Megan Grossman, Esquire

Lewis Brisbois Bisgaard & Smith LLP **Karen Shimonsky, Esquire** Gordon Rees Scully Mansukhani, LLP **Lauren Hulbert, CPCU, AIC, AIS** Senior Claims Examiner, Medmarc **Andy Hall, Esquire** Senior Claims Examiner, Medmarc **Scott Lazzaro** Claims Examiner, Medmarc



A ProAssurance Company



2021: Another Year Unlike Any Other



Forward Looking Statements

This presentation contains Forward Looking Statements and other information designed to convey our projections and expectations regarding future results.

There are a number of factors which could cause our actual results to vary materially from those projected in this presentation. The principal risk factors that may cause these differences are described in various documents we file with the Securities and Exchange Commission, such as our Current Reports on Form 8-K, and our regular reports on Forms 10-Q and 10-K, particularly in "Item 1A, Risk Factors." Please review this presentation in conjunction with a thorough reading and understanding of these risk factors.

Non-GAAP Measures

This presentation contains Non-GAAP measures, and we may reference Non-GAAP measures in our remarks and discussions with investors.

The primary Non-GAAP measure we reference is Non-GAAP operating income, a Non-GAAP financial measure that is widely used to evaluate performance within the insurance sector. In calculating Non-GAAP operating income, we have excluded the after-tax effects of net realized investment gains or losses and guaranty fund assessments or recoupments that do not reflect normal operating results. We believe Non-GAAP operating income presents a useful view of the performance of our insurance operations, but should be considered in conjunction with net income computed in accordance with GAAP. A reconciliation of these measures to GAAP measures is available in our regular reports on Forms 10-Q and 10-K and in our latest quarterly news release, all of which are available in the Investor Relations section of our website, Investor.ProAssurance.com.

Agenda

♦ Welcome

- COVID's continuing impact
 - PREP Act and related issues
 - How is COVID impacting claims/litigation?
- Mass tort updates
- ♦2021's significant verdicts and decisions
- Regulatory update
- What will we be talking about next year?





Presenters

Megan Grossman, Esquire
Karen Shimonsky, Esquire
Lauren Hulbert, CPCU, AIC, AIS
Andrew Hall, Esquire
Scott Lazzaro



Megan Grossman, Esquire

Megan Grossman is a partner in the Philadelphia office of Lewis Brisbois and a vice-chair of the Life Sciences Practice. Megan is a trial attorney representing companies in general liability, products liability and complex litigation matters.



Karen Shimonsky, Esquire

Karen is a partner in the Denver office of Gordon Rees and is a member of the Health Care, Professional Liability Defense, and Appellate practice groups. In addition to health care matters, Karen handles products liability cases, complex business disputes, general professional malpractice including representing clients in administrative board matters, and a variety of diverse issues depending on her clients' needs.





Lauren Hulbert, CPCU, AIC, AIS

Lauren joined Medmarc in August 2005. Lauren is responsible for investigating coverage and liability, managing reserves and litigation, monitoring outside service providers, negotiating settlements, and maintaining good client relations. Due to her varied experience, she has handled claims of increasing complexity and severity in her time at Medmarc.



Andrew Hall, Esquire

Andy joined Medmarc in 2017 as a Senior Claims Examiner. He is responsible for claims investigation, coverage analysis, managing reserves, negotiating settlements, monitoring defense counsel activities, and maintaining good client relations. Andy also works on the product development team where he assists with drafting language for our new products.





Scott Lazzaro

Scott joined Medmarc in September of 2019 as a Claims Examiner. He is responsible for investigating coverage and liability, managing reserves, monitoring defense counsel activities, negotiating settlements, and maintaining good client relations. Scott came to Medmarc after 16 years in the automobile insurance industry. His contributions there ranged from adjusting highvolume bodily injury and property damage negotiations and settlements to staff development and organizational continuous improvement.



VIEDMARC

Covid's Continuing Impact - PREP Act and Related Issues

Noteworthy Rulings in Past Six Months

- Magoli v. Alliance HC Holdings, LLC 16 F.4th 393 (3d Cir. Oct. 20, 2021).
 - Willful misconduct claim is only claim PREP Act preempts
 - PREP Act creates exclusive cause of action for willful misconduct; no complete preemption of state law claims outside scope
 - Requires an act or omission taken to "intentionally achieve a wrongful purpose"
 - Something more than negligence or recklessness

Noteworthy Rulings in Past Six Months

- MEDMARC. Treated Fairly
- Applying Magoli District Court Rulings- Majority Opinion not complete preemption
 - Punitive damage claims do not meet PREP act willful misconduct Hereford v. Broomhall Operating Company, LP 2021 WL 5834384 (U.S.D.C. E.D. Penn. December 9, 2021).
 - Calling claim "Willful Misconduct" not enough if allegations are akin to recklessness Segel v. Sunray Healthcare Center, 2021 WL 5755639 (U.S.D.C. C.D. Cal. December 2, 2021).
 - If claims in Complaint not brought under PREP Act; procedure for raising immunity may be moving to dismiss in state court not removal

HHS Advisory Opinions Not Followed by Courts

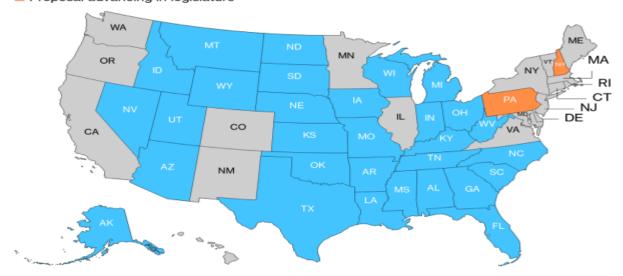
- Advisory Opinions not entitled to deference and not persuasive
 - Courts say HHS Secretary no authority to interpret jurisdiction doctrines
- Decline to follow declaration that failure to use countermeasure falls within Act Mackey v. Tower Hill Rehabilitation, LLC 2021 WL 5050292 (N.D. III Nov. 1. 2021).
- Decline to follow clarification that "Program Planner" under Act is a nursing facility Ostrander et.al. v. The Heights of Summerlin, LLC 2021 WL 5763554 (U.S.D.C. D. Nevada Dec. 1, 2021).

COVID-19 Liability Shield Laws

Covid-19 Liability Shields

States are restricting lawsuits about virus exposures, injuries, or deaths

Broadly covers most or all businesses
Limited or no liability shield
Proposal advancing in legislature



Source: Bloomberg Law analysis; data as of June 4, 2021 Note: Bills in Missouri and Texas are awaiting final action by each state's governor and are expected to be signed into law.

Bloomberg Law

MEDMARC, Treated Fairly Image from https://news.bloomberglaw, com/daily-laborreport/covid-19-shield-lawsproliferate-even-as-liabilitysuits-do-not (last visited December 15, 2021). *Covid's Continuing Impact - How is COVID Impacting Courts and Litigation?*

COVID Effects on the Industry (2020 Reprise)

MEDMARC, Treated Fairly

-Expected overall decrease in Medical Device Market as compared to 2019

-Lockdowns that affect supply chains in manufacturing

-Decreased need for certain products

-Decreased participation in Clinical Trials

-COVID R&D Alliance -COMMUNITY – CT Platform

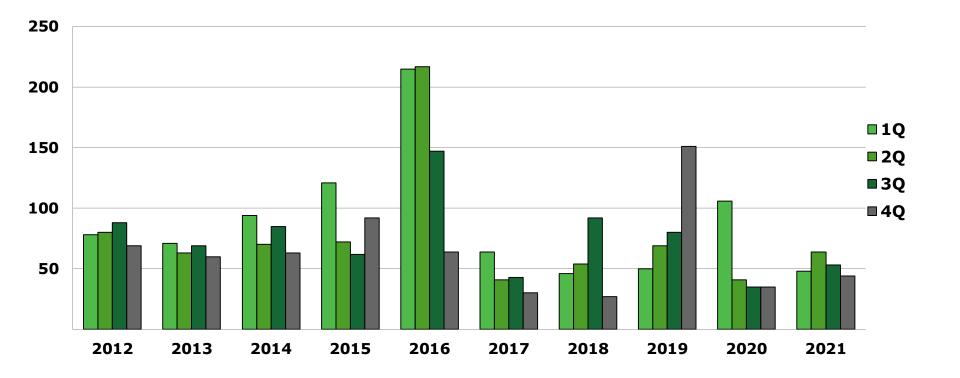
-Operational Adaptations

-Increase manufacturing of Needed Medical Equipment and Devices

-Increase of lesser publicized products

Positive Impacts

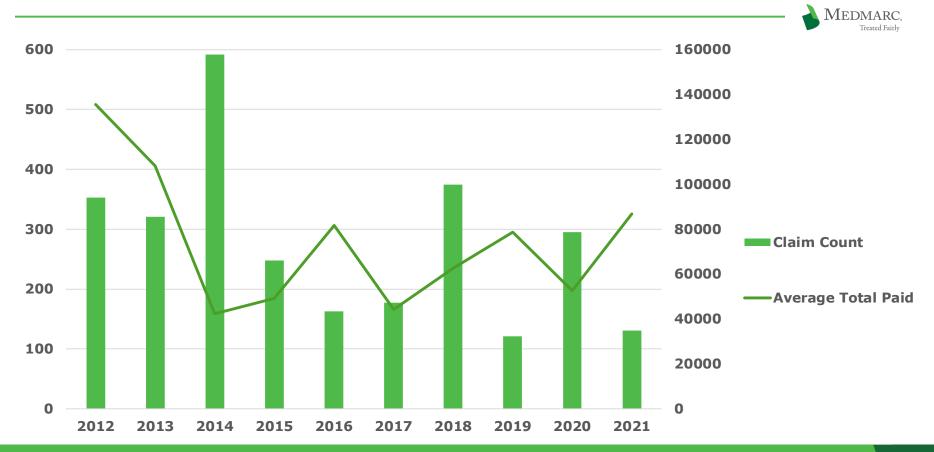
COVID Effects on New Claims



MEDMARC,

Treated Fairly

COVID Effects on Medmarc Claims



COVID Coverage Litigation Tracker

- The COVID Coverage Litigation Tracker is a multi-sourced database and dashboard through which to view the unfolding insurance litigation arising out of the pandemic in federal and state courts.
 - The data collected for each coverage case include policyholder name and industry code; insurer name and AM Best number; policyholder and insurer law firms; the court in which the case is litigated; the coverage sought; the type of insurance policy and state of issue; the relevant insurance policy forms; whether class action status is sought and, if so, the alleged class or classes; and information regarding key litigation events.
- Managed by UPenn Law School and Insurance Law Analytics
- https://cclt.law.upenn.edu/

MEDMARC



- Status of Court Re-Openings
 - Varies from Court to Court and Sometimes Judge by Judge
 - Federal Court Orders and Updates
 - <u>https://www.uscourts.gov/about-federal-courts/court-website-</u> <u>links/court-orders-and-updates-during-covid19-pandemic</u>
- Virtual Hearings and Trials
- Attorney Adaptation Techniques



Short Term

Increased Use of Technology

- Virtual Depo Prep
- Court Hearings
- Trials

Annual spend may decrease given less claim activity Extended Claim LifeCOVID Protocols

• Court Closures

Long Term

- Deadlines & SOLs Extended
 - Expert Costs

Possible overall increased litigation costs

Mass Tort Updates

NDMA/NDEA "Contamination" Litigations

♦ In re: Zantac (Ranitidine) Products Liability Litigation

- MDL pending in United States District Court for the Southern District of Florida Case No. 9:20-md-02924-RLR
- Judge Robin L. Rosenberg
- Three Master Complaints and Census Registry
- Generic Defendants Dismissed on Preemption Grounds
 - Appeals Pending in 11th Circuit
- Focus on General Causation Discovery
- Bellwether Trial Selection Protocol

NDMA/NDEA "Contamination" Litigations, cont'd

MEDMARC. Treated Fairly

- In re Valsartan, Losartan and Irbesartan Products Liability Litigation
 - MDL pending in United States District Court for New Jersey Case No. 1:19-md-02875-RBK
 - Judge Robert B. Kugler
 - Three Master Complaints
 - Denial of Preemption Motions
 - Focus on General Causation Discovery
 - Class Certification Briefs Filed

NDMA/NDEA "Contamination" Litigations, cont'd



- In re Metformin Marketing and Sales Practices Litigation
 - Coordinated Litigation pending in United States District Court for New Jersey Case No. 2:20-cv-02324-MCA-MAH
 - Economic Loss/Consumer Class Action Claims only
- Other Related Litigations
 - State Court Personal Injury Cases
 - Prop 65
 - Attorney General Cases

Other Litigations

MEDMARC. Treated Fairly

- Drugs
 - Belviq
 - Elmiron
 - Xeljanz
 - Truvada
 - Risperdal

- Medical Devices
 - IVC Filters
 - CPAP Machine Lawsuits
 - Paragard
 - Hernia Mesh
 - Hip Replacements

Attorney General
Third Party Payor

2021 Significant Decisions and Verdicts

2021 Significant Decisions and Verdicts—Opioids

- Manufacturers prevail in California bench trial
 - Trial against four manufacturers brought by four large California jurisdictions
 - Court ruled in favor of defendants finding:
 - Plaintiffs did not produce evidence of medically inappropriate prescriptions; and
 - Plaintiff produced insufficient evidence to prove false advertising or unlawful business practices
 - Appeal is likely



MEDMARC, Treated Fairly

Image from https://www.ocgov.com/ (last visited December 8, 2021).

28

2021 Significant Decisions and Verdicts—Opioids, cont'd

- Manufacturers prevail in Oklahoma Supreme Court.
 - Trial judge awarded Oklahoma \$465M finding J&J liable to Oklahoma under the state's public nuisance law.
 - Oklahoma Supreme Court disagreed saying:
 - Oklahoma's public nuisance law does not cover the state's alleged harm; and
 - The Oklahoma Supreme Court would not extend Oklahoma public nuisance law to cover Oklahoma's alleged damages.
 - Many other opioid cases hinge on public nuisance. This decision could be a roadblock for plaintiffs in other cases.



IEDMARC.

Image from https://www.oscn.net/schome/ (last visited December 8, 2021).

2021 Significant Decisions and Verdicts—Opioids, cont'd

Treated Fairly

- Two Ohio counties prevail against CVS, Walgreens, and Walmart.
 - Jury found that these companies created a public nuisance through its role in supplying opioids to Lake and Trumbull Counties, Ohio.
 - Judge will decide damages at a trial in April or May 2022.
 - This is the first trial arising out of the opioid MDL.





2021 Significant Decisions and Verdicts—Personal Jurisdiction

- Ford Motor Co. v. Montana 8th Jud. Dist. Court (USSC)
 - When does court have jurisdiction over a defendant?
 - No case specific connection for Ford in Montana
 - Court said that there is no causation requirement between defendant's connection to the state and the conduct giving rise to the plaintiff's claims
 - Defendant's presence in the state (i.e., advertising, sales, etc.) was sufficient to give court jurisdiction
 - Puts limits on 2017 BMS decision, which found no jurisdiction when plaintiff and defendant had no connection to forum



MEDMARC, Treated Fairly

Image from <u>https://mapsofusa.net/free-printable-map-of-the-united-states/</u> (last visited December 9, 2021).

2021 Significant Decisions and Verdicts—Amazon

- MEDMARC. Treated Fairly
- Courts are split whether Amazon can be held liable for defective third-party products sold on its website
 - California said yes in Bolger v. Amazon.com LLC, a case the U.S. Supreme Court declined to hear
 - Texas said no in McMillan v. Amazon.com LLC, stating that Amazon is not a seller under Texas's Products Liability Act
 - CPSC has filed an administrative complaint seeking to hold Amazon accountable for defective or hazardous third-party products sold on the Fulfilled by Amazon platform
 - Amazon says it will pay claims up to \$1,000 for injuries or property damage caused by third-party products. It says this will cover 80% of the claims made against it

2021 Significant Decisions and Verdicts—Talc

- \$2.1B verdict in Missouri upheld on appeal
 - Verdict for two dozen women who linked ovarian cancer to J&J's talc
 - Original verdict was \$4.7B
 - Missouri Supreme Court and U.S. Supreme Court refused to hear appeal
- \$26.5M verdict in California
 - Plaintiff has terminal mesothelioma allegedly from long term use of talcum powder
 - Jury awarded the following damages: \$15M for future noneconomic damages; \$5M for past noneconomic damages; \$4.1M for lost past and future income; \$1.57M for lost household services; \$800K for past medical costs
 - Case moving into punitive damages phase

MEDMARC

2021 Significant Decisions and Verdicts—Surgical Warmers

MEDMARC, Treated Fairly

- 8th Circuit reversed trial court decision dismissing thousands of lawsuits.
 - Allegation is that 3M's Bair Hugger forced air warming device caused bacterial infections.
 - Device used to prevent hypothermia during surgery.
 - 8th Circuit overturned trial judge's decision that excluded three of plaintiff's medical experts on causation grounds.
 - Lawsuits revived and will proceed forward in an MDL.
 - 8th Circuit also upheld defense verdict in a bellwether trial in a separate MDL involving the product.



Image from https://www.dailymail.co.uk/health/article-8424577/How-risky-operation.html (last visited December 8, 2021).

2021 Significant Decisions and Verdicts—Freezer

- Plaintiffs lost harvested eggs and embryos after freezer failed
 - Five plaintiffs brought claims in California against freezer manufacturer
 - Crack allegedly developed in freezer's tank, which caused liquid nitrogen to leak out and cause the tank to implode. Manufacturer allegedly knew about issue
 - \$14.98M jury verdict
 - Motion for new trial denied. Judge cited plaintiff's trauma and anguish in justifying amount of award

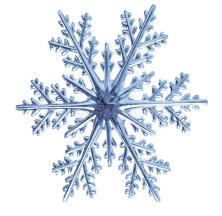


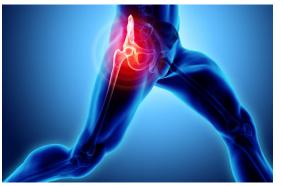
Image from https://www.dreamstime.com/photos-images/snowflake.html (last visited December 9, 2021).



35

2021 Significant Decisions and Verdicts—Hip Implants

- \$21M jury verdict due to allegedly defective hip implants
 - Plaintiff sustained multiple hip dislocations and revision surgeries allegedly due to metal on metal hip implant
 - Judge denied post trial motions finding, in part, that plaintiff was entitled to higher damages than other MoM implant plaintiffs due to her hip dislocations and revision surgeries



Treated Fairly

Image from https://www.istockphoto.com/search/2/image?phrase=hip+repla cement+surgery (last visited December 9, 2021).

Regulatory Update

FDA Commissioner- Biden's Recent Pick

Dr. Rob Califf

- Appointed under Obama from Feb 2016 Jan 2017
- Was flexible on pharmaceutical approvals; sought to permit advertising of off-label uses
- Recently worked as senior adviser Verily Life Sciences and Google Health
- HELP Committee confirmation hearing December 14, 2021

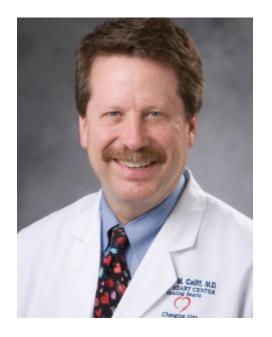


Image from https://medicine.duke.edu/faculty/robert-m-califf, Last visited 12/14/2021



- MEDMARC. Treated Fairly
- FDA published a draft for its "Content of Premarket Submissions for Device Software Functions"- Nov. 2021
 - Will replace 2005 guidance
 - Recommendations pertain to SiMD and SaMD
 - Big changes:
 - Basic or Enhanced level of documentation
 - Device Hazard Analysis Replaced
 - Allows declaration of conformity IEC 62304

What Will We Be Talking About Next Year?

What Will We Be Talking About Next Year?





Thank You! Questions?

- Megan Grossman
 - Megan.Grossman@lewisbrisbois.com; (215) 977-4087
- Karen Shimonsky
 - KShimonsky@grsm.com; (303) 200-6865
- Lauren Hulbert
 - LaurenHulbert@medmarc.com; (703) 652-1387
- Andy Hall
 - AndyHall@medmarc.com; (703) 652-1328
- Scott Lazzaro
 - ScottLazzaro@medmarc.com; (703) 652-1336

Medmarc.com