober reported having no pertinent conflicts of interest. ■

the first dose. No increased risk of intussusception following administration of ROTARIX was observed within a 31-day period following any dose, and rates were comparable to the placebo group after a median of 100 days (Table 2). In a subset of 20,169 infants (10,159 received ROTARIX and 10,010 received placebo) followed up to one year after dose 1, there were 4 cases of intussusception with ROTARIX compared with 14 cases of intussusception with placebo [Relative Risk: 0.28 (95% CI: 0.10, 0.81)]. All of the infants who developed intussusception recovered without sequelae.

Table 2. Intussusception and Relative Risk With ROTARIX Compared With Placebo

Confirmed Cases of Intussusception	ROTARIX N = 31,673	Placebo N = 31,552
Within 31 days of diagnosis after any dose	6	7
Relative Risk (95% CI)	0.85 (0.30, 2.42)	
Within 100 days of dose 1^a	9	16
Relative Risk (95% CI)	0.56 (0.25, 1.24)	

CI = Confidence Interval.

^aMedian duration after dose 1 (follow-up visit at 30 to 90 days after dose 2).

Among vaccine recipients, there were no confirmed cases of intussusception within the 0- to 14-day period after the first dose (Table 3), which was the period of highest risk for the previously licensed oral live rhesus rotavirus-based vaccine.

Table 3. Intussusception Cases by Day Range in Relation to Dose

Day Range	Dose 1		Dose 2		Any Dose	
	ROTARIX N = 31,673	Placebo N = 31,552	ROTARIX N = 29,616	Placebo N = 29,465	ROTARIX N = 31,673	Placebo N = 31,552
0-7	0	0	2	0	2	0
8-14	0	0	0	2	0	2
15-21	1	1	2	1	3	2
22-30	0	1	1	2	1	3
Total (0-30)	1	2	5	5	6	7

Kawasaki Disease: Kawasaki disease has been reported in 18 (0.035%) recipients of ROTARIX and 9 (0.021%) placebo recipients from 16 completed or ongoing clinical trials. Of the 27 cases, 5 occurred following ROTARIX in clinical trials that were either not placebo-controlled or 1:1 randomized. In placebo-controlled trials, Kawasaki disease was reported in 17 recipients of ROTARIX and 9 placebo recipients [Relative Risk: 1.71 (95% CI: 0.71, 4.38)]. Three of the 27 cases were reported within 30 days post-vaccination: 2 cases (ROTARIX = 1, placebo = 1) were from placebo-controlled trials [Relative Risk: 1.00 (95% CI: 0.01, 78.35)] and one case following ROTARIX was from a non-placebo-controlled trial. Among recipients of ROTARIX, the time of onset after study dose ranged 3 days to 19 months.

6.2 Postmarketing Experience: The following adverse events have been reported since market introduction of ROTARIX. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccination with ROTARIX. **Gastrointestinal Disorders:** Intussusception (including death), hematochezia, gastroenteritis with vaccine viral shedding in infants with Severe Combined Immunodeficiency Disease (SCID). **Blood and Lymphatic System Disorders:** Idiopathic thrombocytopenic purpura. **Vascular Disorders:** Kawasaki disease. **General Disorders and Administration Site Conditions:** Maladministration.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration: In clinical trials, ROTARIX was administered concomitantly with US-licensed and non-US-licensed vaccines. In a US coadministration study in 484 infants, there was no evidence of interference in the immune responses to any of the antigens when PEDIARIX® [Diphtheria and Tetanus Toxoids and Acellular

Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined], a US-licensed 7-valent pneumococcal conjugate vaccine (Wyeth Pharmaceuticals Inc.), and a US-licensed Hib conjugate vaccine (Sanofi Pasteur SA) were coadministered with ROTARIX as compared with separate administration of ROTARIX. **7.2 Immunosuppressive Therapies:** Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to ROTARIX. [See Warnings and Precautions (5.2).]

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with ROTARIX. It is also not known whether ROTARIX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **8.4 Pediatric Use:** Safety and effectiveness of ROTARIX in infants younger than 6 weeks or older than 24 weeks of age have not been evaluated. The effectiveness of ROTARIX in pre-term infants has not been established. Safety data are available in pre-term infants (ROTARIX = 134, placebo = 120) with a reported gestational age ≤36 weeks. These pre-term infants were followed for serious adverse events up to 30 to 90 days after dose 2. Serious adverse events were observed in 5.2% of recipients of ROTARIX as compared with 5.0% of placebo recipients. No deaths or cases of intussusception were reported in this population.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: ROTARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (17.2) of full prescribing information. **17.1 Patient Advice:** Parents or guardians should be informed by the healthcare provider of the potential benefits and risks of immunization with ROTARIX, and of the importance of completing the immunization series. The healthcare provider should inform the parents or guardians about the potential for adverse reactions that have been temporally associated with administration of ROTARIX or other vaccines containing similar components. The parent or guardian accompanying the recipient should be instructed to report any adverse events to their healthcare provider. The parent or guardian should be given the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control (CDC) website (www.cdc.gov/vaccines).

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Full prescribing information for ROTARIX is available at www.rotarix.com.

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